S. HRG. 112–337

# *Senate Hearings*

***Before the Committee on Appropriations***

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# Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations

## *Fiscal Year* 2012

112*th* CONGRESS, FIRST SESSION

S. 1599

**DEPARTMENT OF EDUCATION**
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**DEPARTMENT OF LABOR**
**NONDEPARTMENTAL WITNESSES**
**SOCIAL SECURITY ADMINISTRATION**

# Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations, 2012 (S. 1599)

S. HRG. 112–337

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2012

## HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

ON

## S. 1599

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2012, AND FOR OTHER PURPOSES

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**Department of Education**
**Department of Health and Human Services**
**Department of Labor**
**Nondepartmental Witnesses**
**Social Security Administration**

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# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2012

**WEDNESDAY, MARCH 9, 2011**

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 9:35 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Reed, Mikulski, and Shelby.

## SOCIAL SECURITY ADMINISTRATION

### STATEMENT OF MICHAEL J. ASTRUE, COMMISSIONER

#### OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies will now come to order.

Our topic today is administrative funding for the Social Security Administration. Normally, this time of the year, we'd be talking about the President's budget request for the upcoming year. However, since this is not a normal year, we're also here to discuss funding for the rest of fiscal year 2011.

Today's hearing is very timely. Three weeks ago, the House passed a spending bill for the rest of this year that cuts $102 billion from the President's request. The Senate majority has offered an alternative that meets the House halfway, cuts $51 billion.

I believe the Senate plan represents a reasonable approach. But, that's just my own opinion, my own views on this, to reduce the deficit while protecting programs that help meet the basic needs of the most vulnerable Americans: seniors, children, those living in poverty, people with disabilities.

And we're here to discuss one of the most important programs. And that's Social Security. Created in 1935, Social Security is the centerpiece of America's social safety net, providing insurance against poverty from old age, the loss of a spouse, or a debilitating disability. Today, 58 million Americans receive Social Security benefits. Eight million will file, this year. Social Security field offices will receive 45 million visitors. And Social Security's 1–800-number will take 67 million calls this year.

Because of the economic downturn and the aging population, in the last few years the number of Americans turning to Social Security and filing for retirement and disability benefits has increased significantly. You know, as the economy goes down and unemployment goes up, and it's harder and harder for people at or near the age of 62, they can't find work; they take early retirement because they just can't find jobs. So, the number of people applying has gone up. Also, people who may have had a minor disability—they've tried to overcome it and work, but now they're out of work and they simply can't find a job—they file for disability. So, that's why we've got a huge increase in an economic downturn.

While the backlogs still persist, the administrative funding, so far, has largely kept pace with this increased demand. This, for one thing, has allowed Social Security to significantly step up its program integrity activities. Social Security Administration periodically conducts reviews to determine if beneficiaries are still eligible under the—both the income and disability guidelines.

Since 2007, the Social Security Administration has increased the number of continuing disability reviews by over 50 percent, and redeterminations of nonmedical eligibility, by over 140 percent. Combined, these activities save taxpayers—save taxpayers—an average of about $8 in future Social Security, Medicare, and Medicaid benefits for every $1 spent in administrative funding. So, we spend $1, we save $8.

Today, however, adequate funding for the Social Security Administration to properly administer these programs is at risk. The House continuing resolution H.R. 1 would cut administrative funding for SSA by $125 million below last year's level—fiscal year 2010 level—even though, as I pointed out, their workloads on disability claims, hearings, retirement claims, are staying at record high levels.

Under the House plan, the SSA, the Social Security Administration, would have to cut its staff by 3,500 by the end of the year, and may ultimately have to resort to furloughs. As a result, millions of Americans filing disability claims this year will have to wait much longer for benefits. Everyone will have to wait. You probably won't get online, and you probably won't get your phone call answered right away—and the program integrity efforts, the one I just mentioned, about making sure that we save money by making sure that people that are on disability or filing claims are still eligible—so, delaying these isn't just bad for the economy, but it's devastating for the individuals, on both sides.

The Senate majority plan would provide, on net, $600 million more for the Social Security Administration's administrative expenses. This is less than the President's request, but it will keep the offices open and allow the agency to meet its most basic service commitments to the American public and prevent its backlog of work from growing any bigger than it is today.

So, that's what this hearing is about. We need to know what the impact will be on the Social Security Administration, on their ability to respond to the huge workload, and the effect it will have on recipients and people who rely upon their disability or their supplemental security income (SSI) or their old-age survivors' benefits.

So, that's why we're having this hearing today. We need to know what this means.

So, I look forward to hearing the testimony from our distinguished panels on this matter. But, first, I yield to Senator Shelby for any opening remarks.

STATEMENT OF SENATOR RICHARD C. SHELBY

Senator SHELBY. Thank you, Mr. Chairman.

Thank you for calling this hearing to examine the fiscal year 2012 Social Security Administration's budget request. I look forward, as you do, to hearing the panels' testimony and their views on this critical program.

The greatest obstacle to our Nation's fiscal stability is ignoring our increasing entitlement obligations. Simply put, there is no way to control our debt without getting serious about entitlement reform. And, while we can argue about how to reform Social Security, we cannot argue about whether it should be reformed. It's a question of when.

In 2010, for the first time in the history of the Social Security Program, the system paid out more in benefits than it received in payroll taxes. This is a critical threshold that was not expected to be reached until at least 2016. Social Security is now at the tipping point, the first step of a long, slow march to insolvency if we don't do something about it.

According to the Social Security Board of Trustees, the Social Security Trust Fund surplus will be completely exhausted by 2040. At that juncture, Social Security will have to rely solely on revenue from the payroll tax, which will not be sufficient to pay all the promised benefits.

There are currently 50 million Social Security beneficiaries, and their numbers are increasing faster than the number of taxpayers. The number of workers per retiree has fallen from 42 to 1 in 1940 to about 3 to 1 today. Social Security is unbalanced because contributions are insufficient to provide the promised benefits. In a sense, it's a classic Ponzi scheme, with new contributions used to pay off earlier investors.

I think we must also recognize that the Social Security Disability Insurance (SSDI) Program contributes more than its share to Social Security's looming insolvency. During the economic recession, the unemployment rates soared, as did applications to the SSDI program. The number of individuals receiving SSDI benefits has jumped more than 10 percent in the last two recessionary years. The increase will accelerate the exhaustion of the SSDI reserves by 2018, and was recently described by the Congressional Budget Office (CBO) as "not financially sustainable."

And, while the SSDI program faces the same fundamental issue as the retirement program—that is, there are fewer workers to pay for an ever-increasing population receiving benefits—its questionable structure adds complexity. What was supposed to be a narrowly tailored program to help individuals who could no longer work grew into a gigantic budgetary burden that looks more like an unemployment program, to some people.

What makes the problems worse is that, unlike the Federal Unemployment Program, there is no time limit for how long an indi-

vidual can receive SSDI. But, more significantly, among those receiving SSDI benefits, the incentive to return to work is very low. In fact, revealing one's ability to go back to the workforce could result in permanent loss of SSDI benefits. The strong work disincentives under the SSDI results in workers never seeking gainful employment, at the risk of losing future benefits. Clearly, Congress must face the potential fiscal collapse of the Social Security system in the future.

However, today's hearing focuses on the near-term issues facing the program and the only aspects of the $817 billion fiscal year 2012 budget the Appropriations Committee has control over, $12.5 billion that funds administration costs and the Office of the Inspector General.

The fiscal year 2012 budget requests an additional $1 billion over the fiscal year 2010 budget to reduce the daunting 744,130 disability claims and 722,872 hearings case backlog. On top of the significant backlog, the processing time for disability claims is 112 days, and the wait time for a Social Security appeal hearing is 371 days.

Interestingly, two-thirds of those who appeal a Social Security decision win their case on appeal. And, while I understand the disability process is complex, it's also highly subjective. With an appeal-over rate so high, why are so many people winning on appeal. Instead, shouldn't they win at the beginning?

As the Social Security Administration continues to tackle the backlogs in their caseload, I think it's important that funding to pursue continuing disability reviews remains strong. SSDI benefits are not, and should not be, benefits for life. Only those who continue to qualify for benefits should receive them.

We need, I believe, to ensure that fraud and abuse of the system are rooted out. Those who take advantage of the system ruin it for those who are genuinely in need. In a program where there are no fines and virtually no prosecution for those who attempt to fraudulently collect benefits, we need to examine ways to stop fraudulent applicants.

The administration of Social Security, while only a small percentage of the entire system, is a vital component to the success and the fiscal stability of the overall program. This, however, does not mean that it can operate without stringent oversight from this subcommittee. We need to ensure that that money is being spent wisely and in the best interest of the U.S. taxpayer.

Mr. Chairman, I look forward to working with you on this panel, and look forward to the hearing.

Senator HARKIN. Thank you very much, Senator Shelby.

I'd like to just ask my colleagues if they have some short remarks they'd like to make.

Senator Mikulski.

STATEMENT OF SENATOR BARBARA A. MIKULSKI

Senator MIKULSKI. Thank you very much, Mr. Chairman. My remarks will be brief.

I joined the Labor-HHS Subcommittee at the start of this Congress, and I'm delighted to be here. As both the chair and the ranking on the Commerce, Justice, Science Subcommittee, Senator Shel-

by and I are used to talking to rocket scientists, Federal Bureau of Investigation agents, and those in the Commerce Department who advance the trade for the United States. But, whether you're a rocket scientist or whether you're a janitor, Social Security is your program. This is the one program that the entire United States Government effects. So, whether you were a Nobel Prize winner, whether you are the cop protecting the lab where they work, or whether you're the person who cleans up that lab when everybody goes home, Social Security is your program.

I'm very proud of the fact that Social Security is headquartered in my State. Thousands of people work there every day to make sure that this benefit is a guaranteed benefit, not a guaranteed gamble for those who want to privatize it, but they guarantee also that the checks will be delivered on time, to the right person, with the right actuarial assignment or payment given to it. I'm very proud of them.

And, quite frankly, Mr. Chairman, I'm deeply troubled about where we are on the cuts to Social Security, the contemptuous attack on Social Security as a benefit, and then the even overt hostile attack on Social Security employees. They're on the front line every day—some in harm's way, when a disgruntled person shows up off their meds—but, they're there every day, every way, serving the people of the United States of America, and we have to make sure they have the right pay, the right resources, and the right respect.

Senator HARKIN. Thank you, Senator Mikulski.

Senator Reed.

Senator REED. No, thank you.

## INTRODUCTION OF COMMISSIONER MICHAEL J. ASTRUE

Senator HARKIN. Well, thank you all very much.

We'll start with our first panel.

Michael J. Astrue serves as a Commissioner of the United States Social Security Administration. He was sworn in on February 12, 2007. Prior to joining Social Security, the Commissioner served as counsel to the Social Security Commission, general counsel and Department of Health and Human Services, and as an associate counsel to the President, in both the Reagan and George Bush, Sr., administrations. He's a graduate of Yale University and Harvard Law School.

Mr. Astrue, welcome to the subcommittee. Your testimony will be made a part of the record in its entirety. And, if you could sum it up in several minutes or so, we'd be most appreciative.

Commissioner ASTRUE. Great.

Senator HARKIN. Thank you.

## SUMMARY STATEMENT OF MICHAEL J. ASTRUE

Commissioner ASTRUE. Chairman Harkin, Ranking Member Shelby, and members of the subcommittee, thank you for this opportunity to discuss the important work of the Social Security Administration.

For a number of years, going back to the 1990s, we did not receive full funding, and service deteriorated. When I became commissioner in 2007, I promised improvements. And Congress has supported those improvements. With necessary investments, great-

er productivity, and new initiatives, we have reversed the trend of declining service and increasing backlogs.

Our top priority remains eliminating the hearings backlog. And we've made significant progress 4 years in a row. We have decided over one-half a million of the oldest, most complex cases, some as old as 1,400 days. We have cut the waiting time for a hearing decision, from nearly 18 months in August 2008 to exactly 1 year in February 2011.

We have made the most progress in some of our most backlogged offices. For example, our Atlanta downtown office had an average waiting time of 1,020 days in August 2007. We have slashed that time by 70 percent. The average waiting there is now 297 days.

Without your continued support, however, we will not meet our commitment to eliminate this backlog by 2013. Our staff and our State disability determination services (DDS) partners kept our pending level of claims well below our fiscal year 2010 projected level, while achieving the highest level of accuracy in over a decade, even as they faced furloughs and a huge influx of claims, due in part to the economic downturn.

In fiscal year 2010, callers to our national 800 number had the shortest waiting time and lowest busy rates since we began tracking these measures, nearly a decade ago. We reduced the average waiting time in our field offices. We have increased our important program integrity work, which is improving payment accuracy in the Supplemental Security Income Program.

Every $1 we spend on continuing disability reviews yields $10 in lifetime program savings. Every $1 spent on SSI redeterminations yields more than $7. To do this complex work, we need an adequate number of well-trained employees.

Since 2007, our dedicated employees have averaged nearly a 4-percent annual increase in productivity, which is fueled by hard work, better business processes, and smart investments in information technology. Few, if any, organizations can boast productivity gains of this magnitude.

The fiscal year 2012 President's budget request of $12.5 billion is what we need to reduce our remaining backlogs and to increase our deficit-reducing program integrity work. But, achieving that performance depends on receiving the President's budget request in fiscal year 2011.

Because of the uncertainty of our budget and the length of the continuing resolution, I've already had to make choices that will begin to erode service. I cut back on hiring, last July, and have continued to scale back on hiring and other areas. We now expect a net loss of 3,500 Federal and State employees this fiscal year. Most of these employees work in offices across the Nation, and they will not leave those offices uniformly. Some offices are already understaffed. Our employees continue to serve the public as best they can, but they are disappointed about the prospect of watching what we have worked so hard to achieve potentially slip away.

I regret that we may not be able to keep our commitments to the American people because we do not have the necessary support to move forward. Millions of people we serve cannot afford to wait. People with disabilities lose their homes, medical coverage, and

dignity. That outcome does not serve Americans or the economy well.

In addition to other cuts we've made, we are discontinuing service at over 300 remote sites and are considering field office consolidations. We will not open eight needed hearing offices, and we will not be able to staff the new Jackson, Tennessee, Teleservice Center this year and maybe not next year or in future years. We're suspending printing and mailing of annual earnings statements, which will save about $70 million annually.

If you look at what we have accomplished in just 4 years, you'll see that we are a good investment. With adequate and timely resources and the superb efforts of our employees, we deliver on our promises. Nevertheless, we cannot eliminate our disability backlogs, provide accurate and responsible service, and meet our stewardship duties, unless Congress provides us with the resources to do the job. Suddenly reduced funding halfway through the fiscal year could eliminate most of the progress that we have made.

I'm happy to answer any questions that you may have.

PREPARED STATEMENT

Senator HARKIN. Mr. Astrue, thank you very much for a very concise statement. I know you have a longer statement, which I went over the other evening, and it will be made a part of the record, as I said, in its entirety.

I thank you for——

Commissioner ASTRUE. Thank you, Mr. Chairman.

Senator HARKIN [continuing]. Summing it up.

[The statement follows:]

PREPARED STATEMENT OF MICHAEL J. ASTRUE

Chairman Harkin, Ranking Member Shelby, and Members of the Subcommittee: Thank you for the opportunity to discuss the President's fiscal year 2012 budget request for the Social Security Administration.

For over 75 years, Social Security has touched the lives of virtually every American, whether it is after the loss of a loved one, at the onset of disability, or during the transition from work to retirement. Our programs provide a safety net for the public and contribute to the increased financial security for the elderly and disabled. Each month, we pay more than $60 billion in benefits to almost 60 million beneficiaries. These benefits not only provide a lifeline to our beneficiaries and their families, but also are vital to the Nation's economy.

Americans request a staggering amount of service from our agency. We respond to their needs through a network of 1,500 offices that provide service to local communities across the country. Nearly all of our employees work in these local offices where they do a wide range of work including issuing Social Security cards, handling applications for benefits, maintaining workers' earnings records and the accuracy of our benefit records, deciding appeals, answering our 800 number, and assisting with Medicare.

In fiscal year 2010 we:

—Completed 4.7 million retirement and survivors claims;
—Completed 3.2 million initial disability claims;
—Served 45.4 million field office visitors;
—Completed over 67 million transactions over the telephone;
—Verified over 1 billion Social Security numbers;
—Issued 17.2 million new and replacement Social Security cards;
—Conducted 325,000 full medical continuing disability reviews (CDRs) and 312,000 work CDRs;
—Completed 2.5 million Supplemental Security Income (SSI) non-disability redeterminations;
—Paid $1.4 billion in attorney fees;
—Completed 738,000 hearings;

—Defended 12,000 new Federal court cases;
—Facilitated over 1,500 data exchanges with Federal, State, local and foreign government entities as well as some private sector companies;
—Oversaw approximately 5.6 million representative payees;
—Completed 240 million earnings items for crediting to workers' earnings records; and
—Mailed out 152 million Social Security statements.

We have a long-standing and well-deserved reputation as a "can-do" agency. Despite years of underfunding, our hard-working and dedicated employees have done their utmost to maintain the level of service that the American people expect and deserve. We have been innovative and proactive in adopting strategies to allow us to meet the challenges we face. To the extent resources allowed, we have hired and trained staff to handle our increased workloads, and we have used technology to complement our traditional work processes and make them more efficient.

In retrospect, our remarkable successes planted the seeds for many of our current challenges. Congress, confident that those successes coupled with our "can do" attitude meant that we could always find ways to adapt, appropriated less than the President requested each year from 1992–2007. At the same time, requests for our core services rose as the population grew and baby boomers aged, passing through their most disability-prone years before retiring. Even with this new and unavoidable demand, we managed to maintain our high service levels for some time.

Inevitably, though, we could no longer hold out. Unprecedented workloads combined with declining budgets damaged our service delivery. We could not keep up even with a long string of employee productivity increases. Throughout most of the past decade, the amount of program integrity work our employees could keep up with while handling other priority work dropped dramatically, even though we know that program integrity work saves the taxpayer about $10 for each dollar spent. The time claimants waited for disability hearings rose to an average of 800–900 days in many cities, and some claimants waited as long as 1,400 days. Waiting times for in-person and telephone service increased, as did the public's and Congress's frustration with us.

## RECENT ACCOMPLISHMENTS

In the last 3 years, we have demonstrated the nexus between adequate funding and our ability to deliver—the Congress increased our funding, and we made real and measurable progress. We reversed many negative trends, most notably with the hearings backlog, and significantly improved service and stewardship efforts. We made these improvements even though we have had to absorb huge unexpected increases in workloads due to the worst economic downturn since the Great Depression.

When I became Commissioner, the Congress made it clear that I had to reduce the amount of time it takes a claimant to receive a hearing decision. I recognized their concerns and committed to eliminating the hearings backlog. Although we have many pressing workloads, we have never wavered from this top priority, demonstrating what it means to be a results-driven organization.

With your help, we attacked the backlog and made incredible progress in the last 4 years. We have cut the national average time claimants wait for a hearing decision by one-third, from an all-time high of nearly 18 months in August 2008 to exactly 1 year in February 2011. We have made the most progress in offices that had the largest backlogs. For example, the Atlanta offices had some of the longest wait times in the country. In the summer of 2007, the Atlanta Downtown office had an average waiting time of 1,020 days, and the Atlanta North office averaged about 900 days. By January 2011, we reduced the wait in the Atlanta Downtown office to 297 days, a 70 percent reduction, and to 307 days in the Atlanta North office, a two-thirds reduction.

During this time, we focused on the most urgent part of the backlog—the oldest, most complex cases. In 2007, we had claimants who waited for a hearing decision for as long as a staggering 1,400 days. Since 2007, we have decided over a half million of the oldest cases. By the end of fiscal year 2010, we had virtually no cases pending for more than 825 days. This year we are focusing on the cases that are 775 days or older, and through January 2011, we have decided over 60 percent of these cases.

We expect that once we eliminate the backlog, we will be able to decide hearings in an average of 270 days. In 2007, 50 percent of the pending hearing requests were older than 270 days. Today, about 30 percent of our cases are over 270 days, and that percentage continues to drop.

Another indicator of our progress is the number of our administrative law judges (ALJ) who are on pace to meet our productivity expectation to decide between 500–700 cases each year. When we established the expectation in late 2007, only 47 percent of the ALJs were achieving it. By the end of fiscal year 2010, 74 percent of the ALJs met the expectation.

We have made considerable progress, despite the significant increase in disability claims. More disability applications result in more appeals. Last year, we received nearly 100,000 more hearing requests than we received in fiscal year 2009. This trend of increasing claims has continued. In our highest month for hearing requests last year, we received approximately 73,800 requests. This year, that number rose to a record monthly high of about 82,000.

In fiscal year 2010, we handled more than 3,161,000 initial disability claims—a record number that is 300,000 more than the year before. Even with this huge increase in determinations, we could not keep up with the number of disability claims we received. The number of pending initial disability cases rose to over 842,000. We have begun working this number down, and as of February 2011, we have reduced the pending claims to 774,000.

The State disability determination services (DDS), the State agencies that make initial disability decisions for us, are not sacrificing quality to gain productivity. The DDSs have steadily increased the accuracy of their decisions since fiscal year 2007. In fiscal year 2010, the DDSs achieved an accuracy rate of 98.1 percent, the highest level in over a decade.

These accomplishments are particularly remarkable considering the unjustifiable—because we fully fund this work—furloughs of disability determination services employees in many States.

To help States with mounting disability claims, we created Extended Service Teams (EST) modeled after our successful National Hearing Centers. The ESTs are located in State DDSs that have a history of good quality and high productivity. These centralized DDS teams are helping us reduce the initial claims backlog as we electronically shift claims to them from the hardest hit DDSs. We have also expanded our Federal capacity to decide disability claims. We currently have 12 Federal units that assist those DDSs most adversely affected by the increase in initial claims.

Identifying and paying eligible claimants early in the disability process clearly benefits those with severe disabilities and helps our backlog reduction efforts. In fiscal year 2010, we used our fast-track initiatives, Compassionate Allowances and Quick Disability Determinations, to issue favorable disability determinations to over 100,000 disability claimants within 20 days of filing. We implemented these initiatives while maintaining a very high accuracy rate.

In fiscal year 2011, we implemented a new regulation to allow disability examiners to make fully favorable determinations for claimants with the most severe disabilities without consulting a medical professional. This change allows us to decide claims even faster.

Last year, more than 45 million people, a record number, visited our field offices across the Nation. Despite the increased number of visitors, we reduced wait times in our field offices more than 10 percent from fiscal year 2009.

We completed more than 67 million transactions over the telephone—another record number. Callers to our national 800-teleservice centers had the shortest wait time and lowest busy signal rates since we began measuring these services over a decade ago. In the last 2 years, we cut our busy rate by more than half, from 10 percent in fiscal year 2008 to 4.6 percent in fiscal year 2010. We also reduced the time spent waiting for an agent by over 37 percent, from 326 seconds in fiscal year 2008 to 203 seconds in fiscal year 2010.

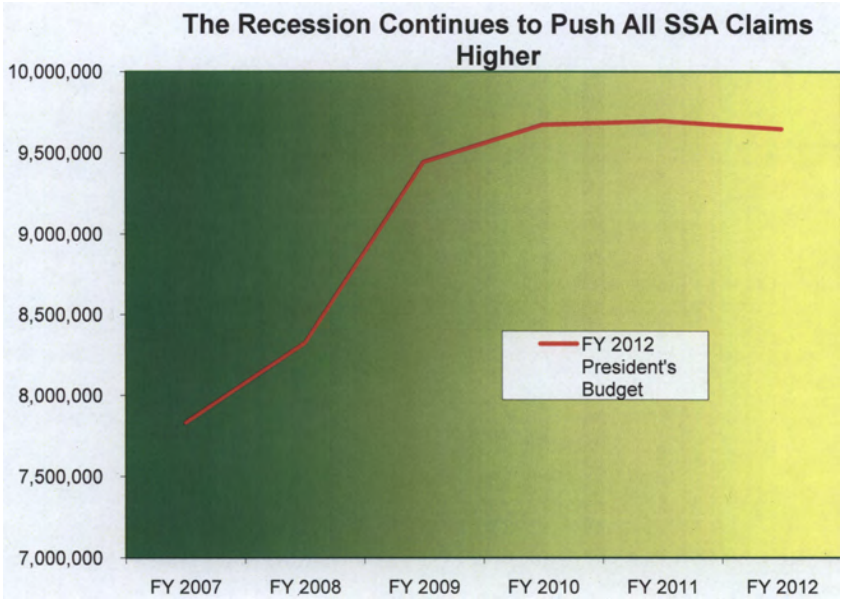
Our online applications have been indispensible in helping us keep up with the enormous growth in retirement claims. For that reason, we made it easier to file disability claims online. In January 2010, we released a streamlined disability report, which we use to collect information about a claimant's disability. This user-friendly report allows a claimant to complete an application more quickly and improves the quality of the information we receive.

We continue to expand and improve our online offerings. In March 2010, we introduced an online Medicare-only application. In July 2010, we introduced our Life Expectancy calculator, which helps people decide when to start collecting retirement benefits. In December 2010, we launched a Spanish version of the Retirement Estimator—the first non-English interactive online application in the Federal Government. We have the three best electronic services in the Federal Government, as measured by the University of Michigan public satisfaction survey. Our Spanish-language retirement estimator is on track to become the fourth. These easy-to-use

online tools encouraged 37 percent of retirees and 27 percent of disability claimants to file online in fiscal year 2010.

We have increased our program integrity work, which saves taxpayers dollars. In fiscal year 2010, we completed over 700,000 more SSI nondisability redeterminations than in fiscal year 2009. Completing more of this important stewardship work, helps us increase the payment accuracy in the SSI program.

Our employees deserve the credit for these successes. From fiscal year 2007 to fiscal year 2010, their productivity increased by an astounding average of nearly 4 percent per year. I am privileged to lead a workforce dedicated to the highest standards of public service. Despite the pressures that increased workloads bring, our employees understand how important our mission is, voting us one of the top ten best places to work in the Federal Government for the third consecutive year.




We are proud of the hard-earned progress we have made over the past 3 years. However, demographics, rising workloads, and heightened fiscal austerity will threaten our recent achievements and make further progress at this level unlikely.

EFFECTS OF CONTINUING RESOLUTIONS

We understand the economic reality that is driving budget decisions. I have looked for and found ways to cut back. We have trimmed non-essential travel, training, and even systems enhancements. By far the largest part of our budget funds payroll. Eighty percent of our employees work in local offices across the Nation. I have even cut this critical area—the people we all depend on to get the work done—by freezing hiring and offering early out.

Beyond payroll costs, most of our remaining costs are mandatory expenses to maintain our operations. For example, we must pay rent and maintenance on the 1,500 facilities we occupy; we must pay postage on more than 390 million notices we send annually; we must pay for medical and vocational evidence and expertise; and we must pay for armed guards in our offices to protect our employees and the public. Unfortunately, these guards are particularly vital now given the increase in threats against our employees.

A theoretically level-funded continuing resolution does not consider that our costs do not remain flat—we have to absorb mandatory cost increases with last year's funding level. In addition, the $350 million Recovery Act funding we used in fiscal year 2010 to handle claims was not included in our continuing resolution level. Between having to cover mandatory cost increases and not having Recovery Act funding, we are operating at a significant loss over last year.

In this modern era, we are completely dependent on information technology. Not only do we need stable and robust systems to handle our day-to-day work, tech-

nology makes us more efficient. Unfortunately, under a continuing resolution, our information technology (IT) funds are severely constrained. Many of our investments in technology to improve our productivity have been curtailed. If the continuing resolution reduces our funding further, or the funding reduction continues into future years, our ability to continue keeping our technology environment operating smoothly will be threatened.

Our technology to this point has enabled us to implement work processes that are less costly, more accurate, and require fewer employees to accomplish the same amount of work. Without our current investments, we would not have been able to keep pace with the recent increases in claims. We would not have realized the increases in productivity that have enabled us to serve the public as we have. IT investments are critical if we are to continue to improve productivity and achieve our performance targets. We must maintain and invest in technology.

Because of the uncertainty of our budget and the length of the continuing resolution, I have had to make choices that will begin to erode service. Our employees continue to churn out work, but they are disappointed and are becoming demoralized about the prospect of watching what they have worked so hard to achieve slip away. I regret that we may not be able to keep our commitments to the American people because we do not have the necessary funding to continue moving forward.

Our employees come face-to-face with the public every day, and they are acutely aware of how the public will suffer. As I mentioned earlier, there is a direct nexus between our funding and our service level. We want to prepare you for what a deep cut would mean. Our backlogs will skyrocket, and people will wait considerably longer to receive decisions. As our backlogs grow, it will become more difficult, expensive, and time-consuming for us to eliminate them. Waiting times in field offices and on our 800-number will increase dramatically. Deep cuts will cause billions of dollars of payment errors that will take years to address, hardly a wise use of taxpayers' dollars. Even if we have specific funding for program integrity work, we need the people to do that work plus all of their other fundamental responsibilities.

A full-year continuing resolution will require us to put on the brakes, reversing the tremendous progress we have made in the last few years. Common sense dictates that we need enough skilled employees to handle mounting workloads. A continued hiring freeze means we will lose about 2,500 Federal employees and 1,000 DDS State employees this year. Our field employees will not leave the agency uniformly. Attrition is random, leaving some offices seriously understaffed.

While we regret the resulting loss in service, we have tried to prepare for the continuing resolution. In July, we instituted a full hiring freeze for all headquarters and regional office staff, and then we further restricted hiring to allow only those components critical to the backlog reduction effort to replace staffing losses. Under a continuing resolution, we will continue—and likely expand—the hiring freeze. We will reduce or eliminate, overtime, which our front line employees depend on to keep up with their work.

We have decided not to open eight needed hearing offices, and we will not have staff to open our new Jackson, Tennessee Teleservice Center this year, and perhaps not even next year. We are discontinuing service in over 300 remote service sites throughout the United States. Most of these sites are "contact stations" housed in locations like libraries, senior centers, or other facilities where a Social Security employee travels, typically once or twice a month, to take applications for Social Security cards or benefits, as well as answer questions. We have also begun looking at field office consolidation where that decision makes fiscal sense.

Each year we send Social Security Statements to non-beneficiaries who are over age 25. These annual Statements cost us approximately $70 million each year to print and mail. In order to conserve funds, we will suspend the current contract and stop sending out these Statements. Individuals contemplating retirement can get real-time information about the amount of their benefits on our highly regarded Retirement Estimator, available on-line at www.socialsecurity.gov. Field offices may also provide Statement data. After we negotiate a new contract, we will send Statements only to people age 60 and over and people under age 60 upon request. We also are working on making the Statements available online.

ONGOING FUNDING—FISCAL YEARS 2011 AND 2012

The President's fiscal year 2012 budget request includes $12.522 billion for our fiscal year 2012 LAE account. This level of funding will allow us to maintain staffing in our front-line components, fund ongoing activities, and cover our inflationary increases. It will allow us to reduce our hearings and initial disability claims backlogs and to continue to reverse the decline in our program integrity work. Our fiscal

year 2012 request is a very modest increase from our fiscal year 2011 request; the increase of $143 million is primarily to fund additional program integrity efforts.

However, this level of funding will be sufficient to meet these goals only if we receive the full amount that the President requested for fiscal year 2011. While full funding of the President's budget request will allow us to build on the tremendous progress we achieved over the past few years, it will not allow us to keep up with some of the important, statutorily mandated, and less visible work we do, such as representative payee accountings and benefit recomputations.

Even with full funding, we will not have sufficient resources to do all that you and America expects us to do. Accordingly, we will use our fiscal year 2011 and 2012 funding to focus on our three priorities.

—Continuing to reduce the disability backlogs;
—Improving service to the public; and
—Saving taxpayer dollars.

We will continue to operate very efficiently, holding administrative costs in fiscal year 2012 to just 1.6 percent of benefit payments.

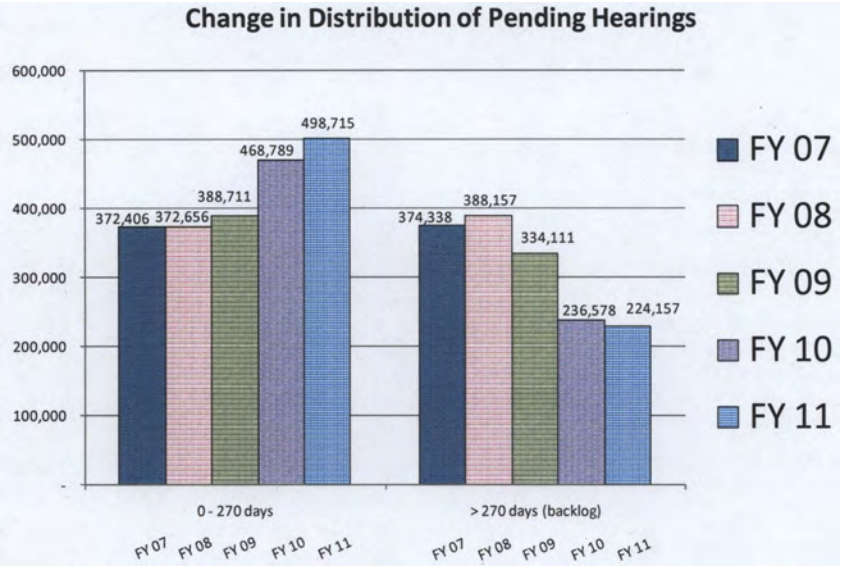
CONTINUING TO REDUCE THE DISABILITY BACKLOGS

*Hearings Backlog*.—Eliminating the hearings backlog continues to be our number one priority, and we have made real and measurable progress in reducing both the number of pending hearings and the amount of time a claimant must wait for a hearing decision.

In fiscal year 2012, with full funding of both the fiscal year 2011 and 2012 President's budget requests, we will continue our progress toward our goal of eliminating the hearings backlog in 2013. Resources permitting, we plan to hire an additional 130 ALJs in late fiscal year 2011—particularly if hearing requests remain so high—to ensure that we can meet our commitment to eliminate the hearings backlog by the end of fiscal year 2013. We expect to complete a record number of hearings—over 800,000 in fiscal years 2011 and 2012, which is more than double the number we handled 10 years ago.

We continue to focus on eliminating our oldest cases. In fiscal year 2011, we are targeting the 106,715 cases that will be 775 days or older by the end of the year. In fiscal year 2012, we will lower our threshold to 725 days.

While we have made significant progress, people still wait too long. That wait has very real implications—many people with disabilities lose their homes, medical coverage, and dignity while waiting for a decision on a hearing. We want to maintain our momentum and eventually restore an appropriate level of service. Without the President's budget, it is highly likely that we will miss our goal of eliminating our hearings backlog in 2013. If that happens, gains that we have achieved in prior years will vanish.

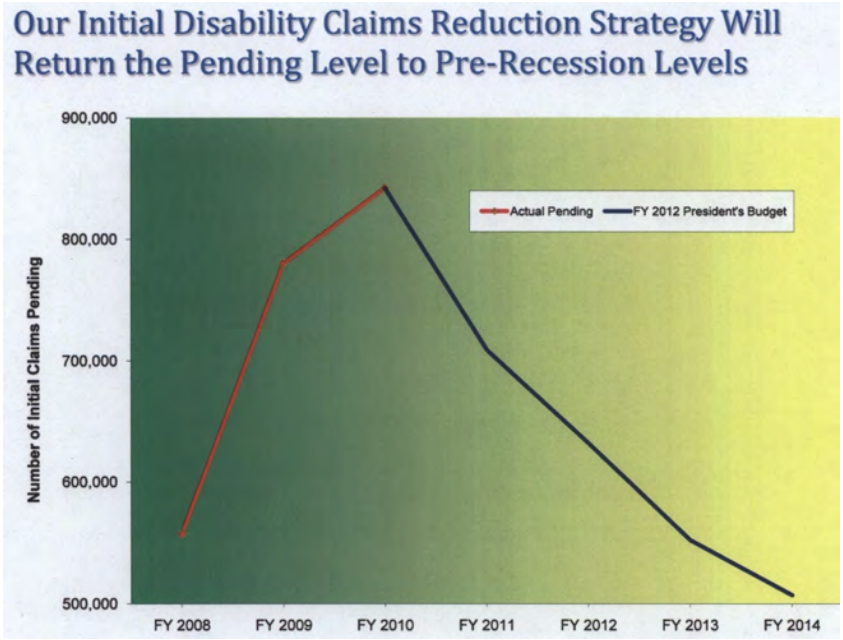


*Initial Claims Backlog*.—We remain committed to returning our initial disability claims pending to its pre-recession level by 2014. However, in order to meet this commitment, we will need sustained, adequate funding.

Another significant obstacle to tackling this backlog is the decisions by a number of States to furlough federally paid State employees who make our disability determinations. To address that problem, in July 2010, we submitted a legislative proposal to Congress that would prohibit States, without our prior authorization, from reducing the number of State personnel who make disability determinations for Social Security. I look forward to working with you on this important issue.

If we receive full funding, we estimate we will complete 3,409,000 disability claims in fiscal year 2011, and 3,268,000 in fiscal year 2012. We have several initiatives planned and underway to help us achieve our goal.

We are dedicated to fast-tracking disability claims that obviously meet our disability standards and to providing decisions within 20 days of filing. With the effective use of screening tools, expanded technology, and electronic services, we have increased our ability to identify and quickly complete cases that we are likely to approve. We continue to refine our methods for identifying these cases so we can increase the number of fast-tracked claims while maintaining accuracy. We plan to increase the number of fast-tracked claims to 5.5 percent of all new claims filed in fiscal year 2012.




IMPROVING SERVICE TO THE PUBLIC

The availability of online services is vital to good and efficient public service. Increasingly, the public expects to have the option to conduct business over the Internet at their convenience and at their own pace. Even though our employees continue to review online benefit applications and contact applicants to resolve questions or discrepancies, these online services reduce the average time our employees spend completing claims, giving them additional time to address more complex issues.

We plan to continue to expand and improve our online services. We plan to implement a new, even more secure authentication process to provide a safe environment for people who are interested in conducting additional business with us online. This protocol will be the gateway to allow the public to access their personal information online. We are also working on an initiative that may provide access to a variety of personalized online services, such as verifying earnings history, receiving notices, and requesting certain routine actions.

Investing in online services is critical for providing better and more efficient service to the public. We will only be able to meet our budget commitments if we continue to see growth in our online applications. In fiscal year 2011, we plan to implement a shorter online application for cases in which a claimant alleges a Compassionate Allowance condition. In fiscal year 2012, we expect that 50 percent of all retirement applications and 38 percent of all disability applications will be filed online.

Because calling our 800-number continues to be the option the public chooses most frequently to access our services, we are committed to improving our telephone service. In fiscal year 2010, we awarded a contract to replace our 800-number telecommunications infrastructure. The new system will include state-of-the-art features such as providing immediate telephone assistance to people who visit our website. It will also allow us to redesign our call flow to eliminate lengthy navigation menus that are frustrating to the public. We plan to implement these and other enhancements in fiscal year 2011 and fiscal year 2012.

We also recognize the importance of improving our field office service. Despite a record number of visitors, we reduced wait times in our field offices for those without an appointment from 23.3 minutes in fiscal year 2009 to 20.7 minutes in fiscal year 2010. We will continue improving our field office service in fiscal year 2011 with Social Security Television (SSTV). SSTV broadcasts to our reception areas information about our programs and services, such as what documents visitors need to apply for benefits or to request a Social Security card. It saves the public and our staff time.

We are improving field office telephone service by continuing to replace obsolete telephone systems in all of our field offices. Nearly 70 percent of our field offices have the new system, and we are on schedule to complete the rollout in 2012, although abrupt budget cuts may slow that rollout. The new system reduces operating costs and replaces increasingly unreliable outdated telephone systems. It also will allow us to improve both service and efficiency. For example, with the new system, we will be able to implement a Dynamic Forward-On-Busy feature, which will offer field office callers who would otherwise get a busy signal the option of being transferred to our 800-number during non-peak times.

Video service can provide an efficient and innovative way to provide Social Security services to the public. For example, we negotiated an agreement with the Walter Reed Army Medical Center to install onsite video service delivery equipment that connects hospitalized military service members with Social Security claims representatives to apply for disability benefits. Video service allows our offices to link together to provide help to busy or understaffed offices. With adequate funding, we can continue to expand our use of video services to reach our customers in remote sites such as American Indian Tribal centers, local community centers, senior centers, hospitals, and homeless shelters, and end the inefficiency of traveling to remote sites on a regular basis.

## SAVING TAXPAYER DOLLARS

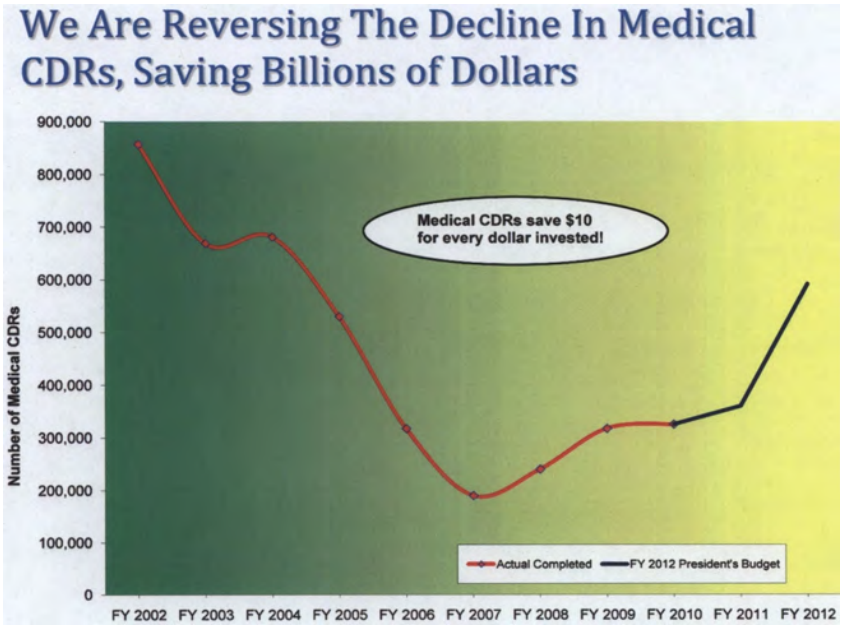
We continue to find better ways to conduct our business. We are committed to minimizing improper payments and protecting program dollars from waste, fraud, and abuse. We pay over $60 billion in benefits each month and have a duty to protect taxpayer dollars. We invested $758 million toward our program integrity efforts in fiscal year 2010, and our budgets propose to invest even more in fiscal years 2011 and 2012.

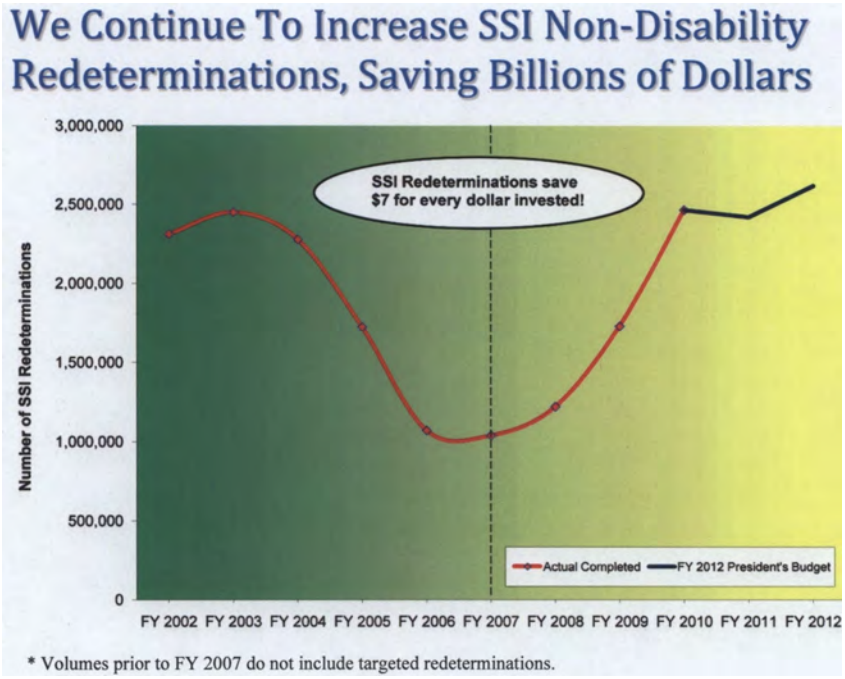
We have many stewardship activities that are critical to helping us prevent and detect improper payments. These include our program integrity reviews, our initiatives to reduce improper payments, and our joint Cooperative Disability Investigations effort with our OIG.

We have two types of program integrity reviews for which we receive special funding: CDRs, which are periodic reevaluations to determine if beneficiaries are still disabled, and SSI redeterminations, which are periodic reviews of non-medical factors of SSI eligibility, such as income and resources. We estimate that every dollar spent on CDRs yields at least $10 in lifetime program savings. Every dollar spent on SSI redeterminations yields more than $7 in program savings over 10 years, including savings accruing to Medicaid.

For many years, we had to cut back on these reviews due to inadequate funding. However, with your support, we have been able to increase the number of program integrity reviews we complete, saving billions of program dollars. In fiscal year 2012, we plan to conduct 592,000 full medical CDRs, up from the 360,000 we plan to conduct this fiscal year. We also plan to conduct 2.6 million redeterminations, up from an estimated 2.4 million in fiscal year 2011.

The fiscal year 2012 President's budget includes a legislative proposal to require employers to report wages quarterly. Increasing the frequency of wage reporting would improve program integrity for a range of programs by generating more timely information for retrospective checking and quality control.




* Volumes prior to FY 2007 do not include targeted redeterminations.

We have several initiatives underway to reduce improper payments. In fiscal year 2009, over 99 percent of all OASDI payments were free of payment error. Our SSI payment accuracy is improving, but it is still not acceptable. In fiscal year 2009, 91.6 percent of all SSI payments were free of overpayments, while 98.4 percent of all SSI payments were free of underpayments.

To help improve our SSI accuracy rate, we have developed several program initiatives that are both cost-effective and prevent or minimize improper payments. These include:

—*Access to Financial Institutions (AFI)*.—In 2004, we began piloting AFI, which runs data matches with financial institutions that allow us to quickly and easily identify assets of SSI applicants and recipients that exceed the statutory limits. In November 2007, we expanded AFI to California. Currently, 25 States use AFI, and we expect to complete our rollout by the end of fiscal year 2011. Once we have fully implemented AFI, we project roughly $900 million in lifetime program savings for each year that we use the fully implemented process. We are working with other agencies to see if they would benefit from this initiative.

—*Telephone Wage Reporting*.—Wages earned by SSI recipients can affect their payment amounts. We do not always receive reports of income timely; in fact, this is a major cause of SSI improper payments. Using our SSI Telephone Wage Reporting System (SSITWR), recipients can call a dedicated toll-free number to report their wages via a voice recognition system. In fiscal year 2010, we received over 331,000 calls to our SSITWR. These reports generally require no additional evidence, which saves time in our field offices. Wages reported using this method are 92.2 percent accurate, compared to the 75.5 percent dollar accuracy of wages reported through traditional means. Based on the positive results of electronic reporting in the SSI program, we are planning to expand telephone wage reporting to Social Security disability beneficiaries.

With adequate funding, we plan to continue to modernize our information technology infrastructure. If our systems are down, we cannot function. We must continue to provide service that is more efficient, continually refresh our technology before it becomes obsolete, and ensure that we can continue to protect our data from security threats.

We will expand our use of Health Information Technology (HIT). This promising technology has reduced the amount of time it takes for us to obtain medical records, which in turn decreases the time it takes to complete a disability claim. In fiscal year 2010, we funded technological support for a number of healthcare providers to send us medical records electronically.

## DISABILITY WORK INCENTIVES SIMPLIFICATION PILOT (WISP)

The fiscal year 2010 President's budget request proposes a 5-year reauthorization of our section 234 demonstration authority for the DI program, which would allow us to test program innovations. One such innovation is the WISP program, which would provide beneficiaries with a simple set of work rules and would no longer terminate benefits based solely on earnings. Many DI beneficiaries want to return to work but they do not attempt to because they are worried about losing monthly benefits and health insurance if their work attempt fails. Additionally, the current work incentive rules are complex and can sometimes result in large overpayments.

WISP is intended to address these concerns by replacing complex rules with a clear, simple, unified process that is both easier to understand and easier to administer. Work would no longer be a reason for terminating DI benefits. We would continue to pay cash benefits for any month in which earnings were below our established threshold, but would suspend benefits for any month in which earnings were above the threshold. A beneficiary would maintain an attachment to DI and Medicare as long as the disabling impairment continues.

Testing WISP under rigorous evaluation protocols would allow us to analyze the effects of these changes on the behavior of beneficiaries and potential applicants across the country.

## CONCLUSION

I am proud that we have significantly improved the service we deliver to the American people. Without the additional funding Congress provided to us since fiscal year 2008, Americans would wait significantly longer to receive decisions on their claims, speak to a representative in our field offices or on the phone, and have their cases heard by an ALJ.

While we hope that the worst of the economic downturn is behind us, unemployment is predicted to remain high. Since high unemployment rates usually result in more benefit applications, we expect the number of new claims, particularly for dis-

ability, will continue to remain high. These additional claims will ultimately result in more hearing requests.

We have made great progress for the American public, but it will be jeopardized without full funding of the President's fiscal year 2011 and 2012 budget requests of $12.379 billion and $12.522 billion, respectively. The American people are still struggling through the economic crisis. We cannot allow our services to deteriorate. A reduction in our funding at this time would reverse the progress we have made over the last few years. Millions of deserving Americans count on us, and we need your continued support to provide the service they expect and deserve.

ADMINISTRATIVE FUNDING FOR SOCIAL SECURITY

Senator HARKIN. So, we'll begin a round of 5-minute questions.

First, I just want to reiterate, for everyone here, we're here today to discuss administrative funding for Social Security. Issues concerning the solvency of the program are not in the purview of this subcommittee. I will be limiting my questions to the very important topic at hand that will impact millions of Americans this year, and I ask my fellow subcommittee members to do the same. Debates on solvency and what needs to be done to "fix" Social Security stuff, that's—as I said, that's not in the purview of this subcommittee. What's in the purview is the funding for the administration of the program, and how that program operates with that funding.

ANNUAL EARNINGS STATEMENTS

So, Commissioner Astrue, just a couple things. One, you said you're suspending printing and mailing of the annual earning statements. Is this the statement that people get every year that says, "Here's how much you have put in and here's what you can expect to get"——

Commissioner ASTRUE. Yes.

Senator HARKIN [continuing]."When you retire"?

Commissioner ASTRUE. Yes, it is, Mr. Chairman.

Senator HARKIN. One of the things that, when Social Security started doing this—I don't know how long ago Social Security started doing this, but——

Commissioner ASTRUE. We started doing this, on a pilot basis, when I was with the agency the last time. So, it would be more or less around 1987——

Senator HARKIN. Somewhere in there.

Commissioner ASTRUE. Mr. Chairman.

Senator HARKIN. Since then, what's happened—correct me if I'm wrong—is that people get these statements and they then have a better idea if they need to save more or put more in some other retirement account or something, because they'll know what their Social Security is going to be. And now they're not going to have that information?

Commissioner ASTRUE. Well, they will substantially have that information in a different form, Mr. Chairman. So, one of the things that we have done on my watch is that almost all Americans can go online now and get an estimate of their retirement earnings. And it's very accurate. What they used to do with the old printed statement is take their 35 years, type those into an online program that was not very accurate, and try to get the same information. So, for the vast majority of Americans, they can now get what they're really looking for, much more accurately.

What we were planning on talking to the Congress about in the next 6 months, we think that we are close to being able provide the earning statement information online. We do not know for sure yet. It's primarily a question of authentication, and we're still working on that. So, we are in the process of canceling the contract, which is very expensive. We think, in the next 6 months, we'll be able to make a decision whether we're going to be able to provide that information safely and efficiently online, or whether we have to revert to the old way of doing things. But, in the meantime, it seemed like it made sense; given the tradeoffs of all the things that we're supposed to do that we can't do efficiently, that this is one of the things that it made sense to take a pause in doing.

PROGRAM INTEGRITY

Senator HARKIN. I understand. Very good.

About program integrity: As you say, the continuing disability reviews save about $10 for every $1 spent. Redeterminations save about $7 for every $1 spent. What are the long-term budget implications of cutting administrative funding for these today, if we do cut them?

Commissioner ASTRUE. Well, I think the key part of the issue, Mr. Chairman, is that even if we continue the same level of program integrity work—and with all the stresses of the agency, you'll note my commitment to program integrity work, because that had dropped steadily with the administrative funding cuts in the beginning of the decade. And they've gone up, year by year, on my watch, although we're not back to where we really should be in order to protect the trust funds appropriately.

But, the issue really is, we are going to make a lot more mistakes that cost the trust fund money if we're not handling the cases upfront correctly. And what's going to happen if we have sudden and severe cuts is, the level of error will increase dramatically, and we'll need more staff, and it will take a lot of time, and it will not be a complete recovery effort, to try to fix that after the fact. As with most things in life, it's better to do it correctly upfront than try to fix the problems after the fact.

DISABILITY WAITING TIMES

Senator HARKIN. Last—I've only got a few seconds left; I'll ask my last question. And that has to do with the amount of time that you have reduced. On your watch, you've reduced the——

Commissioner ASTRUE. Yes.

Senator HARKIN [continuing]. The waiting time considerably. I congratulate you on that. That's great leadership. And so, I've said this to some people, but "Well, okay, then the time will go back up again, for people to get their disability claims." And, quite frankly, some people have said, "Well, you know, so what? So, they have to wait another half a year or year. So what?" Well, what's the response on that?

Commissioner ASTRUE. Well, you know, my response is, I've been through this, personally. Very unexpectedly in 1985, I had to file for disability for my father. And I think that a lot of people who say things like that just don't appreciate what it's like to be in that position and how important—even with the 5-month waiting period

for benefits and the 24-month waiting period for medical benefits—how important it is for the family, for financial planning, to know what's going to be available when. And I think anyone who's been through the process can't possibly say, "Well, another year, another 2 years, is just fine."

Senator HARKIN. Thank you very much, Commissioner.

Senator Shelby.

RECOVERY ACT FUNDING FOR SSA

Senator SHELBY. Thank you, Mr. Chairman.

I'm a little baffled by the assumptions made by the Social Security Administration, in your testimony, with regard to fiscal year 2011 and 2012 budgets. You state, and I'll quote, "The $350 million Recovery Act funding we used in fiscal year 2010 to handle claims was not included in our continuing resolution level. Between having to recover mandatory cost increases and not having Recovery Act funding, we're operating at a significant loss over last year."

It's my understanding that the Social Security Administration received $500 million in the stimulus bill to address workload processing. These were onetime funds that should not, I believe, be considered in addition to the administration's baseline. The 2012 budget request is 9.4 percent higher than 2010. This significant request for additional resources comes, of course, in an austere economic environment, where we should not be looking at how to throw money at a problem, but to work smarter.

Instead of spending onetime stimulus funding on personnel, I believe the Social Security Administration should have been looking at ways to streamline the claims process. Maybe you have. The Social Security Administration's use of one-time funds to build new personnel into its baseline, I think is a dangerous mismanagement of Federal funds. Using one-time Recovery Act money, your agency hired 2,405 employees—more employees—to lower the disability backlog. Your own numbers show initial disability receipts and hearing receipts will start to decline in 2012.

Why did you choose a long-term costly hiring strategy for a short-term problem?

Commissioner ASTRUE. Well, Mr.——

Senator SHELBY. At least that's the way it looks to me.

Commissioner ASTRUE. Mr. Shelby, in large part, because that's what the Congress told us to do. We expressed concern to the committees, at the time, that operating funds were being put into the Recovery Act instead of into the baseline, that there might be confusion in subsequent years. But, the committees of Congress that we talked to were quite clear that they knew that the only way to reduce the backlog in the short-term was to address some of the staffing issues, and said it would be adjusted—we were assured it would be adjusted in the future years. So, we did——

Senator SHELBY. Now, what does that mean, "adjusted"? You include it in——

Commissioner ASTRUE. That, in future authorizations and appropriations, there would be a recognition that these were not onetime capital expenditures. These people are different from a building. So, I agree with you——

Senator SHELBY. Who told you that?

Commissioner ASTRUE. My understanding is that was Members of the Congress and members of committee staff. I mean——

Senator SHELBY. I never heard that.

Commissioner ASTRUE [continuing]. There was no controversy at the time that we were going out and doing that hiring. In fact, I got quite a bit of criticism, from some individual Members, that we were not moving fast enough on some of the hiring. But, the civil service process, you know, is a long and difficult one. So, we did, in my view, exactly what the Congress told us to do.

Senator SHELBY. Well, a lot of people all over America, realize that this stimulus package, this money was—once it ran out, it was gone. I think you should have considered that. Obviously, you didn't.

How will you manage the additional costs, in the future, when your payroll costs already topped $7 billion, over two-thirds of your budget?

Commissioner ASTRUE. Well, most of our——

Senator SHELBY. How could you save money? Have you thought about how could you save?

Commissioner ASTRUE. Oh, I get up every day——

Senator SHELBY. Sure.

Commissioner ASTRUE [continuing]. And think about how to save money and how to make the process more efficient. But, what I think is important for the subcommittee to understand is that, unlike many other agencies that have discretion in terms of what kinds of grants they give or prioritization on enforcement, we have very little that is discretionary. Almost everything we are doing involves an entitlement to the American people, where we don't have choice whether we do it or not.

And, at the end of the day, while we have done the best we can to improve efficiency with information technology and things like that, people have to do that work. And the people are very important to that. And, as it is, we're losing people at a disturbing rate. We're losing 3,500 people this year. We're expecting, under a continuing resolution, if it extends to next year, another 4,100 people. So, we're reducing people at an extremely fast rate.

## REVERSAL RATE FOR DISABILITY DECISIONS

Senator SHELBY. I want to touch on some other stuff.

We've been told that, after being rejected by the Social Security Administration for a disability claimant person, two-thirds of the claimants win their appeal. With such a high overturn rate, why are claimants not approved on initial review, if the work was done? And, if so, it would save a lot of money, it seems to me.

Commissioner ASTRUE. Yeah. I think that's an arithmetic confusion, Mr. Shelby, because the numerator and the denominator are not the same. So, you have to realize that, in addition to the people—probably last year, if I remember correctly, over 1 million people who were approved at the initial level, and there were about 1.2 million people who received an adverse decision and did not appeal to the next level. And so, it's a relatively small number of the closer cases, as a general matter, that go up on appeal. So, the overall number of denials going from the initial decision to an appeal is actually very small.

Senator SHELBY. And how many—number-wise, what—how many cases are denied, then appealed nationwide, roughly, per year?

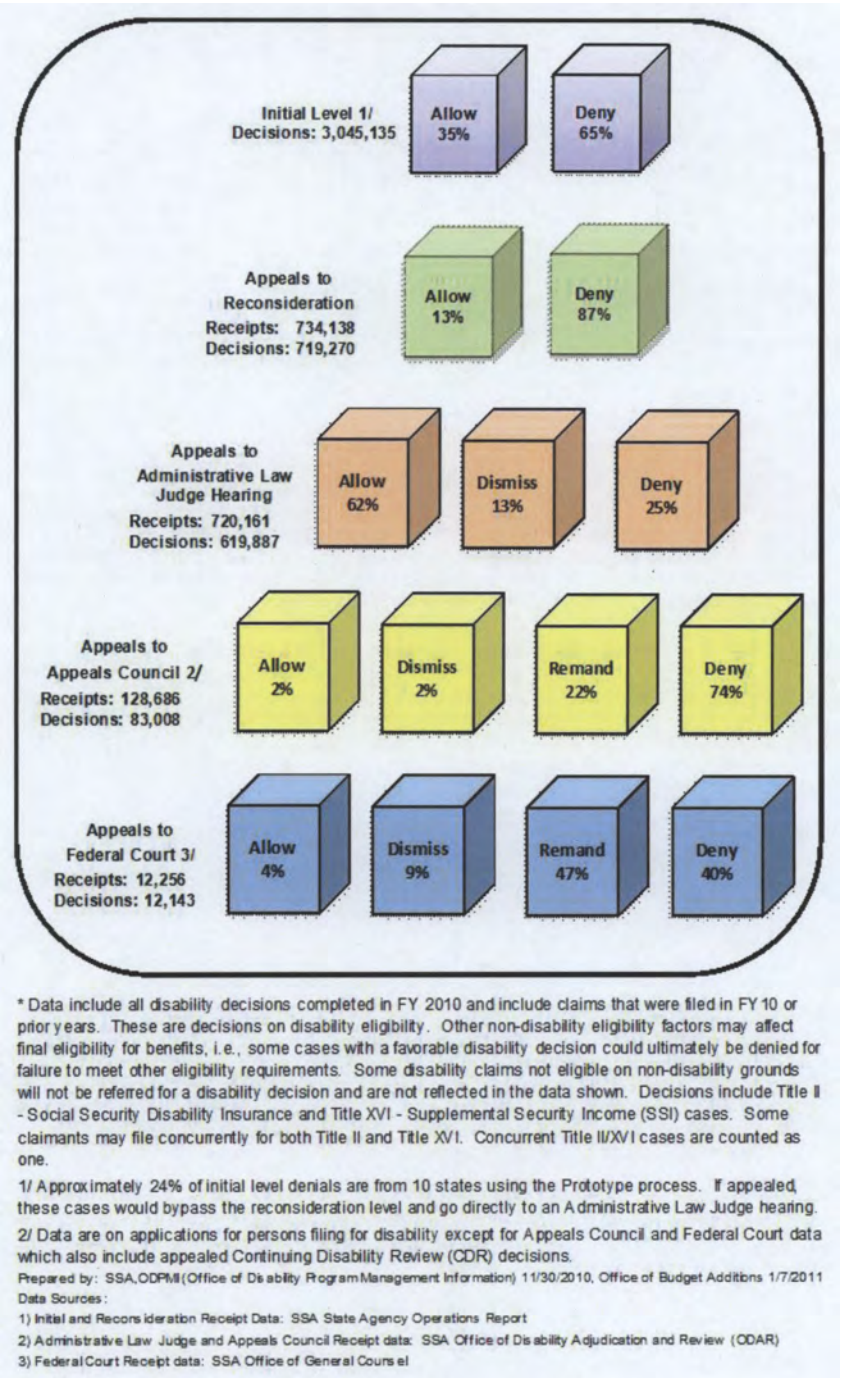
Commissioner ASTRUE. How many are——

Senator SHELBY. Yeah.

Commissioner ASTRUE. The allowance rate is down, I think, not even a statistically significant amount. But, it's my recollection, and we will provide for the record page 103 of our fiscal year 2012 justification of estimates for Appropriations Committees, which shows the flow of disability cases from the initial level all the way to Federal court appeals.

Senator SHELBY. Okay.

[The information follows:]




* Data include all disability decisions completed in FY 2010 and include claims that were filed in FY 10 or prior years. These are decisions on disability eligibility. Other non-disability eligibility factors may affect final eligibility for benefits, i.e., some cases with a favorable disability decision could ultimately be denied for failure to meet other eligibility requirements. Some disability claims not eligible on non-disability grounds will not be referred for a disability decision and are not reflected in the data shown. Decisions include Title II - Social Security Disability Insurance and Title XVI - Supplemental Security Income (SSI) cases. Some claimants may file concurrently for both Title II and Title XVI. Concurrent Title II/XVI cases are counted as one.

1/ Approximately 24% of initial level denials are from 10 states using the Prototype process. If appealed, these cases would bypass the reconsideration level and go directly to an Administrative Law Judge hearing.

2/ Data are on applications for persons filing for disability except for Appeals Council and Federal Court data which also include appealed Continuing Disability Review (CDR) decisions.

Prepared by: SSA,ODPM (Office of Disability Program Management Information) 11/30/2010, Office of Budget Additions 1/7/2011

Data Sources:

1) Initial and Reconsideration Receipt Data: SSA State Agency Operations Report

2) Administrative Law Judge and Appeals Council Receipt data: SSA Office of Disability Adjudication and Review (ODAR)

3) Federal Court Receipt data: SSA Office of General Counsel

FIGURE 1. Fiscal Year 2010 Workload Data: Disability Appeals.

Commissioner ASTRUE. It's about 62 percent at hearing.

Senator SHELBY. And how many cases are there?

Commissioner ASTRUE. It's about 800,000 hearings a year.

Senator SHELBY. Eight-hundred thousand—that's a lot of cases over the next few years.

Commissioner ASTRUE. It is a lot of cases, Mr. Shelby.

Senator SHELBY. Eight-hundred thousand cases.

Commissioner ASTRUE. And I would say, you are correct about the importance of doing things promptly and upfront. So, one of the things that we've done, in the last couple of years, is because we have an electronic system, we can now pull out the cases that should be the easy and automatic cases, and allow them upfront. And that's part of how we've increased our accuracy, which had been flat at the first level at about 94 percent. Even with all the influx of cases, we're up to about a 98-percent accuracy rate now.

COST-BENEFIT ANALYSIS OF HEARING VERSUS APPROVING A CASE INITIALLY

Senator SHELBY. I know I'm under a time constraint, but if you'd just——

Commissioner ASTRUE. I'm sorry.

Senator SHELBY [continuing]. Say it for the record. Has the Social Security Administration performed a cost-benefit analysis to examine the cost of hearing a case versus approving a case initially? That is, an appeal. What—the—if someone's got merit in their initial claim, wouldn't it make sense to do the work to ascertain that, rather than have 800,000 cases on appeal?

Commissioner ASTRUE. Well, we're certainly trying to do that. And, as I said——

Senator SHELBY. Assume it's got merit, you know? And if the appeal process throws back two-thirds of the cases, there's something wrong.

Commissioner ASTRUE. Well, as I said, I think if we were approving a much lower percentage, then we'd be getting the complaint from the Congress that the odds are stacked against the claimants. So, it is a process that has been very carefully prescribed by the Congress, that we try to follow as closely as we can. And you have to realize that each decision, if I remember correctly, at the hearings and appeals level, in terms of net present value, is about a quarter million dollar decision. So, these are important decisions.

And I don't think it's the right answer, from a trust fund point of view, to simply give that money away at the front end of the process. There are some cases that are very close, where reasonable people can disagree. It's very hard to tell with back pain, it's very hard to tell with depression. There are also cases up on appeal that initially are turned down, appropriately, because they're diseases that get progressively worse. And, by the time they get to the appeal, where we look at it fresh—it's not like a legal appeal, where you——

Senator SHELBY. Well, I've known cases where people who have filed for disability claims and have been denied. And, of course, to say they're not really that sick or they're not that disabled, and then they die before the appeal process. You know 'em, too.

Commissioner ASTRUE. Yes, that's——

Senator SHELBY. So, I think——

Commissioner ASTRUE [continuing]. That does happen.

Senator SHELBY [continuing]. What we've got to do is determine the merits of cases.

Commissioner ASTRUE. Absolutely. I agree with you, Mr. Shelby.

Senator SHELBY. Thank you.

FUNDING NEED TO RUN AN EFFICIENT, EFFECTIVE SSA

Senator HARKIN. Thank you, Senator Shelby.

Senator Mikulski.

Senator MIKULSKI. Thank you, Mr. Chairman.

Mr. Administrator, I have two questions: one on what you need to run an efficient, effective Social Security Administration; and then the other, additional info on the impact of the continuing resolution.

I believe that demography is destiny. In other words, the population profile of the United States is predictable. We have a Census Department that tells us who it is. And what they tell us is, the Baby Boomer generation is here. If there are Boomers, there are demands on the application to Social Security. You have no control over it. Congress doesn't have any control over it. No political party or subgroup within a party has it. Tell me, from the standpoint of someone who's devoted his career to public service, what is it that you think you need to have for fiscal year 2012. What is the number of employees you need to have, and what is it that you need to have in the Federal budget to meet the sheer predictable population demands, let alone economic downturns or an unexpected event?

Commissioner ASTRUE. Sure. That's a very fine question.

As you know, Senator Mikulski, by statute my request to the President is disclosed to the Congress, and so that you know, the President's request for 2011 and 2012 was very close to my request. And we've laid out in the President's budget why we need——

Senator MIKULSKI. But, for the record, what amount is it, and what will that buy?

Commissioner ASTRUE. Well, what the President's level would—which is approximately $12.5 billion—would allow us to do is to meet the ongoing service needs of the country and continue on track to reduce the existing backlogs, not only at the hearing level, but at the front level, because we've gotten about two-thirds of 1 million more disability cases than we originally projected a few years ago. And we have to process that work.

EFFECTS OF CONTINUING RESOLUTION

Under the continuing resolution, staff numbers are declining very rapidly. We are barely above the funding level where we need to furlough. And, at that point, we start to see degradation of service. We've been trying to hold the line as best we can. But, if we go much further with these kinds of dramatic staff reductions, the numbers that have been improving so well for the last 4 years——

Senator MIKULSKI. Let me get——

Commissioner ASTRUE [continuing]. Rapidly——

Senator MIKULSKI [continuing]. To the point.

First of all, I'm deeply troubled by the 3,500 employees that will be lost this year. That's 3,500 nationwide——

Commissioner ASTRUE. Yes.

Senator MIKULSKI [continuing]. Not in the headquarters, the——

Commissioner ASTRUE. Yes, that's right.

Senator MIKULSKI [continuing]. The mother ship in Baltimore——

Commissioner ASTRUE. Yes, that's right.

Senator MIKULSKI [continuing]. Is that correct?

Commissioner ASTRUE. That is correct.

Senator MIKULSKI. So, that's nationwide, and that's in the field offices, et cetera.

Commissioner ASTRUE. Yes. And about 80 percent of the people, more or less, are in the field.

Senator MIKULSKI. Now, is it because people now know that there's both a freeze, an impending furlough, and the serious threats of reductions in promised retirement benefits that have been proposed in some deficit reduction plans, such as going to a high five instead of a high three? Are people also getting ready, at the Social Security Administration, to retire at a more increasing rate? So, in addition to that which you need to replace employees who leave through natural attrition, they're going to start to bail out?

Commissioner ASTRUE. Well, I think all those things are factors, and significant ones. I think if you look at it from a broad perspective—because we went 14 straight years with appropriations under the President's request, we did not do very much hiring for a long time. We had been an agency, at one point, of as many as 82,000 people. And we dropped, briefly—in the beginning of my watch, when we were on a continuing resolution for 15 months, if I remember correctly, to under 60,000. So, we're up a little bit over that now, but we have an older workforce; we have a lot of people retiring, as a normal course of business. I think some of the things that have happened with civil service are accelerating that.

But, I have to be candid with you, too; we also just gave everyone, without exception, the ability, earlier in the year, for early out, because we looked at the potential budget situation and, to Mr. Shelby's point, that the Congress is telling us that we can't afford those people. So——

Senator MIKULSKI. Good. Now, let me jump in. We could be headed to a shutdown.

Commissioner ASTRUE. Yes.

POSSIBLE EFFECTS OF GOVERNMENT SHUTDOWN

Senator MIKULSKI. Because, I know that, in my subcommittee, in Commerce/Justice, I can't cut any more. And Senator Harkin must also be facing the same stress. So, we're heading to a showdown.

Now, much has been said about the impact on Social Security. If there is a shutdown, will Social Security checks go out?

Commissioner ASTRUE. So, this answer——

Senator MIKULSKI. And will field offices——

Commissioner ASTRUE. Sure.

Senator MIKULSKI [continuing]. Stay open, or will they be closed?

Commissioner ASTRUE. Sure. This answer gets a little bit complicated, depending on whether the Congress fails to pass a budget at all or takes deep cuts in our budget. So, it's a somewhat different answer.

But, if the answer is addressed to a shutdown, where Congress does not pass a budget, then I think that the White House has made what will happen clear. Mr. Carney correctly laid out that, for most existing beneficiaries, checks will go out and they will not see an interruption of service. If you've had a change of address, if you're a new applicant, then we cannot pretend that we will be able to get a timely and accurate payment out.

Senator MIKULSKI. And what about the field offices? Are they open or closed?

Commissioner ASTRUE. Under a shutdown scenario in the Government, we have some latitude to keep some essential services open, but we will be open only on a very partial basis, for certain types of work, under a Government-wide shutdown.

Senator MIKULSKI. I think this is a very severe crisis.

Commissioner ASTRUE. I agree——

Senator MIKULSKI. And I——

Commissioner ASTRUE.—with you, Senator.

Senator MIKULSKI. And, sir, I appreciate your factual and candid response. And it's our job to resolve the crisis. Thanks for being so candid.

Commissioner ASTRUE. Thank you, Senator Mikulski.

Senator HARKIN. Thank you, Senator Mikulski.

Senator Reed.

Senator REED. Thank you very much, Mr. Chairman.

Thank you, Commissioner, for your testimony and for your very professional service.

Commissioner ASTRUE. Thank you.

SSA ADMINISTRATIVE OVERHEAD

Senator REED. Just as background, sort of contrast, how would you evaluate your overhead, including all of your personnel and your systems, versus a comparable insurance entity in the country?

Commissioner ASTRUE. I think that we stand up against, not only any Federal agency, but pretty much any large financial organization in the country. If I remember correctly—if I'm making a mistake, we'll correct it for the record—about 1.6 percent, I believe, of our budget is for administrative costs. And it's been going down steadily, as a percentage of cost, for a number of years. So, this is, in my book—and I've been a CEO of publicly traded corporations, which relatively few agency heads have—an extraordinarily efficient organization. And I don't think there's a lot of fat left in this organization.

Senator REED. In fact, I think is—and I'm alluding to what was suggested by Senator Mikulski—we're reaching the point where, if we deny effective resources to the Department, this level of efficiency will be compromised——

Commissioner ASTRUE. Yes.

Senator REED [continuing]. That, at some point, you just can't, you know, continue to maintain this level.

Commissioner ASTRUE. Exactly, Senator Reed—we've run this experiment recently. So, we ran down the administrative budget for most of this decade. And very predictable things happened: backlogs grew, and program integrity work plummeted, at a long-term cost to the trust fund. It is only with great difficulty that we've been able to move the agency back in a positive direction and increase the program integrity work and bring the backlogs down.

And what I would say to all of you now is, it's your choice. We've done everything that we know how to do. And whether we go backward or whether we go forward depends on what you decide to choose for funding for the agency.

ADEQUATE RESOURCES NEEDED FOR SSA

Senator REED. Well, I think it's ironic—I'll use that term—that you—we have one of the most effective programs in the history of this country, one of the most efficiently run programs in the history of this country—in fact, as you suggest, from your experience as a CEO of a private-sector country—company—much more effective than most of the vaunted public companies. And yet, we're at the point of disrupting it significantly, in terms of how it operates, if we don't provide adequate resources to you.

So, I think it's clear that, you know, this is one of those cases—and they're not that frequent in any endeavor, particularly Government—where we have to reinforce success, not undercut it. And so, I would hope that we would reject some of the proposals—particularly the House proposal, it would have significant cuts, as I understand them—and support you at a time—and again, to Senator Mikulski's point—where, demographically, your burden is not going to get lighter, it's going to get heavier because of the people like me—not yet, but very soon.

And I want you to be around for my 4-year-old daughter. So, you—we—I've got a vested interest.

Commissioner ASTRUE. Well, my term runs pretty soon. So, I know——

Senator REED. I know it will.

Commissioner ASTRUE [continuing]. I won't be there personally, but the wonderful people behind me will be there.

SERVICE CUTS DUE TO A LACK OF FUNDING

Senator REED. All right. Well, if that's a promise.

Let me just now go down, sort of, the level—and again, suggested by Senator Mikulski—these cuts will come, not from the D.C., Washington, Baltimore, metro area. Most of them are from the local offices. We had the experience, in 2002, where adjudication officers in three of my communities in Rhode Island were consolidated. You know, again, you said, "When you cut the budget every year, you start cutting into the—you know, the efficient operation." They were sent up to Massachusetts. I would assume that if the budget pressure continues to grow as is, you'll be making those same types of decisions.

Commissioner ASTRUE. Exactly right. We are actually moving more work geographically around the country to take advantage of wherever places are less busy. So, we've done more of that than in the past. And, if we go into a crisis, then there'll be more work

moving from one State to another as we try to manage things as best we can.

Senator REED. So, you'll have two situations going on: reductions in force——

Commissioner ASTRUE. Right.

Senator REED [continuing]. Consolidations of offices. What that leaves, though, is big—potentially, big service gaps. I mean——

Commissioner ASTRUE. Yes.

Senator REED [continuing]. It is a difference between a senior citizen in my State getting on a bus or getting—taking their car and driving 10 or 15 or 20 minutes to a local office and the difference of going to Boston, literally——

Commissioner ASTRUE. Yes.

Senator REED [continuing]. And with all of the—that entails.

Commissioner ASTRUE. Yes. You know, you've said it more articulately than I could, Senator, but the only thing I would add is, it's already happening. We're already starting to move backward because of the staff reductions.

Senator REED. Let me just—a final point is that we sometimes focus on the Social Security system as one that deals with seniors. But, you have families and children that we have to worry about. In fact, one of the startling statistics that I've seen recently is that, for the first time, the Great Depression, 25 percent of children in this country are living in poverty.

Commissioner ASTRUE. Right. And——

Senator REED. That's a very, very shocking and, indeed, shameful statistic——

Commissioner ASTRUE. And, in fact——

Senator REED [continuing]. Given this the——

Commissioner ASTRUE [continuing]. If you look at——

Senator REED [continuing]. Wealthiest country.

Commissioner ASTRUE [continuing]. Where the administrative effort is spent, we would be even more efficient if we were just a retirement organization; but we're not. We will take in about 3.3 million disability claims this year, and that's where the vast majority of the administrative effort goes. We're the largest repository of medical records in the world. Sometimes we have over 1,000 pages of medical records we need to review. And a lot of these are very difficult, close calls.

That is, in fact, where a lot of the administrative time is spent, because the retirement process is pretty automatic. We try to make it even more automatic. We've gone from 10 percent to 40 percent of the people filing online, because we've improved—we've made it a much more user-friendly process. And we're trying to find the efficiencies wherever we can. But, the lion's share of the administrative effort is on the disability side. And there are just some limits on how much of that you can automate. And we'll have to make a lot of those decisions.

Senator REED. And—but, that has a huge impact on the quality of life of families and children in this country——

Commissioner ASTRUE. Absolutely.

Senator REED [continuing]. Particularly as we see these growing statistics of childhood poverty. And your agency does make a difference; but if you don't have the resources, you can't.

Commissioner ASTRUE. That's right.

Senator REED. Thank you.

Senator HARKIN. Commissioner, thank you very much for your great stewardship of a wonderful—or a wonderful part of our American society. Thank you for your stewardship of it. We have our work cut out for us, in terms of making sure that you can do your job well and make sure that people who rely upon Social Security—as Senator Reed just reminded us, not just elderly, a lot of kids out there, too, and people with disabilities, survivors—make sure that they can get timely help.

## ADDITIONAL COMMITTEE QUESTIONS

Commissioner ASTRUE. Thank you very much, Mr. Chairman.

Thank you to everyone on the subcommittee. I appreciate this opportunity.

Senator HARKIN. Thanks, Commissioner.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

### QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

*Question.* You are permitted to transfer unobligated regular appropriations authority that is considered "not needed" to your information technology (IT) fund. Since fiscal year 2001 you have transferred $1.3 billion out of the operational Limitation on Administrative Expenses account into the IT Fund. This is at a time of record backlogs and wait times. Why were these Limitation on Administrative Expenses funds considered "not needed?" Wouldn't this funding have been better spent on integrity work, such as, disability and Supplemental Security Income reviews?

Answer. Our ability to transfer unobligated administrative funds to our Information Technology Systems (ITS) account is a funding mechanism that Congress specifically authorized and that the Office of Management and Budget (OMB) manages closely. Congress included language in our fiscal year 2001 appropriation that allowed us to carry forward unobligated Limitation on Administrative Expenses (LAE) funds to invest in ITS costs. Congress has continued to provide this authority in every succeeding appropriations act since fiscal year 2001.

We must justify to OMB any transfer of unobligated balances to the ITS account, and OMB must give us formal approval before we can transfer and spend any funds. Moreover, available ITS transfer funding factors into our annual budget request. During the budget process, we work with OMB to determine how much of our IT needs will be covered with funding we can transfer into the ITS account, thereby decreasing the amount of new funding we need to request in any given fiscal year.

We have a long history of sound financial management practices that avoid Anti-Deficiency Act violations. At the beginning of each fiscal year, we put in place spending plans to use the full budget. We develop performance targets (i.e., numbers of completed claims, hearings, continuing disability review, redeterminations, etc.), estimate related costs, and negotiate these estimates with OMB. We allocate these annual resources as soon as we have an appropriation from Congress and approved apportionments from OMB. We continually monitor our resources and reallocate them to our highest priorities as the year progresses. We typically lapse only about 1 percent of our LAE funding each year. We do not lapse annual funding in order to transfer it to our ITS account. Nevertheless, with the complexity of our budget, two-thirds of which is payroll costs, a small amount of lapsed resources is unavoidable and often necessary to avoid an Anti-Deficiency Act violation. With nearly 80,000 Federal and State employees, even a small shift in salary or benefit costs can create a change of millions of dollars in our administrative budget. We also must be able to address unanticipated requirements, such as court decisions.

When we receive a budget each year, we determine the level of staff we can fund and support in future fiscal years. Your suggestion that we could have better used annual administrative resources to complete more program integrity work would have required us to hire additional staff. Uncertainty about future funding makes it difficult to predict how many employees we can support in future years, and prolonged continuing resolutions can delay the hiring process. We cannot make long-

term commitments to hire employees when future budgets may not support retaining them, potentially forcing us to implement furloughs or other drastic cost saving measures.

ITS transfer authority has allowed us to make technology improvements that help our employees work more efficiently. Our IT investments have helped us achieve average annual employee productivity increases of about 4 percent each of the last 5 years. Most of our annual ITS funding is necessary for ongoing operational costs such as our 800 number service and our online services. It also helps us maintain sufficient capacity to store ever-increasing amounts of data. Prior year resources have helped us fund essential IT projects such as making our disability process fully electronic, developing robust and user-friendly online services, and opening our second data center. Without these IT investments, we would not have kept pace with the recent increases in claims. If we did not have the ITS transfer authority but still invested the same amount of resources in IT enhancements to improve employee productivity, we would have completed nearly 1 million fewer disability claims or nearly 500,000 fewer hearings since fiscal year 2001.

*Question.* Today, what is the total level of funding in the so-called "IT Fund," or the carryover funding from previous fiscal years for information technology and telecommunication activities? Of this amount, what level of funding did the Social Security Administration's fiscal year 2011 budget request state would be used in fiscal year 2011? Is it correct that this would still leave a substantial amount of reserve funding in the IT Fund that would not be spent in this fiscal year? What level of funding specifically would remain in the IT Fund?

Answer. The fiscal year 2011 column of the fiscal year 2012 President's budget assumed that $480.4 million would be available in fiscal year 2011 to transfer to the no-year ITS account. Of that total, our fiscal year 2012 budget assumed that we would use $280 million in fiscal year 2011 and the remaining $200.4 million in fiscal year 2012 for IT costs. Prior to March 2011, we had transferred $680.4 million from previous fiscal year unobligated balances to the no-year ITS account, which was the amount available in prior year accounts that was not needed for potential upward adjustments to prior year obligations. On March 18, 2011, the Additional Continuing Appropriations Amendments, 2011 (Public Law 112–6, the sixth CR for fiscal year 2011) rescinded $200 million of the available $680.4 million. The Department of Defense and Full-Year Continuing Appropriations Act, 2011 (Public Law 112–10, enacted on April 15, 2011) rescinded an additional $75 million.

Due to the rescissions in fiscal year 2011, we carried over only $32.5 million from fiscal year 2011 into the no-year ITS account in fiscal year 2012. In fiscal year 2012, we transferred $129.6 million from previous fiscal year unobligated balances to the ITS no-year account. In total, we have $162.1 million available in the fiscal year 2012 no-year ITS account. This amount is less than the $200.4 million that we assumed would be available in the fiscal year 2012 no-year ITS account.

*Question.* According to the Congressional Research Service, only 3 percent of beneficiaries ever come off Social Security Disability Insurance (SSDI) rolls. In your testimony, you discussed the pilot Work Incentives Simplification Program (WISP) that would allow beneficiaries to return to work and continue to receive SSDI benefits for any month in which earnings were below the established threshold. I believe it is critical to the future of SSDI that beneficiaries who are able to work do. However, I remain concerned that other programs put in place by the Social Security Administration to incentivize work, such as the Ticket to Work program, have been failures. How do you implement this program to ensure those who are able to work in some capacity will do so?

Answer. Congress established the Ticket to Work (Ticket) program in 1999 to expand the universe of service providers to help beneficiaries obtain the services and supports they need to find and maintain employment. In 2008, we made regulatory changes to the Ticket program, which have significantly increased beneficiary and employment network (EN) participation. Since the change, the number of active ENs increased by nearly 50 percent and the number of beneficiaries that ENs placed in a job increased by 319 percent from a little over 4,000 beneficiaries to over 16,895 beneficiaries.

The most important distinction between the Ticket program and the Work Incentives Simplification Pilot (WISP) is that under the Ticket program, we must still apply our complex and often confusing work incentive rules. The Social Security Act (Act) includes a number of incentives to encourage disability beneficiaries to return to work. In the Social Security Disability (SSDI) program, the incentives include the trial work period (TWP) and the extended period of eligibility (EPE). In addition, there are special rules about impairment-related work expenses, expedited reinstatement, and medical insurance. Although we train our field office personnel to explain the work incentives and we publish information to help people understand

the provisions, the work incentive provisions are complex and difficult to administer and understand. The work incentive rules are different for SSDI than they are for Supplemental Security Income (SSI) which make the rules even more complex if a person is entitled to both types of benefits. The goal of WISP, which we would first pilot, is to simplify SSDI work rules to encourage beneficiaries to return to work and reduce our administrative costs. WISP would eliminate complex rules on the TWP and the EPE. It would also eliminate performing substantial gainful activity as a reason to terminate SSDI benefits. If a beneficiary's earnings fell below a certain threshold, we could reinstate monthly benefit payments as long as the person remained disabled. WISP would allow us to replace the complex work continuing disability review process with a streamlined work review process, which would reduce improper payments. Finally, our WISP proposal would better align the SSDI program with the SSI program.

Congress has held hearings to highlight the importance of program integrity and improved service. Program simplification is an answer to Congress' questions about how to improve in these areas.

*Question.* There are no disincentives from fraudulently applying for Social Security Disability Insurance. Claimants are not fined and virtually no one is prosecuted for a false claim. How do we implement specific, targeted fixes to this program when there is no deterrent mechanism?

Answer. One of our most successful efforts against disability fraud is the Cooperative Disability Investigations (CDI) program, which links our Office of Inspector General (OIG) and local law enforcement with Federal and State workers who handle our disability cases. These units are highly successful at detecting fraud before we make a disability decision and identifying overpayments. There are currently 25 CDI units nationwide.

Since its inception in fiscal year 1998, CDI efforts nationwide have resulted in nearly $3.1 billion in projected savings: $1.9 billion to our disability programs and $1.2 billion to other programs, such as Medicare and Medicaid. Due to the success of the CDI program and our increased efforts to prevent improper payments, we plan to open additional units as resources permit.

The Federal Government or States may prosecute an individual for fraudulently receiving SSDI benefits. The determination as to whether to proceed criminally rests with the appropriate prosecutor, either Federal or State. The Department of Justice may also pursue a claim under the False Claims Act. If a U.S. Attorney's Office declines to prosecute the case, our OIG may pursue an action for civil monetary penalties. If the OIG declines the case, we may pursue administrative penalties.

We train our field employees to alert OIG to any cases of suspected fraud. We made nearly 19,000 such fraud referrals related to our disability programs in fiscal year 2011, from which the OIG opened about 4,600 cases. During this period, our OIG initiated 314 civil monetary penalty cases, successfully resolving 67 with $2,798,172 in penalties and assessments imposed.

Additionally, we have nine attorneys assigned to a United States Attorney's Office as Special Assistants. These attorneys prosecute possible fraud cases referred by OIG that would not otherwise be prosecuted in Federal court. From fiscal years 2003 through 2011, our attorneys secured over $43.7 million in restitution orders and 814 convictions or guilty pleas.

*Question.* It is my understanding that the Social Security Administration has implemented two fast-track initiatives, known as Compassionate Allowances and Quick Disability Determinations, to improve processing of claims for those with severe disabilities. Please provide specific data on the decrease in time to approve claims under these programs compared to past claim processing times.

Answer. The State disability determination services (DDS) render disability determinations for initial claims. In fiscal year 2011, the average time from the date the DDS received the claim until the DDS made a disability determination was approximately 80 days for all approved claims, 10 days for approved fast-track claims and 88 days for approved non-fast-track claims.

*Question.* I am told that Continuing Disability Reviews yield more than $10 in lifetime program savings for every $1 spent and Supplemental Security Income redeterminations yield over $7 in lifetime program savings for every $1 spent. I find it alarming that an Office of the Inspector General Report recently found from 2005 to 2010 it is estimated that the Social Security Administration paid between $1.3 billion and $1.6 billion in disability benefits that could have been avoided with full medical Continuing Disability Reviews. In recent years, Congress has provided specific funding for program integrity initiatives. What additional steps would you recommend be taken to support program integrity efforts that could lead to increased savings?

Answer. For many years, the agency was forced to cut back on program integrity reviews due to inadequate funding. The same people who handle initial disability decisions and reconsiderations also complete medical continuing disability reviews. We must balance the amount of program integrity work we undertake with our work on incoming claims. Because of funding cuts, we hit the low point for these reviews in fiscal year 2007. In fiscal years 2008 through 2010, with additional funding, we increased our program integrity work, saving billions of program dollars. However, in fiscal year 2011, we were under a full-year continuing resolution, which prevented us from further increasing our program integrity work. We use complex algorithms to select the most cost-effective cases to review with our limited resources. Adequate funding is critical to our ability to increase this cost-effective work, but it is also important to understand that the same people who handle our program integrity work also handle other work, such as initial applications for benefits. Without sufficient and sustained funding, other work suffers as we increase program integrity work.

*Question.* Please provide detailed information on the number of cases each year that are appealed to Federal district courts after being rejected by Administrative Law Judges at the Social Security Administration. Of this number, how many claimants win their appeals at Federal district courts? With regard to cases that are remanded to the Social Security Administration, how many of these cases are ultimately decided in favor of a claimant? Please describe possible factors that may play a role in claimants' success on appeal. What recommendations would you make to improve the process on the front end so that cases that win on appeal are approved in the beginning?

Answer. In fiscal year 2010, claimants filed 13,158 complaints in Federal district courts concerning Social Security program (disability and non-disability) litigation matters. In fiscal year 2011, this number increased to 15,644, as we issued more decisions.

In 2010, Federal district courts reversed the agency's decision in 447 cases (or 3.7 percent of the 12,182 district court dispositions that year). In 2011, this number decreased to 380 cases (or 2.86 percent of the 13,304 district court dispositions that year). District courts remanded 5,718 cases (46.9 percent) to the agency in 2010 and 6,137 cases (46.12 percent) in 2011.

In 2010, we issued dispositions in 6,028 cases that courts had previously remanded. We issued fully or partially favorable decisions in 4,048 of these cases (67.15 percent). In 2011, we issued dispositions in 6,285 cases that courts had previously remanded. We issued fully or partially favorable decisions in 4,176 of those cases (66.44 percent).

The three most common causes of remand in our disability cases, which represent the vast majority of our program litigation, are: (1) insufficient reasons provided for rejecting a medical source or treating source opinion; (2) failure to consider or properly evaluate a particular impairment at step two of the sequential evaluation process; and (3) failure to accommodate limitations from all impairments in the residual functional capacity.

With regard to recommendations on how to improve our decisionmaking so that we approve claims as early as possible. We hold nationwide training for our Administrative Law Judges at which attorneys from our Office of the General Counsel participate to discuss how to best evaluate medical evidence and draft decisions. In addition, we have initiatives to improve the quality of the information in a disability case file. For example, we have an Electronic Claims Analysis Tool, a web-based tool that automatically prompts an examiner with case-relevant regulations and instructions and requires the examiner to enter the necessary documentation before he or she can close a case.

Senator HARKIN. Now we'll turn to our second panel.

Senator MIKULSKI. Mr. Chairman, I regret, I've to get to another hearing. But, this was a terrific hearing, and you've got a great panel, here.

Senator HARKIN. We've got a——

Senator MIKULSKI. I think we're——

Senator HARKIN [continuing]. Great panel, yeah.

Senator MIKULSKI. Yeah. And what we're seeing in this is, under every rock is another rock.

Senator HARKIN. Right, exactly.

Senator MIKULSKI. And we're now heading to the hard place.

Senator HARKIN. This is the——

Senator MIKULSKI. We don't want a hard landing.

Senator HARKIN. These are the hard places. Thank you very much, Senator Mikulski.

W. Lee Hammond is the president of the AARP and has been a member of its board of directors since 2002. He is a retired teacher, who served in the—Wicomico?

Mr. HAMMOND. Wicomico.

Senator HARKIN [continuing]. Wicomico County schools for 30 years. He currently serves on the U.S. Attorney's Healthcare Fraud Task Force and is a member of the Maryland Commission on Aging.

Marty Ford is the acting director of the Arc of the United States and the United Cerebral Palsy Disability Policy Collaboration. She was previously the chair of the Consortium for Citizens with Disabilities and has continued to work with the consortium as a co-chair of the Task Force on Social Security and Long-term Services and Supports; received her law degree from the George Washington University National Law Center and her B.A. from the University of Virginia.

Mr. Joe Dirango was—Dirago or——

Mr. DIRAGO. Dirago.

Senator HARKIN. Dirago.

Mr. Dirago—sorry about that—was elected the president of the National Council on Social Security Management Associations in November 2009. He previously served on the New York Region Management Society, for 13 years, and as chair of the National Council's Labor Relations Committee for 2 years. Mr. Dirago has worked for Social Security for 30 years. A graduate of State University of New York at New Paulz with a bachelor of science degree in economics.

And, before we start with this panel, I'm also told that Nancy Shor, who is the executive director of the National Organization of Social Security Claimants' Representatives, is also with us here today. She's done great work on behalf of persons with disabilities.

I have spoken and met with NOSSCR in the past, so I just wanted to take a moment to recognize both NOSSCR and Nancy Shor. I don't—I can't see where—right there in front of me.

Nancy, thank you very much. And thank you for the great work that your organization does on behalf people, especially, with disabilities.

Now, we'll start with our panel. All your statements will be made a part of the record in their entirety. I ask you to sum up, if you can, in 5 minutes or so.

And we'll start Mr. Hammond and work across.

**STATEMENT OF W. LEE HAMMOND, PRESIDENT, AMERICAN ASSOCIATION OF RETIRED PERSONS (AARP)**

Mr. HAMMOND. Chairman Harkin, Ranking Member Shelby, and members of the subcommittee, good morning to all of you.

And, Mr. Chairman, Wicomico presents a challenge wherever I go. So.

Senator HARKIN. Okay, thank you.

Mr. HAMMOND. As the largest nonprofit, nonpartisan organization representing the interests of Americans age 50 and older, their families, AARP would like to thank the chairman and ranking member for holding this hearing and giving us the opportunity to voice our concerns about the ability of the Social Security Administration to adequately serve current recipients while responding to the needs of the new Boomer retirees and other program beneficiaries.

AARP recognizes the budget deficit provides many challenges, and our members believe that it's important to work together across party lines to find responsible budget solutions that consider the health and financial well-being of all Americans.

We also believe the Federal budget reflects the priorities of this Nation and her people. First and foremost, we must always consider the impact each proposed budgetary cut will have on people. We're not just talking about numbers and statistics. We're talking about our families, our loved ones, friends, and neighbors: real people.

The Social Security Administration interacts with millions of Americans when they retire and seek the benefits that they've earned over a lifetime of work; with those who, through sickness or injury, become disabled and cannot longer support themselves or their families; with orphans of the 9/11 terrorist attack; with families of soldiers killed in Iraq and Afghanistan; and with countless widows, widowers, and surviving dependents, who must continue on after the loss of a loved one: real people.

Now, I'd like to address AARP's major concerns regarding the funding of the Social Security Administration. SSA was made an independent agency in 1995 to provide the program with consistent direction and professional management and to help insulate it against decisions not based on Social Security-related issues. However, becoming an independent agency has also placed added administrative burdens on the Social Security Administration, and we're very concern with the impact these additional responsibilities are having on the timely delivery of services to Social Security beneficiaries.

The Social Security Administration performs this additional work as it meets the challenges of Boomers reaching the retirement age at a rate of 1 every 8 seconds by the end of this decade. Nearly 80 million new beneficiaries will be added to the Social Security rolls. It's not difficult to understand the enormity of the administrative task the agency is facing.

With the increases in funding Congress has provided over the last 3 years, and significant increases in employee productivity, SSA has been able to make some progress in customer service. However, the longer-than-foreseen economic downturn has resulted in a record level of claims for the retirement and disability benefits. In fiscal year 2010, SSA received nearly 3.25 million initial disability claims, the highest in its 75-year history. Yet, at a time when additional funding is needed to handle the increased workload, the agency is dealing with the possibility of a Government shutdown as well as cutbacks resulting from enactment of spending levels below the current fiscal year. The House passed long-term continuing resolution H.R. 1, with a result in the aggregate funding loss of over $1 billion for the Social Security Administration. That proposal is unacceptable.

As if service reductions were not enough, even the status quo would prevent program integrity efforts from realizing their potential. Congress has consistently provided for separate additional funds for SSA to conduct continuing disability reviews and SSI eligibility redeterminations. We believe that not enabling the agency to pursue these activities, simply because of an artificial barrier like the discretionary spending caps, would be downright foolish.

Mr. Chairman, AARP strongly urges the subcommittee, and the Senate as a whole, to reject the deep cuts to SSA funding that are included in the House-passed resolution. Today, the bottom line is nothing—is that nothing short of the $11.5 billion, with no rescission of IT funds for fiscal year 2011, will ensure the ability of the SSA to adapt to the many critical challenges that confront them for the balance of this year. Social Security Administration customers, whether older, younger, or somewhere in between, are real people. They have the right to expect better service than they're receiving today. We sincerely hope that Congress and the President will not let them down, by providing the funding necessary to enable SSA to serve them promptly and properly.

On behalf of the millions of AARP members, and of all Americans who are served by SSA, thank you for the opportunity to address the subcommittee.

Senator HARKIN. Mr. Hammond, thank you very much.

[The statement follows:]

PREPARED STATEMENT OF W. LEE HAMMOND

Chairman Harkin, Ranking Member Shelby, and members of the Labor, Health and Human Services, and Education, and Related Agencies Subcommittee, good morning.

As the largest nonprofit, nonpartisan organization representing the interests of Americans age 50 and older and their families, American Association of Retired Persons (AARP) would like to thank to Chairman Harkin, and Ranking Member Shelby for holding this hearing. AARP appreciates this opportunity to appear before the subcommittee to voice our concerns about the ability of the Social Security Administration (SSA) to adequately serve current recipients while responding to the needs of new Boomer retirees and other program beneficiaries. I am here today to speak

to AARP's priorities with respect to funding for the SSA for fiscal year 2011 and beyond.

While SSA funding is of great importance, we have equal concern for many other vital healthcare services and economic security programs. For example, AARP is concerned about sufficient funding for the Qualified Individual-1 program which helps more than 156,000 seniors nationwide afford to pay their Medicare premiums that would otherwise be unaffordable or cause great financial hardship; programs authorized under the Older Americans Act which provide needed assistance, including nutrition programs which free hundreds of thousands of our seniors from hunger, as well as job training and other services; and, the Low Income Home Energy Assistance that help millions of households with seniors avoid making that horrible choice between heating and eating, or paying for all the medicine they need to live healthy lives in homes, not institutions.

As you complete action on the fiscal year 2011 budget and begin work on the fiscal year 2012 budget, we ask that you note the framework we have set forth for our appropriations and budget advocacy:

—AARP recognizes that the Federal budget deficit provides many challenges, and AARP members believe it is important to work together across partisan lines to find responsible budget solutions that consider the health and financial well-being of all Americans.

—We believe the budget reflects the priorities of this Nation and any budgetary cuts will impact people, not just programs.

—AARP supports budget proposals that will help make healthcare more accessible and affordable for all Americans, including implementation of the Affordable Care Act.

The SSA touches the lives of nearly every American, and was once known as the standard for Government agency service by which all others were measured. Over time, however, the agency's mission has been diluted by additional responsibilities not related to its core mission while the agency itself has faced a loss of staff and a budget that is woefully inadequate, especially given the increasing number of beneficiaries.

The SSA was made an independent agency in 1995 to provide the program with consistent direction and professional management and help insulate it against decisions not based on SSA-related issues. However, in the ensuing years, the agency has been tasked with numerous other responsibilities that fall outside its core mission of managing the old age and survivors insurance, disability insurance, and Supplemental Security Income (SSI) programs. SSA now plays a key role in assessing the correct premium levels for parts B and D of Medicare. In addition, SSA processes applications for the Low Income Subsidy of Medicare part D and conducts outreach to those who may potentially qualify for the extra help.

In recent years, the agency has also become an important element in the Nation's homeland security efforts as it conducts millions of Social Security Number (SSN) verifications for employment purposes and other immigration-related activities. In light of the added administrative burden these activities have placed on the agency, and the impact that burden has on the timely delivery of services to beneficiaries, AARP has grave concerns about proposals that would further expand these activities or mandate new ones.

This extra work given to SSA by Congress comes at a time when the Nation is confronting a significant, long-anticipated demographic challenge, the coming of retirement age of the Baby Boom generation, which will add nearly 80 million new beneficiaries to the SSA rolls—nearly 13 million in the next 10 years alone, and upwards of 16,000 per working day. At the end of this decade, these Boomers will reach traditional retirement age at the rate of 1 every 8 seconds. It is not difficult, then, to understand the enormity of the task the agency faces in foreseeable work alone.

For the most part, Congress has understood these challenges and has responded with added resources for SSA to handle this spike in demand. With the increases in funding Congress has provided over the last 3 years and significant increases in employee productivity, SSA has been able to make some progress in customer service. However, the unforeseeably long-lasting economic downturn has caused even more Americans to turn to the SSA. Claims for retirement and disability benefits have risen to record levels.

In fiscal year 2010, SSA received nearly 3,225,000 initial disability claims, the highest in its 75-year history. SSA ended fiscal year 2010 with initial disability claims pending at an all-time high of more than 842,000 cases. This year, SSA expects a record number of visitors to its field offices above the 45.4 million customers that requested assistance from the field offices in fiscal year 2010. These field offices are also responsible for processing an additional 1.2 million SSI redeterminations

in fiscal year 2011 as compared to fiscal year 2008, an increase of 100 percent. Furthermore, answer rates on telephone calls coming into the field offices remain at an unacceptably low level nationally as the rates of calls answered are less than 65 percent.

SSA field offices also processed more than 18 million requests for new and replacement SSA cards; field offices served thousands of people each day needing to report changes of address, changes in direct deposit information, and other issues that could affect their benefit payments. Field offices also play a significant role in helping people with their Medicare benefits and often work with State and local agencies regarding Medicaid and SNAP (formerly known as food stamps).

Eliminating the hearings backlog continues to be SSA's highest priority, and one that AARP strongly supports. SSA ended fiscal year 2010 with just more than 700,000 pending hearings nationwide—the lowest level in 5 years. At its peak, it took an average of 18 months for a hearing decision. As of January 2011, it took just more than a year.

At a time when it would additional funding is needed to handle the incoming and pending workload, the agency is unfortunately dealing with the possibility of a Government shutdown, as well as cutbacks resulting from the enactment of spending levels below the current fiscal year.

The House passed long-term continuing resolution, H.R. 1, would result in an aggregate funding loss of $1.093 billion for the SSA. That proposal is clearly unacceptable.

SSA is already operating under a partial hiring freeze because of the current continuing resolution, which is likely to result in nearly 3,500 lost jobs for 2011. These additional cuts could lead to SSA offices closing their doors, stopping all claims processing, and not answering the phones for about a month—1 month out of the seven remaining in 2011. In addition to office closures, many locations are already seriously understaffed due to employee attrition. Employees who retire or otherwise leave the agency are not replaced because the resources are just not available. In fiscal year 2009 staffing reached its lowest level since 1972, before SSI was established; yet SSA today has twice the number of beneficiaries it had in 1972.

If the SSA shuts down for a month, it would be devastating to both the public and to SSA employees. Extended to the national level, it would mean that about 182,000 visitors would not be seen, about 33,000 claims would not be taken, and almost 10,000 redeterminations would not be completed. Even 1 furlough day could be devastating to someone in a dire need situation desperate for a critical or immediate payment, or for a beneficiary needing verification information to qualify for food stamps, to obtain housing, or to get Medicaid. Another 70,000 fewer people will get a disability appeals hearing this year, which means workers waiting to present an appeal to a judge, who already wait more than a year, will wait longer. And, SSA would complete 32,000 fewer continuing disability reviews, which means wasting millions of dollars on improper payments now.

As if service degradations were not enough, even the status quo would prevent program integrity efforts from realizing their potential. Congress has consistently provided for separate, additional funds for SSA to conduct Continuing Disability Reviews (CDR) and SSI eligibility redeterminations. When fully utilized, CDR's result in savings of more than $10 in program costs for every $1 in administrative funding used to conduct the reviews. SSI redeterminations help save $7 for every $1 spent. Not enabling the agency to pursue these activities simply because of an artificial barrier like the discretionary spending caps would be very un-penny wise and grossly pound foolish.

Mr. Chairman, AARP strongly urges the subcommittee and the Senate as a whole to reject the deep cuts to SSA funding that are included in the House-passed legislation. Today, the bottom line is that nothing short of $11.679 billion, with no rescission of IT funds for fiscal year 2011 will ensure the ability of the SSA to adapt to the many critical challenges that confront them for the balance of this year. Additional resources will also be required to fulfill its obligations in the next fiscal year and beyond. The SSA customers, whether they are older, younger or anywhere in between, have the right to expect better service than are receiving today—we sincerely hope that the Congress and the President will not let them down and provide the funding necessary to enable its workforce to serve them promptly and properly.

On behalf of the millions of AARP members and all Americans who are served by SSA, I thank you for the opportunity to address the subcommittee.

Senator HARKIN. And now we'll turn to Ms. Ford.

Ms. Ford.

**STATEMENT OF MARTY FORD, CO-CHAIR, CONSORTIUM FOR CITIZENS WITH DISABILITIES TASK FORCE ON SOCIAL SECURITY; ACTING DIRECTOR, THE ARC AND UCP DISABILITY POLICY COLLABORATION**

**ACCOMPANIED BY NANCY G. SHOR, EXECUTIVE DIRECTOR, NATIONAL ORGANIZATION OF SOCIAL SECURITY CLAIMANTS' REPRESENTATIVES**

Ms. FORD. Chairman Harkin, Ranking Member Shelby, thank you for this opportunity to testify on behalf of the consumer advocacy provider and professional organizations working on behalf of children and adults with disabilities, and their families, in the United States.

This hearing is extremely important to people with disabilities who may need the programs administered by SSA: the Supplemental Security Income Program and the disability programs in Title II, including the Disability Insurance Program and Medicare. These are crucial income-support programs serving disabled workers and their families, and children and adults with disabilities, who have limited incomes and resources.

We believe that it is critical to continue to ensure that SSA provides adequate services to people applying for SSI entitled to disability benefits. We have worked for many years with the Congress and the administration to ensure that SSA has the funding necessary to reduce the huge backlogs in disability decisions. Just as the agency was bringing down the backlog, the recession began to have a substantial impact in building a new backlog in initial claims. Once again, we are facing the prospect of significantly increasing waiting times for disability decisions.

Behind the numbers are individuals with disabilities whose lives are unraveling while waiting for decisions. Families are torn apart, their homes are lost, claimants' medical conditions deteriorate, their once-stable financial security crumbles, and some individuals die. Over the past few years, we have described extraordinary and unnecessary hardships that people with disabilities have endured as they wait for decisions on their claims.

In my written testimony, we have included a very small sample of what is happening across the country to claimants who are forced to wait many months for their decisions.

A woman in Oregon has received an eviction notice. Her husband's paycheck has already been garnished to pay for her medical bills. She has been waiting for a hearing, and then for the decision, since August.

A young man in Texas has applied for SSI in February 2010, more than 1 year ago, due to a combination of intellectual and mental disabilities. He has just received a notice of denial at the reconsideration stage, and now will have to wait for a hearing, and then for a hearing decision.

A man in North Carolina, with a combination of impairments, who needs a pacemaker, has been waiting for a hearing on his SSI claim since September. His representative estimates, based on the claims in that State, that he will have to wait til mid- to late-summer 2011 for his hearing.

Your own constituent services staff are likely well aware of similar situations in your States. It is important to note that these are

situations that are current when the processing times are improving, at least at the hearing level, as described by the Commissioner earlier.

We are extremely concerned about what might happen if SSA's budget is further reduced to the level included in H.R. 1. Under the current continuing resolution, the Social Security Administration is already operating at a very bare-bones level. The cuts at the level in H.R. 1 will severely punish people who most rely on Social Security and SSI. The delivery of services should be strengthened, not weakened, during economic crisis.

The Senate bill, the continuing resolution for the rest of 2011, in total would provide $600 million more than H.R. 1 for SSA's operation. While this is not entirely what SSA requires to continue to meet the needs of the public and to address its IT needs for fiscal 2011, the Senate amount is certainly better than the House-passed bill. And we urge its adoption at a minimum of that amount of $11.8 billion.

PREPARED STATEMENT

Finally, regarding fiscal year 2012, we believe that the President's budget proposal for SSA for 2012, of $12.5 billion, is the minimum needed to continue to reduce the backlogs and to increase the deficit-reducing/program-integrity work.

The speed and quality of the disability process must continue to improve and should not be allowed to regress into the longer waiting periods of the recent past. These challenges can only be addressed if Congress and the administration work together to ensure that Social Security continues to be the safety net it was designed to provide for people with disabilities and their families, as well as retirees and survivors.

Thank you for this opportunity to testify, and I'm happy to answer any questions.

Senator HARKIN. Thank you, Ms. Ford.

[The statement follows:]

PREPARED STATEMENT OF MARTY FORD

Chairman Harkin, Ranking Member Shelby, members of the subcommittee, thank you for this opportunity to testify at today's hearing on the fiscal year 2012 budget request for the Social Security Administration (SSA) and the impact of possible cuts to the fiscal year 2011 budget.

I am Marty Ford, Acting Director of the Disability Policy Collaboration of The Arc and United Cerebral Palsy. I am here in my capacity as a Co-Chair of the Consortium for Citizens with Disabilities (CCD) Social Security Task Force. CCD is a working coalition of national consumer, advocacy, provider, and professional organizations working together with and on behalf of the 54 million children and adults with disabilities and their families living in the United States. The CCD Social Security Task Force (hereinafter "CCD") focuses on disability policy issues in the title II disability programs and the Title XVI Supplemental Security Income (SSI) program.

The focus of this hearing is extremely important to people with disabilities. The SSA administers the Disability Insurance (SSDI) and other title II disability benefits and Supplemental Security Income (SSI), significant crucial income support programs for people with disabilities. SSDI provides benefits to disabled workers and their families and SSI provides financial support to aged, blind, and disabled adults and children who have limited income and resources.

We believe that it is critical to continue to ensure that SSA provides adequate services to people applying for SSI and title II disability benefits.

IMPACT OF H.R. 1 ON REMAINDER OF FISCAL YEAR 2011

The House-passed H.R. 1, Full-Year Continuing Appropriations Act, 2011, reduces the SSA's administrative spending level to $11.3 billion, a decrease from the fiscal year 2010 spending levels of $11.4 billion and leaving an already cash-strapped agency with fewer resources with which to process claims for people with disabilities and seniors.

Under H.R. 1, the SSA would receive $430 million less than if it operated the rest of fiscal year 2011 under the current Continuing Resolution (CR), which is already $1.7 billion less than the President's proposed fiscal year 2011 budget. If SSA is forced to furlough employees to address the full $430 million shortfall from the current CR spending level, it will result in nearly a month of furloughs, having devastating effects on service to the American public. In 1 month of furloughs, SSA would complete 400,000 fewer retirement, survivor, and Medicare claims; 290,000 fewer initial disability claims (with processing time increasing by a month); 70,000 fewer hearings; and 32,000 fewer continuing disability reviews. In addition, H.R. 1 severely cuts funds for vital information technology (IT) improvements and funds to build the critical new National Computer Center, which must be built to protect SSA electronic information and infrastructure.

Under the current CR, the SSA is already operating at a very bare bones level. The proposed cuts in H.R. 1 will punish people who must rely on SSA and Medicare. We need to remember that there are real people behind these numbers. The delivery of services must be strengthened, not weakened, during economic crisis.

IMPACT OF SENATE AMENDMENT 149 TO H.R. 1

Senate Amendment 149, the full-year fiscal year 2011 continuing resolution offered by Senator Inouye on March 4, would provide $500 million more for SSA's administrative expenses than would H.R. 1 for the remainder of fiscal year 2011. In addition, it rescinds $100 million less from the special reserve fund for IT expenses. In total, the Senate bill provides $600 million more than H.R. 1 for SSA's operation. While this is not entirely what SSA requires to continue to meet the needs of the public and to address its IT needs for fiscal year 2011, the Senate amount is certainly better than the House-passed bill. We urge the adoption, at a minimum, of the amount included in Senate Amendment 149, totaling $11,821,500,000.

IMPACT ON CLAIMANTS FOR SOCIAL SECURITY AND SSI BENEFITS

Behind the numbers are individuals with disabilities whose lives unravel while waiting for decisions—families are torn apart; homes are lost; medical conditions deteriorate; once-stable financial security crumbles; and many individuals die. Over the past few years, we have described the extraordinary and unnecessary hardships endured by people with severe disabilities as they wait for decisions on their claims. The following stories are only a sampling of what is happening across the country to claimants who are forced to wait months and years for decisions on their appeals. Your own constituent services staff are likely well aware of similar situations in your State. It is important to note that these situations are current, when the processing times are improving, at least at the hearing level. We are extremely concerned about what will happen if SSA's budget is further reduced to the level proposed in H.R. 1.

—Ms. C, a 46-year-old woman with fibromyalgia and depression lives in Omaha, Nebraska. She filed her request for hearing on August 2, 2010. Her utilities were shut off on December 30, 2010, and she received an eviction notice on January 4, 2011. Although her husband works, his checks are being garnished for her medical bills. She cannot afford her medications and does not qualify for Medicaid because her husband works. Her representative requested critical case status (for expedited processing) on December 30, 2010. Her hearing was held on February 18, 2011, but she has not yet received a decision. The delay in scheduling a hearing and receiving a decision has been extremely difficult for her and her family. (From a representative in Omaha, Nebraska)

—A 19-year-old young man lives with his foster mother in Plano, Texas; she is his sole source of support. He has a full-scale IQ of 65 and all of his schooling has been in special education classes. He also has some mental health diagnoses and has been in several inpatient psychiatric facilities. He was born prematurely with a positive drug screening and put into foster care at 13 months of age. He has chronic encephalopathy with psychomotor delays. He applied for SSI disability benefits in February 2010 and, more than 1 year later, he received his reconsideration denial in February 2011. Now he will have to wait for a hearing and hearing decision.

—Mr. E is a 52-year-old man who formerly worked as a security guard. Because he has no income, he lives in a homeless shelter in eastern North Carolina. He is constantly in and out of the hospital. He has bipolar disorder and is an insulin-dependent diabetic with associated neuropathy, which causes burning pain in his feet and legs. He has a history of two heart attacks for which he has had stents. He needs a pacemaker for his heart but cannot get one until he is determined Medicaid eligible. He cannot get Medicaid until he is found eligible for SSI. He asked for a hearing on his SSI claim in September 2010, but he will probably wait until mid to late summer 2011 to get a hearing—if he lives that long. (From a representative in Raleigh, North Carolina)

—A homeless woman in Manchester, New Hampshire requested her hearing in January 2010. After her representative submitted a "dire need" request for expedited processing, her hearing was held 1 year later (January 6, 2011). She has had no access to medical care for her severe mental impairments (bipolar disorder, paranoia, and anxiety). She has not yet received a decision.

—The same New Hampshire representative assisted a man who received a partially favorable decision from an Administrative Law Judge after a 15-month wait. He now has to wait an additional 90 days while his case lingers at the Decision Review Board for possible review. His home is being foreclosed on while he waits for the board to act on his partially favorable decision.

SSA'S LIMITATION ON ADMINISTRATIVE EXPENSES FOR FISCAL YEAR 2012

We believe the President's budget proposal for the SSA for fiscal year 2012 of $12.522 billion is the minimum needed to continue to reduce key backlogs and increase deficit-reducing program integrity work. With your support, SSA could continue to build on the progress achieved thus far, progress that is vital to millions of people who depend on their services, including people with disabilities. This funding level will allow SSA to continue working down disability backlogs, to implement efficiencies in programs, and to increase program integrity work.

The budget will provide for the continuance of crucial income support programs. In fiscal year 2012, SSA expects to provide SSDI benefits to almost 11 million disabled workers and their family members and provide SSI benefits to more than 8.3 million beneficiaries.

It is imperative that the SSA continue to reduce its disability hearings backlog and initial disability claims backlog. This budget request will allow SSA to reduce hearings and initial disability claims backlogs and simplify the work incentives in the Disability Insurance program. With the continued support of Congress, SSA is on track to meet its commitment to the American public to eliminate the backlog by fiscal year 2013. However, to reach this goal, it will need to adjudicate more than 800,000 cases in fiscal years 2011 and 2012, which is more than double what was handled 10 years ago. Yet, progress continues to be challenged with the current skyrocketing number of hearing receipts due to the increased number of people who are applying for benefits.

We are pleased that SSA has implemented many productivity improvements which help provide fast and accurate service to the public at a lower cost, but the administration needs adequate funding to continue this. Congress and the administration must work together to ensure that millions of Americans do not experience significant waiting times for decisions on their claims. To do this, SSA needs full funding of the President's budget for fiscal year 2012.

The President's proposed fiscal year 2012 budget will aid in processing mounting disability claims by creating programs such as Extended Service Teams for more efficiency, and expanding Federal capacity to decide claims and to assist Disability Determination Services in handling claims, improving online services, fast-tracking cases that obviously meet SSA's disability standards, paying medical consultants per case as opposed to per hour to increase productivity, and developing a disability case processing system.

The President's budget request proposes a 5-year reauthorization of section 234 demonstration authority for the Disability Insurance Program, which would allow SSA to test program innovations. Using this authority, SSA has proposed a new Disability Work Incentives Simplification Pilot to provide beneficiaries with a simple set of work rules that would no longer terminate benefits solely based on earnings. As a result, beneficiaries would have more flexibility to try working, without fear of losing their benefits. After years of making similar recommendations to improve work incentives, we look forward to working with SSA on the details of this proposal.

The budget request also proposes an extension through 2013 of SSI eligibility for 9 years for refugees, asylees, and certain other humanitarian immigrants.

We also support SSA's plans to explore potential improvements to programs, such as the Disability Research Consortium to address the shortage of disability policy research and collaboration and to enhance efforts to expand disability research within and across disability programs. We would also like to work with SSA on the SSI Children's Pilot—Promoting Readiness of Minors in SSI (PROMISE)—to improve outcomes for children and families in the SSI program.

We are also concerned that Amendment 195 to H.R. 1 would make it more difficult for people whose disability claims have been denied to take their claims to Federal district court since no funds would be available for payment of fees or expenses under the Equal Access to Justice Act. We believe that this could make legal representation unavailable to claimants who need to pursue their claims in Federal court. We urge the subcommittee to oppose inclusion of such language in the fiscal year 2011 and 2012 spending packages.

CONCLUSION

For the remainder of fiscal year 2011, H.R. 1 would have a devastating impact on administration of the SSA programs and we urge the subcommittee to reject such drastic cuts. The harmful impact on the American people, particularly people with disabilities waiting for decisions on their claims for disability benefits, would be too great. Instead, we urge the adoption of at least the amount included in Senate Amendment 149 to H.R. 1.

The President's budget proposal for fiscal year 2012 is the minimum needed to continue driving down disability backlogs, improve services to people with disabilities, increase efficiency, and keep pace with the rising demands of the American public. The speed and quality of the administration's disability process must continue to improve and should not be allowed to regress into the longer waiting periods of the recent past. These challenges can only be addressed if Congress and the administration work together to ensure that Social Security continues to be the safety net it was designed to provide for people with disabilities and their families, as well as retirees and survivors of workers and retirees.

Thank you for this opportunity to testify. I would be happy to answer questions or provide you with additional information.

This testimony is submitted on behalf of the undersigned organizations:

—American Association of People with Disabilities
—American Foundation for the Blind
—Association of University Centers on Disabilities
—Bazelon Center for Mental Health Law
—Children and Adults with Attention-Deficit/Hyperactivity Disorder
—Community Action National Network
—Corporation for Supportive Housing
—Council of State Administrators of Vocational Rehabilitation
—Disability Rights Education and Defense Fund
—Easter Seals
—Epilepsy Foundation
—Health and Disability Advocates
—Lutheran Services of America—Disability Network
—National Alliance on Mental Illness
—National Association of Councils on Developmental Disabilities
—National Association of Disability Representatives
—National Council for Community Behavioral Healthcare
—National Council on Independent Living
—National Disability Rights Network
—National Multiple Sclerosis Society
—National Organization of Social Security Claimants' Representatives
—National Spinal Cord Injury Association
—The Arc of the United States
—United Cerebral Palsy
—United Spinal Association
—VetsFirst, United Spinal Association
—World Institute on Disability

Senator HARKIN. And now, Mr. Dirago, please proceed.

**STATEMENT OF JOE DIRAGO, PRESIDENT, NATIONAL COUNCIL OF SOCIAL SECURITY MANAGEMENT ASSOCIATIONS, INC., NEWBURGH, NEW YORK**

Mr. DIRAGO. Chairman Harkin, Ranking Member Shelby, and members of the subcommittee, I am the president of the National Council of Social Security Management Associations, NCSSMA, and the district manager of the Social Security office in Newburgh, New York. I appreciate this opportunity to speak on behalf of 3,400 Social Security managers in field offices and teleservice centers around the country.

NCSSMA's top priority is a strong and stable Social Security Administration, and we have significant concerns about funding the agency to maintain service levels vital to millions of Americans. Workloads are exploding as a result of the economic downturn and the 80 million Baby Boomers who will file for benefits by 2030. Even with increases in Internet filing in 2010, over 45 million customers were served in field offices, and Social Security completed 100 million telephone calls last year.

Appropriations for SSA are an excellent investment. With the additional funding Congress has provided, tremendous progress has been made. Annual productivity has increased an average of 4 percent, the last 4 years. In 2010, SSA produced approximately $6 billion in savings from our program integrity efforts.

However, the repercussions of the current continuing resolution have already been felt. Feedback from our busy urban offices indicates many are struggling. The manager of an Alabama office indicates, "Our employees are stretched to the limit, trying to keep up with the increased walk-in and telephone traffic. I really don't know how much more these hardworking people can absorb."

Most of SSA has been under a hiring freeze during the continuing resolution. If this continues for the rest of the year, it could result in the loss of 3,500 employees. A Kentucky manager says, "The American public does not care that we are short on staff. They want to be seen quickly, have their calls answered, and get their issues resolved."

SSA projects that 50 percent of its employees will be eligible to retire by 2018. Because it takes 2 years to train a claims representative, concerns exist about this loss of institutional knowledge. Geographical staffing imbalances will occur, leaving some offices severely understaffed. This is especially problematic for small and rural offices. A manager in Iowa says, "Our service area includes several counties. Last year, we lost two employees, now we find it very difficult to handle our telephone traffic and other priority workloads. Although the use of the Internet is rising, this is not the magic answer."

SSA offices provide valuable services to many diverse customers. My Newburgh office delivers assistance to the Wounded Warrior Transition Unit, at West Point, which has soldiers from eight States in the Northeast. Without replacement staff, benefits to these soldiers will be delayed.

We respectfully request Congress consider our recommendations. For 2011, we urge you to fund SSA at no less than $350 million above the fiscal year 2010 enacted levels, with no rescission of funds. This level of funding will cover increased fixed costs and is

essential to keep up with our workloads. We strongly support the President's fiscal year 2012 budget request, and ask that Congress consider full funding to sustain the momentum achieved.

NCSSMA also endorses additional funding to address program integrity workloads. For every $1 invested in medical continuing disability reviews and SSI redeterminations, $7 to $10 in program savings is realized.

SSA must also be properly funded so that it may continue to invest in user-friendly online services and to allow for IT investments to improve service delivery. Any rescission of funds could jeopardize initiatives to implement technological efficiencies.

Social Security is the safety net of America, and must be maintained as such. If adequate funding is not provided, public service will suffer, resulting in significant hardship for millions.

We sincerely appreciate the subcommittee's ongoing support to ensure that we have the resources necessary to properly serve the American public.

Thank you for the opportunity to testify at this hearing, and I respectfully request that you consider our recommendations.

Senator HARKIN. Mr. Dirago, thank you.

[The statement follows:]

PREPARED STATEMENT OF JOE DIRAGO

Chairman Harkin, Ranking Member Shelby, and members of the subcommittee, my name is Joe Dirago and I am president of the National Council of Social Security Management Associations (NCSSMA). I have been the manager of the Social Security Administration (SSA) office in Newburgh, New York for 10 years and have worked for the SSA for 31 years, with 27 years in management. On behalf of our membership, I am pleased for the opportunity to submit this written testimony to the subcommittee.

NCSSMA is a membership organization of nearly 3,400 SSA managers and supervisors who provide leadership in 1,299 community based field offices and teleservice centers throughout the country. We are the front-line service providers for SSA in communities all over the Nation. We are also the Federal employees with whom many of your staff members work to resolve issues for your constituents who receive SSA retirement, survivors or disability benefits, or Supplemental Security Income (SSI). Since the founding of our organization more than 41 years ago, NCSSMA has considered our top priority to be a strong and stable SSA, one that delivers quality and prompt service to the American public. We also consider it a top priority to be good stewards of the taxpayers' moneys.

Our testimony focuses on the key issues confronting the SSA. We have critical concerns about the dramatic growth in our workloads and receiving the necessary funding to maintain service levels vital to millions of people. Despite agency strategic planning, expansion of online services, significant productivity gains, and the best efforts of management and employees, SSA is faced with many challenges to providing the service that the American public has earned and deserves. Our testimony also provides our recommendations for addressing the obstacles confronting the SSA, information on the state of SSA operations, a review of the funding situation, and our detailed assessment of the major agency challenges.

RECOMMENDATIONS

The NCSSMA offers the following key recommendations to address the challenges confronting the SSA and to provide the service the American public has earned and deserves.

—NCSSMA respectfully urges this subcommittee and Congress to consider funding SSA in fiscal year 2011 at no less than $350 million above the fiscal year 2010 enacted levels with no rescission of Carryover Information Technology (IT) funds. Based upon our analysis of the President's proposed budget request, assessment of the current workload situation, and a projection of workloads for fiscal year 2012, we believe that funding SSA below this level would have a devastating impact on the agency's ability to deliver vital services to millions of

Americans. This level of funding will cover inflationary increases and is critically necessary to keep up with our growing claims receipts, maintain the progress achieved on reducing the disability hearings backlog, process program integrity workloads, and to meet customer service expectations.

—We strongly support the President's fiscal year 2012 budget request for the SSA and respectfully request that Congress consider its full funding to sustain the momentum achieved on our key priorities, maintain our front-line staffing levels, and to ensure appropriate levels of service to the American public.

—NCSSMA strongly encourages Congress to consider providing SSA with additional funding to address program integrity workloads and other quality initiatives to improve the accuracy of payments. This would include the elimination of the medical Continuing Disability Review (CDR) backlog and conducting additional SSI redeterminations. For every $1 invested in program integrity initiatives, $7 to $10 in program savings is realized. Investment in program integrity workloads ensures accurate payments, saves taxpayers' dollars, and is fiscally prudent.

—SSA must be properly funded so that it may continue to invest in improved user-friendly online services to allow more Internet transactions. This would result in fewer visitors and telephone calls to the field offices and provide relief from increasing claims and other workloads.

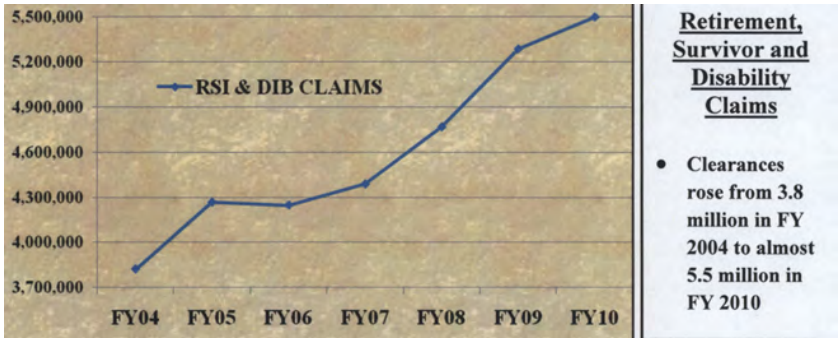
—SSA is confronted with major challenges in managing its IT programs to keep up with rapidly expanding workloads. NCSSMA believes it is critical that SSA be adequately funded to allow for IT investments. This is necessary for SSA to replace our aging National Computer Center (NCC), to maintain systems continuity and availability, and improve IT service delivery. Any rescission of Carryover IT funds could seriously jeopardize SSA's initiatives to implement automation and technological efficiencies that address service delivery demands.

—NCSSMA recommends consideration of legislative and/or regulatory proposals that can improve the effective administration of the SSA program, with minimal effect on program dollars. We believe these proposals have the potential to reduce operational costs and increase administrative efficiency. This includes enacting the Work Incentives Simplification Program (WISP) pilot, requiring quarterly reporting of wages, requiring that SSA be automatically provided with information on workers compensation cases, and developing an automated system to report State and local pensions affecting the Windfall Elimination Provision and Government Pension Offset (WEP/GPO).

## CURRENT STATE OF SSA OPERATIONS

*Claims Workloads*

Over the last 7 years, the SSA has experienced a huge increase in retirement, survivor, dependent, disability, and SSI claims. The additional claims receipts are driven by the initial wave of the nearly 80 million baby boomers who will be filing for SSA benefits by 2030—an average of 10,000 per day. Concurrently, there has been a surge in claims filed due to the economic downturn, which began in 2008. In fiscal year 2010 and fiscal year 2011, disability and retirement receipts alone are expected to exceed 1 million more than in fiscal year 2008.




*Field Office Visitors and Telephone Service*

While SSA field offices are processing many more claims, we are also seeing visitors in much greater numbers. Nationally, visitors to SSA field offices increased sig-

nificantly from fiscal year 2007 through fiscal year 2010. In fiscal year 2010, field offices experienced 5 weeks with more than 1 million visitors.

—SSA visitors in fiscal year 2007—41,900,000.
—SSA visitors in fiscal year 2008—44,457,180.
—SSA visitors in fiscal year 2009—45,082,487.
—SSA visitors in fiscal year 2010—45,430,364.

In addition to the increased visitor traffic, SSA is experiencing unprecedented telephone call volumes. In fiscal year 2010, SSA completed 67 million transactions over the 800 number telephone network—the most ever. NCSSMA estimates that field offices received an additional 32 million public telephone contacts.

*Internet Contacts*

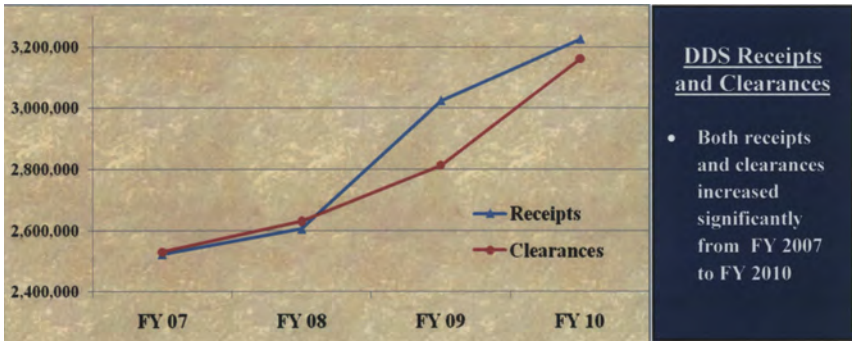
SSA's online electronic services, also known as "eServices," offer the public access to SSA services via the Internet. The use of SSA's Web site is growing and the American public is accessing it more often to receive information and report changes. eServices has helped significantly in dealing with the dramatic increases in SSA workloads resulting from the baby boomers and the economic downturn.

SSA has promoted eServices extensively, including national public campaigns to promote awareness. The following data illustrates the volume and growth in SSA eServices.

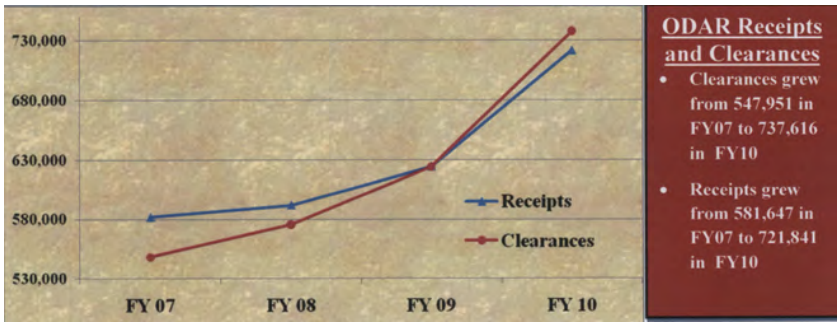
—Social Security Online had 133.6 million unique visitors in fiscal year 2010, an increase of more than 52 million from fiscal year 2009. There have been 47 million visitors in the first 4 months of fiscal year 2011.
—In fiscal year 2010, SSA's Web site had 34.8 million contacts to the Frequently Asked Questions, 11.6 million to the Field Office Locator menu, and 3.7 million contacts to the Retirement Estimator.
—Online retirement claims increased 9.6 percent more than fiscal year 2009. The percentage of retirement claims filed online in fiscal year 2010 reached 36.8 percent, with 913,473 applications taken.
—Online disability claims usage increased 34.5 percent in fiscal year 2010 with 801,060 applications taken. For the first 4 months of fiscal year 2011, 30.3 percent of all disability claims were filed online.

*Disability Workloads*

Nationwide, more than 3.2 million new initial disability claims were filed and sent to the Disability Determination Service in fiscal year 2010, an increase of more than 600,000 as compared to fiscal year 2008.




SSA's largest backlogs are in hearings to appeal initial decisions, processed by Administrative Law Judges (ALJs) at the Office of Disability Adjudication and Review. The chart below illustrates that hearing receipts continue to rise, and reached 721,841 in fiscal year 2010. However, clearances exceeded receipts beginning in fiscal year 2009, which helped reduce the backlog of SSA hearings to 705,367 pending.




SSA FUNDING FISCAL YEARS 2010, 2011, AND 2012

*SSA Funding Accomplishments Fiscal Year 2010*

Appropriations to the SSA are an excellent investment and return on taxpayer dollars. With the additional funding Congress has provided in recent fiscal years and significant increases in employee productivity, tremendous progress has been made to enhance service to the public, reduce the hearings backlog, and to process additional workloads received because of the aging of the baby boomers and the economic downturn. In fiscal year 2010, SSA achieved the following:

—Completed more than 300,000 more initial disability claims than in fiscal year 2009.

—Served 45 million people who visited our 1,300 field offices.

—Wait times in field offices for those without an appointment were reduced from 23.3 minutes in fiscal year 2009 to 20.7 minutes in fiscal year 2010.

—With innovation and automation efforts, along with the hard work and dedication of our staff, SSA's annual productivity increase has averaged about 4 percent over the last 4 years.

—In fiscal year 2010, SSA completed 67 million transactions over the 800 number telephone network—the most ever. The telephone busy rate for the 800 number was reduced by half, from 10 percent in fiscal year 2008 to 4.6 percent in fiscal year 2010. Time spent waiting for an agent was reduced by more than 37 percent, from 326 seconds in fiscal year 2008 to 203 seconds in fiscal year 2010. Field office busy rates have also dropped dramatically from more than 50 percent to nearly 20 percent.

—Program integrity efforts to process 2.4 million SSI redeterminations and 325,000 medical Continuing Disability Reviews (CDRs) produced more than $6 billion in estimated savings.

—SSA expanded the Access to Financial Institutions (AFI) Initiative, which data matches assets of SSI individuals that exceed statutory limits. Expansion is to be completed in fiscal year 2011 and SSA projects $900 million in lifetime program savings for each year the AFI process is used.

—Cooperative Disability Investigation (CDI) units combat disability fraud. Since their inception in fiscal year 1998, the efforts of CDI units have resulted in nearly $2.6 billion in savings: $1.6 billion in disability programs and $967 million in projected savings in programs such as Medicare and Medicaid.

*SSA Funding for Fiscal Year 2011*

SSA is facing unprecedented workload challenges due to the economic downturn and the demand for SSA services from the baby boomers. We greatly appreciate the increased funding that SSA received for fiscal year 2009 and fiscal year 2010. This includes the $1 billion SSA received from the American Recovery and Reinvestment Act (ARRA). About half of that funding was directed to reducing the backlogs in SSA. Had SSA not received this funding, the service we provide in SSA would be much worse and the disability backlog would be unconscionable.

For fiscal year 2011, the President requested $12.379 billion for SSA's administrative budget. The Limitation on Administrative Expenses (LAE) account budget request is an increase of $932 million or 8.1 percent more than the fiscal year 2010 enacted level. Much of this increase is needed to cover inflationary costs for fixed costs such as rent, guards, postage, periodic step increases, career ladder promotions, and increased health benefit costs. Funding above current levels is absolutely necessary to keep up with our growing workloads, maintain the progress achieved on reducing the disability hearings backlog, process program integrity

workloads, including SSI redeterminations and medical CDRs, and to meet customer service expectations.

NCSSMA recognizes that there is no simple way to provide the necessary resources to SSA. However, we believe that funding SSA for fiscal year 2011 at the fiscal year 2010 level without covering inflationary increases would have a devastating impact on the agency's ability to deliver critical services to millions of Americans. SSA is the safety net of America and if adequate funding is not provided, public service will deteriorate, with longer waiting times, unanswered calls, increased backlogs, and significant hardship on needy beneficiaries.

Funding SSA at the level passed by the House of Representatives (H.R. 1) would result in serious negative consequences to public service. If enacted in its current form, this legislation would reduce SSA's appropriated funding $125 million from the fiscal year 2010 enacted level, rescind $500 million from the Carryover IT funding, and rescind $118 million from the NCC funding as part of an overall reduction in unobligated ARRA funding. This would likely result in an agency-wide hiring freeze, with no overtime available to address critical workloads, and employee furloughs. Drastic cutbacks would be necessary that would have a negative impact on operations and significant delays in all workloads would result. Disability backlogs could grow an additional 160,000 cases. Significant financial hardships could be created because of delays in payments. Agency productivity would erode significantly. Waiting times and telephone service would experience major deterioration. This would necessitate cutbacks in other budget areas, such as supplies and training, and in IT development expenditures. Spending in these areas would be purely for maintenance.

NCSSMA is very concerned that the agency will be forced to impose furloughs if the fiscal year 2011 budget is not adequate. Furloughs would have a devastating effect on the public that depends on SSA for vital services, as well as our employees. Nationally, the furloughs could translate to the following approximate daily impact on SSA's operations:

—180,000 daily visitors might not be seen in the 1,266 SSA field offices across the country;
—16,000 retirement and survivors claims might not be taken from applicants;
—12,600 disability applications might not be processed for individuals who are unable to work;
—385,000 telephone calls to SSA could go unanswered;
—50,000 individuals could fail to have a SSA card application processed;
—1,440 medical CDRs, which save $10 for every $1 SSA invests in processing them, might not be processed;
—10,000 fewer SSI recipients might not have redeterminations of their benefits completed to make sure payments are accurate. These reviews save $7 for each $1 SSA spends performing them.

If SSA is funded at the fiscal year 2010 level for fiscal year 2011, without covering inflationary increases of $350 million, this could reverse the positive progress that has been achieved in the last few years with all of SSA's workloads. Attempting to address the fiscal year 2011 workload demands at SSA with fiscal year 2010 resource levels is not a prudent course of action and would lead to significant cutbacks that would be devastating for members of the public who rely on SSA for essential services and assistance.

*President's Proposed Fiscal Year 2012 SSA Budget*

NCSSMA strongly supports the President's fiscal year 2012 budget request for the SSA. The total SSA budget request is $12.667 billion, which includes $12,522,200,000 in administrative funding through the LAE account. This is an increase of $143.3 million more than the fiscal year 2011 President's proposed SSA budget request.

The following is a direct quote from the SSA fiscal year 2012 budget overview:

"In fiscal year 2012, we will need a minimum administrative budget increase of $300 million just to cover our fixed costs, including rent, guards, postage, and employee salaries and benefits. We will need funding above that level to keep up with our growing workloads, reduce existing backlogs, and meet rising customer service expectations."

We respectfully request that Congress consider full funding of the President's fiscal year 2012 budget request for SSA to sustain the momentum achieved on our key priorities, maintain our front-line staffing levels, and to ensure appropriate levels of service to the American public. This funding request would allow SSA to do the following in fiscal year 2012:

—Reduce the initial disability claims backlog to 632,000 by processing more than 3 million initial disability claims;
—Conduct disability hearings for 822,500 cases in 2012 and reduce the waiting time for a hearing decision to below a year (to 326 days) for the first time in a decade;
—Reduce pending disability hearings to 597,000 from the fiscal year 2011 level of 668,000 (estimated) and fiscal year 2010 level of 705,367;
—Complete additional program integrity workloads—process 592,000 medical CDRs (up from 325,000 completed in fiscal year 2010) and 2.6 million SSI redeterminations (up from 2.4 million in fiscal year 2010). $938 million is dedicated in the fiscal year 2012 budget request to continue these reviews that save significant program dollars by avoiding improper payments to beneficiaries. SSA estimates this program integrity funding in fiscal year 2012 will result in nearly $9.3 billion in savings over 10 years, including Medicare and Medicaid savings. The increased funding also improves the savings in fiscal year 2012 over fiscal year 2010 by more than $3 billion.

It is important to note that any backlogs and service deterioration related to inadequate fiscal year 2011 funding levels would have a collateral negative impact on fiscal year 2012 and beyond. Backlogs make SSA much more inefficient. Substantially more dollars are required to reduce a backlog than to prevent one because of the reworking of cases. Hiring delays also have long-term effects because of the amount of time it takes for new employees to gain proficiency.

REVIEW AND ASSESSMENT OF SSA CHALLENGES

*Field Office Service Delivery Challenges*

Despite staff replacements authorized in recent SSA budgets, significant overtime hours worked, and increases in the use of Internet services, field offices are still struggling with tremendous workload demands. SSA field offices vary in terms of size, demographics, and location. However, all types of field offices are experiencing tremendous stress because of our increased workloads and additional visitor traffic. The effect of funding the SSA in fiscal year 2011 at fiscal year 2010 levels exacerbates the situation and has already had a significant impact on local field offices around the country.

Frontline feedback from our busiest urban offices indicates that some have seen their visitor traffic explode with overflowing reception areas and increased waiting times. This can result in standing room only, lack of seating availability for disabled clients, and visitors waiting in the hallway or even outside. Managers of busy SSA field offices recently provided these comments:

—We handle close to 2,000 visitors a week in my office. Recent losses due to retirement are affecting the service we provide, as we cannot interview the public fast enough. It seems like the more employees we put up to interview, the more the public comes in. Pulling employees from the back creates a backlog and reduction in staffing reduces our ability to handle those backlogs. If we cannot hire to fill losses, the public will wait longer and be disadvantaged. In addition, the safety of the employees becomes at risk as the public becomes frustrated at the long waits. (California)
—Working in a busy office in Alabama, I can honestly say a yearlong continuing resolution at fiscal year 2010 funding levels would be catastrophic. Our employees are stretched to the limit trying to keep up with the increased walk-in and telephone traffic and I really do not know how much more these hard-working people can absorb. They are working at a dangerous level—working overtime to keep up—stress levels are high and this is evident if you spend some time in a field office. They will only be able to continue this pace for so long. Less funding and staffing will mean a decreased level of service to our deserving public. We talk about world-class service in our staff meetings; this will disintegrate into second-class service if we do not have the staff or the funding to handle the increasing workloads.

We expect our working Americans to dutifully pay their SSA taxes; however, this comes with a promise. We promise to safeguard this money as an investment toward their retirement or the horrible possibility of a career-ending disability—a reward for their hard work and contribution to this great country. Inadequate funding and staffing will mean we have to tell them we appreciate their contribution, but we cannot fulfill our promise to provide timely benefits in their time of need, or when they are eligible for well-deserved retirement. They will just have to wait until we can "get to their claim". This is unacceptable. We don't give people the option of "opting out" of SSA taxes when they experience financial troubles, but isn't that what we are doing here? We under-

stand budget woes, but does this give us a valid excuse for punishing hard-working Americans? We seem to find funding for important causes and I can't think of a better cause than the public we serve who have spent their lives making a positive contribution to make America what it is today—let's take care of them. (Alabama)

—On a daily basis, we average between 400 and 500 telephone calls on top of claims and postentitlement interviews. We assign six employees to telephones daily and we cannot handle the calls we receive. Last October we had 1 day in which we received more than 1,100 phone calls. How can we be expected to answer so many phone calls? Because of assignments to phone duty, I am unable to process approximately 240 SSI redetermination clearances a week. We are behind by about 20 percent in SSI redetermination clearances. (Florida)

Most of SSA has been under a hiring freeze because of the current funding situation. A hiring freeze for all of fiscal year 2011 could result in a loss of more than 2,500 SSA Federal employees and up to 1,000 State employees in the Disability Determination Services (DDSs). SSA field office managers recently provided the following frontline feedback about the effect of the current SSA hiring freeze on their offices:

—A hiring freeze will be detrimental, especially to the processing of our disability workloads. Under the Commissioner's direction, we have made tremendous improvement in the time it takes to get a decision. Every year the bar is set higher and every year SSA staff exceeds expectations. However, in the past 6 months alone, our office staff has been reduced from 57 to 53 employees. We are anticipating a minimum of 4 more losses and will be down to 49 by the end of the year—a 14 percent decline in staff. SSA employees take pride in their work knowing that the American public depends on us for their financial security. Not having the resources to process workloads in a timely manner undermines the positive morale of the staff as well as undermining the public's trust in our agency. Meeting the demands of the public is a struggle every day. We juggle phones, walk-ins, appointments, and Internet claims daily. Despite the flexibility of our staff, we consistently have wait times of more than an hour. Claims Representatives consistently interview all day and have little time to work through mail or return phone messages. Not getting to mail or messages daily directly influences processing time to pay benefits. (Texas)

As in-office visitors increase in already busy offices, there has also been an increase in the number of reported security incidents. Tensions escalate when visitors are in crowded reception areas and many become frustrated because of the extensive wait to be served. The societal trend of disruptive visitors to offices continues to be a challenge. The Office of the Inspector General (OIG) issued a report, Threats against SSA Employees or Property, on November 30, 1010. According to the report, "SSA has experienced a dramatic increase in the number of reported threats against its employees or property. The number of threats increased by more than 50 percent in fiscal year 2009 and by more than 60 percent in fiscal year 2010." This SSA manager expresses the connection between staff losses, increased workloads, public dissatisfaction and security concerns.

—A hiring freeze for all of fiscal year 2011 would be devastating. We lost two employees over the past 8 months and could not replace them. As a result, we are seeing our visitor waiting times increase and we are not able to answer telephone calls, as we would like. By going from a staff of 18 to 16 employees, we are barely able to hold the line on our workloads and basic services. Another loss without replacement will undoubtedly cause the dam to break. We must have the resources to do the work. We are already seeing much more stress on our staff members due to assuming the workloads of the employees we lost, and we are seeing higher frustration levels from our callers and visitors. The American public does not care that we are short on staff, they want to be seen quickly, have their call answered quickly and get their issues resolved. I am concerned that this type of frustration will lead to more threats and acts of violence toward our staff members, not only in our own office, but also in field offices across the country. (Kentucky)

SSA has a highly skilled, but aging workforce with about two-thirds of its more than 60,000 employees involved in delivering direct service to the public. SSA projects 50 percent of its employees, including 66 percent of supervisors, will be eligible to retire by fiscal year 2018. Serious concerns exist about the agency's ability to sustain service levels with the tremendous loss of institutional knowledge from SSA's front-line service personnel. This SSA field office manager relates the challenges of dealing with staff retirements.

—A recent article provided staggering statistics—by 2025, nearly 1 in 4 Montanans will be older than age 65. This month, a tidal wave of baby boomers,

7,000 Americans each day reach that milestone. By 2015, projections rank Montana fourth in the Nation in percentage of seniors. By 2025, "mature" Montanans will number 240,000—up more than 100,000.

By the end of the month, I will lose two employees—one to another Federal agency and the other cannot take the stress of the job. We ask a lot of our public servants in the SSA and deal daily with people living in stressful times. It is very difficult to please people living through hard economic times. As I lose two trained employees, I wonder what the impact will be on the level of service we provide. I have a very conscientious staff. They like to go the extra mile, and do whatever they can to help people. The impact of losing two staff members in these times of doing more with less will cause great strain to an already strained staff. The number of people that walk through our door and the number of phone calls we answer has risen tremendously. Staff and management alike are already filling in on the phones and at the counter to provide the public with the best possible service.

It takes at least 2 years to train an individual to work in one of our offices. As we lose two individuals, we are already 2 years and two people behind in providing public service to our aging population with a trained staff. A hiring freeze is not only demoralizing to our remaining staff members, but causes more stress to a demoralized public. (Montana)

Geographical staffing disparities will occur with attrition leaving some offices significantly understaffed, which is especially problematic for the rural SSA field offices. These offices serve customers who often live vast distances away, may have no Internet service, and lack access to public transportation. In some rural areas, SSA may be one of the only Government agencies with a local office. SSA is the face of the Federal Government in many communities and the public expects their local SSA field office to help them with all of their Government-related issues. This SSA manager relates recent service delivery issues in their rural office.

—We are a small office in Iowa and our service area includes several counties, which include some with the highest poverty rates in the State. For several years, we have had the necessary staff to handle our workloads and been able to provide some assistance to other offices. Last year we lost two employees, leaving us with a depleted staff. Now we are not able to handle our own workloads. Because we have a potential driving distance for claimants of 75 miles to come into the office, we have high telephone traffic. We find it very difficult to handle our telephone traffic and all of the workloads and priorities that should be done. Although use of the Internet is rising, this is not the magic answer. Stress on employees who are dealing with rising workloads, pending cases, priorities, deadlines, and unmet expectations (especially from within themselves) affect their outlook and physical health. (Iowa)

SSA field offices provide valuable services to many diverse customers throughout the country. The service provided to our disabled veterans is vitally important. In September 2009, the U.S. Government Accountability Office (GAO) reported on SSA disability benefits to wounded warriors. The GAO report indicated that from 2001 to 2008, SSA processed more than 16,000 applications for disability from wounded warriors and their approval rate was about 60 percent. As the manager of the office that serves the USMA at West Point, I have concerns about our ability to assist our Wounded Warriors.

—My office delivers vital services to the U.S. Army Wounded Warrior Transition Unit (WWTU) through the Soldier and Family Assistance Center. We visit this facility regularly and provide support and SSA services to soldiers from eight States in the Northeast. There are approximately 150 soldiers in the WWTU on an ongoing basis and we process more than 200 leads per year for SSA-related matters. My office staffing has been reduced from 35 employees in 2005 to 30, despite large increases in workloads. Without sufficient resources and replacement staffing, benefits to these members of our Armed Forces will be delayed or become seriously backlogged (New York)

SSA workloads are expected to grow exponentially as the baby boomers retire. Reducing resources while work is significantly increasing is a prescription for substantial service delays and resulting inefficiencies as SSA tries to cope with the mounting backlogs and recontacts by the public. SSA is a very productive agency that efficiently uses the taxpayers' moneys and must be maintained as such.

*Program Integrity Investments*

SSA takes great pride in its stewardship responsibilities by ensuring individuals receive accurate payment of benefits. The agency is responsible for issuing more than $700 billion in benefit payments annually to approximately 60 million people.

Tax dollars must be effectively managed to minimize the risk of making improper payments.

Balancing service commitments with stewardship responsibilities is difficult given the complexity of the programs SSA administers, but the reduction of improper payments is one of SSA's key strategic objectives. The two most powerful tools for reducing improper payments are conducting medical CDRs and SSI redeterminations.

—CDRs are periodic reviews of a disability beneficiary's medical condition to determine whether an individual is still disabled, or if benefits should be ceased because of medical improvement. Medical CDRs yield more than $10 in lifetime program savings for every $1 spent.

—SSI redeterminations review nonmedical factors of eligibility, such as income and resources, to identify payment errors. SSI redeterminations yield a return on investment of more than $7 in program savings over 10 years for each $1 spent, including Medicaid savings accruals.

Investment in program integrity workloads to ensure accurate payments and save taxpayers' dollars is necessary and prudent. Adequate final appropriations from fiscal year 2008–fiscal year 2010 allowed SSA to address critical program integrity work. SSA invested $759 million toward program integrity efforts in fiscal year 2010. The 2.4 million SSI redeterminations and 325,000 medical CDRs completed in fiscal year 2010 produced more than $6 billion in estimated savings (in overpayments prevented or projected to be collected).

The President's fiscal year 2011 SSA budget request proposes SSA will accomplish 2.422 million SSI redeterminations and increase the number of medical CDRs conducted by 31,000 to 360,000 cases. If SSA is able to fulfill its fiscal year 2011 program integrity targets for medical CDRs and SSI redeterminations, the estimated program savings over the next 10 years is nearly $7 billion, including savings to Medicare and Medicaid.

Program integrity investments have an important impact. Inadequate SSA funding in fiscal year 2011 may lead to furloughs or cutbacks that would prevent the completion of SSI redeterminations and medical CDRs.

## LOST PROGRAM INTEGRITY DOLLARS IN FISCAL YEAR 2011

| Fiscal year 2010 workload period | SSI redeterminations and limited issues [1] | Medical continuing disability reviews [2] | Cost savings/loss redeterminations and limited issues [3] | Cost savings/loss medical CDRs [4] | Total cost savings/loss redeterminations and limited issues [5] | FO/DDS estimated employee salary [6] | Long-term gain/loss [7] |
|---|---|---|---|---|---|---|---|
| Fiscal year 2011 | 2,464,684 | 360,044 | $2,708,687,716 | $3,931,680,480 | $6,640,368,196 | $1,809,240,000 | $4,831,128,196 |
| 1 work day | 9,859 | 1,440 | $10,834,751 | $15,726,722 | $26,561,473 | $6,935,276 | $19,626,197 |
| 10 work days | 98,587 | 14,402 | $108,347,509 | $157,267,219 | $265,614,728 | $69,352,755 | $196,261,973 |
| 15 work days | 147,881 | 21,603 | $162,521,263 | $235,900,829 | $398,422,092 | $104,029,133 | $294,392,959 |
| 20 work days | 197,715 | 28,804 | $216,695,017 | $314,534,438 | $531,229,456 | $138,705,510 | $392,523,945 |

[1] SSI redeterminations and limited issues represent projected 551 redetermination and limited issue cases for fiscal year 2011.

[2] Medical CDRs are based on fiscal year 2010 projected to fiscal year 2011 (actual number may be higher).

[3] Cost savings/loss redeterminations and limited issues fiscal year 2011 projections in administrative costs to process this workload for the year; 1, 10, 15, and 20 work days represent long term program savings of $7 saved to $1 administrative dollars spent.

[4] Cost savings/loss medical CDRs fiscal year 2011 projections is adminstrative costs to process CDRs for the year; 1, 10, 15, and 20 work days represent long-term program savings of $10 saved to $1 administrative dollars spent.

[5] Total cost savings/loss redeterminations and medical CDRs is total for this workload.

[6] FO/DDS estimated employee salary is estimated for FO/DDS employees for fiscal year 2011; 1, 10, 15, and 20 work days.

[7] Long-term gain/loss is fiscal year 2011 projection of total saved moneys (cost savings by processing SSI redeterminations and limited issues and CDRs minus salary costs); 1, 10, 15, and 20 work days is total dollars lost (total dollars lost minus salary costs).

SSA's OIG issued a report dated December 1, 2010, titled "Top Issues Facing Social Security Administration Management—Fiscal Year 2011." This report provides OIG's perspectives on the most serious management challenges facing SSA. The full report is available at http://www.ssa.gov/oig/ADOBEPDF/mgmt%20challenges%202011.pdf, but in part, the OIG report indicates there is a significant need to increase the number of medical CDRs conducted by SSA.

"From CY 2005 through CY 2010, we estimate SSA will make between $1.3 and $2.6 billion in disability benefit payments that could potentially have been avoided if full medical CDRs were conducted when they became due. Furthermore, although SSA plans to conduct an increased number of full medical CDRs in fiscal year 2011, a backlog of approximately 1.5 million full medical CDRs will most likely remain."

SSA budgetary constraints have caused the shortfall between the number of CDRs due and the number conducted each year. Adequate funding is needed for SSA to conduct all CDRs when they become due and to save program dollars. If SSA completes all of the 1.5 million medical CDRs, the lifetime program savings would be more than $15 billion.

The OIG report also identifies potential cost-savings, which could be realized by SSA conducting additional SSI redeterminations:

"SSA decreased the number of SSI redeterminations conducted between fiscal years 2003 and 2009 by more than 40 percent. We estimated in a July 2009 report, SSI redeterminations, that SSA could have saved an additional $3.3 billion during fiscal years 2008 and 2009 by conducting redeterminations at the same level it did in fiscal year 2003."

The President's fiscal year 2012 SSA budget request indicates the funding recommended would allow SSA to conduct at least 592,000 medical CDRs and at least 2.6 million SSI redeterminations of eligibility in 2012. SSA estimates that increased program integrity funding in fiscal year 2012 will result in nearly $9.3 billion in savings over 10 years, including Medicare and Medicaid savings.

NCSSMA strongly encourages Congress to provide SSA with the necessary funding to reduce the medical CDR backlog and to conduct additional SSI redeterminations. Investment in program integrity workloads ensures accurate payments, saves taxpayers' dollars and is fiscally prudent. Failure to process these reviews has adverse consequences on the Federal budget and the ongoing administration of SSA programs.

*Quality Concerns*

With the ever-increasing workloads SSA must handle, concerns exist about the accuracy of work being performed. SSA employees are working at a high rate of production and their primary focus is on getting work processed, oftentimes at the expense of quality. Given the significant overall dollars involved in SSA's payments, even the slightest errors in the overall process can result in significant improper payments.

Reduced staffing affects not only the number of employees available to complete production work, but also management and review positions that ensure quality work is completed. SSA is making efforts to improve quality of the work product with its new trainees. Most offices are completing proficiency reviews after new employees complete their training class. This will help develop a more technically proficient employee and improve our quality, but resources are necessary for this.

SSA places a high priority on meeting workload goals, but meeting these goals and maintaining quality requires sufficient resources. The core problem relative to addressing quality concerns is the time and pressure to complete workloads. NCSSMA believes that conducting process reviews of cases is necessary and cannot be sacrificed at the expense of production.

—The complexity of the SSI program makes the redetermination process a significant area of concern relative to accuracy of changes. A targeted assessment review of error-prone areas would be beneficial to ensuring a quality product.

—Process reviews are necessary to address the accuracy of disability reports referred to the Disability Determination Services (DDSs). Improved report accuracy would result in appropriate decisions rendered in a shorter period of time, a critical factor given the pressure on our disability program.

—Reviews of retirement and survivor claims are necessary to ensure that entitlement to benefits is not missed and claimants are selecting the most advantageous month of election, whether filing by telephone, in person or via the Internet. Having sufficient time to review a sample of all our work would allow managers to provide proper feedback and mentoring to employees and ensure continuing quality service.

*SSA Online eServices To Assist With Service Delivery Challenges*

The expansion of services available to the American public via the Internet has helped to alleviate the number of visitors and telephone calls to field offices. However, Internet services currently available represent only a portion of the total workloads accomplished by SSA. In spite of SSA's efforts to educate the public regarding Internet services, the willingness and ability of individuals to utilize the Internet is not keeping pace with the increasing demand for service.

The agency goal for fiscal year 2012 is to process 50 percent of retirement applications and 38 percent of disability claims via the Internet. A study of SSA claims indicates that online claims take less time to process on average, with a timesaving for a retirement claim of 12 minutes and 21 minutes for a disability claim. While eServices has assisted significantly with the high number of applications received, field office staff must still spend significant time to adjudicate these electronically initiated actions.

Many of the high-volume transactions currently processed in field offices are not available on the Internet or are only being used by the public to a limited degree. In fiscal year 2010 SSA processed more than 14.7 million SSA card-related actions and 5.4 million benefit verifications. This represents more than 40 percent of the 45.4 million visitors to SSA field offices. SSA cards cannot be processed online because there are security and authentication issues.

NCSSMA believes that SSA must be properly funded in fiscal year 2011 and beyond so that it may continue to invest in improved user-friendly online services to allow more online transactions. If individuals were able to successfully transact their request for services online, this would result in fewer contacts with field offices, improved efficiencies, and better public service. The agency requires the necessary funds for finalizing the authentication process to allow more postentitlement transactions to be processed via the Internet. With increasing workloads, it is also imperative that SSA offers a seamless Internet disability application that is easy to use and fully integrated with the medical portion of the claim.

*Disability Workload Processes*

Eliminating the disability hearings backlog continues to be SSA's top priority, and the agency has made a major resource investment to improve this situation. The agency's goal is to eliminate the backlog by 2013 and to improve processing time to 270 days. The Commissioner has implemented several initiatives to achieve this goal, including improving processes, compassionate allowances, improving efficiency with automation, and increasing adjudicatory capacity. Achieving these goals will depend on the available resources provided by SSA funding and the volume of new hearings received.

It is important to understand that annual appropriated funding levels for SSA have a critical impact on the hearings backlog. One of the most significant reasons for the increase in disability hearing backlogs was the significant underfunding of SSA. From fiscal year 2004 to fiscal year 2007, the final appropriated funding levels approved by Congress totaled $854 million less than the President's requests and $3.071 billion less than the Commissioner's requests.

However, as you can see from the chart below, from fiscal year 2008 to fiscal year 2010, the cumulative final appropriation level was $203 million more than the President's requests. In addition, SSA received nearly $1 billion in ARRA funding. Half of the ARRA funds were designated to replace the aging SSA NCC. Much of the other ARRA funding has been utilized to help address the hearings backlog at SSA.

SSA FUNDING REQUESTS AND FINAL APPROPRIATIONS: FISCAL YEAR 2008–FISCAL YEAR 2010

[In billions of dollars]

| | Commissioner's request | President's request | Final appropriation | Final vs. President | Final vs. Commissioner |
|---|---|---|---|---|---|
| Fiscal year 2008 | 10.420 | 9.597 | 9.745 | .148 | −.675 |
| Fiscal year 2009 | 10.395 | 10.327 | 10.454 | .059 | .127 |
| Fiscal year 2010 | 11.793 | 11.451 | 11.447 | −.004 | −.346 |
| Total | 32.608 | 31.375 | 31.646 | .203 | −.894 |

The increased resources for SSA became even more essential as the agency's workloads grew at a very rapid pace following the beginning of the economic downturn. With the increased funding SSA has received in the last 3 fiscal years, the agency has hired 228 ALJs and 1,300 additional support staff. The agency has also

opened or expanded 19 hearing offices, including a fifth National Hearing Center and 8 more hearing offices are to be opened this year.

SSA's efforts have resulted in significant progress in reducing both the number of pending hearings and the amount of time a claimant must wait for a hearing decision. At the end of fiscal year 2010, the pending hearings were reduced to 705,367 cases nationwide, the lowest level in 5 years. In February 2010, the average processing time for a hearing was 365 days, the lowest level since December 2003. At its peak, it took nearly 18 months for a hearing decision.

Even though this is positive news, the hearing offices are facing a significant wave of new hearings that are being filed, as seen in the chart below.

ODAR PERFORMANCE DATA THROUGH FEBRUARY 2011

| Fiscal year | Pending SSA hearings | Hearing processing times | Yearly hearing receipts | Yearly dispositions | Average ALJ dispositions |
|---|---|---|---|---|---|
| 2011 [1] | [2] 722,872 | 371 | [2] 829,373 | [2] 784,693 | 2.44 |
| 2010 | 705,367 | 426 | 721,841 | 737,616 | 2.38 |
| 2009 | 722,822 | 491 | 625,003 | 660,842 | 2.37 |
| 2008 | 760,813 | 514 | 591,888 | 550,805 | 2.3 |
| 2007 | 746,744 | 512 | 581,687 | 547,951 | 2.19 |
| 2006 | 715,568 | 483 | 561,609 | 558,978 | 2.2 |
| 2005 | 708,164 | 443 | 598,726 | 519,359 | 2.2 |
| 2004 | 635,180 | 391 | 634,175 | 561,461 | ([3]) |
| 2003 | 556,369 | 343 | 662,733 | 571,928 | ([3]) |
| 2002 | 463,052 | 333 | 596,959 | 532,106 | ([3]) |
| 2001 | 392,397 | 307 | 554,376 | 465,228 | ([3]) |

[1] Fiscal year 2011 information is from October 2010 through February 2011.
[2] Fiscal year 2011 data is projected figure based on October 2010 through February 2011 performance.
[3] Not applicable.

This chart projects that approximately 400,000 additional hearings will be filed from fiscal year 2009 through fiscal year 2011 than were filed in fiscal year 2008. This is attributable to the increased number of disability claims being filed since the economic downturn that began in 2008.

The Congressional Budget Office (CBO) released a report July 22, 2010: "Social Security Disability Insurance: Participation Trends and Fiscal Implications." According to this report, disability beneficiaries tripled from 2.7 million to 9.7 million people from 1970 to 2009. The CBO projects the number of disability beneficiaries will grow to 11.4 million by 2015. In fiscal year 2010, SSA received 619,306 more initial disability claims than in fiscal year 2008. In fiscal year 2011, SSA anticipates receiving 629,000 more initial disability claims than in fiscal year 2008.

The rise in disability claims filings has also created backlogs in the State DDSs. At the end of fiscal year 2010, the number of pending initial disability claims was at an all-time high of 824,192 cases, which was 258,522 more than at the end of fiscal year 2008, a 46 percent increase. In the first 5 months of fiscal year 2011, the number of initial disability claims pending has been reduced to 774,130. This foreshadows the second wave of cases coming to the hearing offices.

To eliminate the hearings backlog in fiscal year 2013, SSA will need to adjudicate a record number of cases in fiscal years 2011 and 2012—more than 800,000 each year. Complicating this monumental task is the furloughing of workers in 10 States, including DDS employees, despite the fact that SSA provides 100 percent of the funding necessary for the DDSs to operate. SSA must also deal with an anticipated retirement wave of ALJs, with 59 percent currently eligible for optional retirement.

Despite these unprecedented challenges, SSA continues to utilize the additional resources received in the last 3 fiscal years to clear more disability claims and hearing cases. Unfortunately, the number of claims and hearings pending is still not acceptable to the thousands of Americans who depend on the SSA for SSI for their basic income, meeting healthcare costs, and support of their families. It is essential that adequate funding be provided to SSA to replace lost staff and work overtime to maintain the momentum achieved in reducing the number of disability cases pending and the time it requires to process these cases.

*Information Technology Investments*

SSA is confronted with major challenges in managing its Information Technology programs to keep up with rapidly expanding workloads. NCSSMA believes it is critical that SSA receive adequate funding to allow for much-needed IT investments. This is vitally necessary for SSA to replace our aging NCC, to maintain systems continuity and availability, and to improve IT service delivery. Any rescission of

Carryover IT funds could seriously jeopardize SSA's initiatives to implement automation and technological efficiencies to address service delivery demands.

The agency is in the process of replacing its NCC and has received ARRA funding for this purpose. The existing NCC is more than 30 years old and has significant structural issues that necessitate its replacement. Additionally, the NCC's capacity is severely strained by increasing workloads and expanding telecommunication services to support the agency's business.

In the previously referenced OIG report dated December 1, 2010, managing the timing of the transition from the existing data center to a new center has become a concern.

"SSA estimates that by 2012, [its National Computer Center] as a stand-alone data center will no longer be able to support this expanding environment."

SSA has also made a major investment in improving its telephone service. The agency is in the midst of replacing telephone equipment with Voice over Internet Protocol (VOIP). The VOIP technology telephone system integrates SSA's networks and provides faster call routing. The agency is approximately 74 percent complete with this initiative, with 936 of its 1,266 field offices now have the new VOIP equipment. SSA anticipates completion of this project by March 2012.

With SSA's volume of telephone calls increasing, successfully implementing VOIP is essential to address growing public service demands. While early VOIP installations experienced problems with the equipment and services, the agency has made significant strides in addressing those concerns. Voice quality, management information data, and programming issues are being addressed and resolved, but SSA IT funding is critical to the successful completion of this major initiative.

*Legislative and/or Regulatory Actions To Improve SSA Program Efficiency*

NCSSMA recommends consideration of the following legislative and/or regulatory proposals that can improve the effective administration of the Social Security Program, with minimal effect on program dollars. NCSSMA believes these proposals, which are included in the fiscal year 2012 budget request, have the potential to increase administrative efficiency and lower operational costs.

—*Enact the WISP*.—This proposal would replace the complex work provisions in the Social Security Disability Program, including the trial work period, substantial gainful activity determinations, extended period of eligibility and expedited reinstatement, and replace these provisions with an earnings test comparable to that of RSI beneficiaries under full retirement age. This provision would simplify the entire work incentive process for the beneficiary and SSA. Work years saved by SSA currently spent in enforcing the prior provision could be redirected to other priority workloads.

—*Federal Wage Reporting*.—This proposal would require employers to report wages quarterly; the proposal would not affect reporting of self-employment. Increasing the timeliness of wage reporting would enhance tax administration and improve program integrity for a range of programs. This program would give SSA more immediate access to earnings information for the SSI program, thereby decreasing underpayments.

—*Require That SSA be Provided With Information on Workers Compensation*.—Provision of this information in an electronic fashion would greatly reduce the number of contacts necessary by SSA personnel to State and local governments, along with private insurance providers. Having accurate information at the time of determinations would ensure more accurate decisions, thereby reducing incorrect payments. This proposal would save both administrative and program dollars.

—*WEP/GPO*.—NCSSMA supports the proposal to develop automated data exchanges for States and localities to submit useful and timely information on pensions that are based on work not covered by Social Security. These cases are complex and error-prone. Availability of this information would allow for more efficient case processing, as well as prevent future overpayments.

CONCLUSION

The management and staff of the SSA are highly committed to serving the American public, but we must have the tools and resources to do so. SSA is the safety net of America and if adequate funding is not provided, public service will deteriorate, with longer waiting times, unanswered calls, increased backlogs, and significant hardship on needy individuals. The appropriated funding levels for fiscal year 2004 through fiscal year 2007 did not adequately fund SSA and contributed to a degradation of service to the public. We hope there will be a careful assessment of

what may be done to provide adequate funding for the SSA in fiscal year 2011 and beyond.

In our view, which is shared by many others, Social Security is the most successful Government program in the world. We are a very proud and productive agency that efficiently uses the taxpayers' moneys, and the SSA must be maintained as such for future generations. NCSSMA sincerely appreciates the subcommittee's interest in the vital services the SSA provides and the ongoing support to ensure SSA has the resources necessary to serve the American public. We remain confident this increased investment in SSA will benefit our entire Nation.

On behalf of the members of NCSSMA, I thank you again for the opportunity to submit this written testimony to the subcommittee and state our viewpoints. NCSSMA members are not only dedicated SSA employees, but are also personally committed to the mission of the agency and to public service. We respectfully ask that you consider our comments, and would appreciate any assistance you can provide in ensuring the American public receives the critical and necessary service they deserve from the SSA.

Senator HARKIN. And thank you all very much for your testimonies.

We'll start a round of 5-minute questions, here.

Mr. Dirago, we'll start with you. I held a field hearing at the University of Northern Iowa campus on February 5 this year. And we discussed these budget cuts like this, including to the Social Security Administration, on communities in Iowa. Jerry Nelson, a field office manager from Waterloo field office, testified. And he presented a pretty stark picture of the impact that budget cuts on Iowan's filing for disability benefits and walking through their door for even basic services.

As a field office manager in Newburgh, New York—again, the impact—what is the impact of potential cuts like this on those who walk through your door and call you on the phone? Again, just give me a good example.

Mr. DIRAGO. Well, waiting time in our offices is really an issue. In terms of the number of people walking into our offices on a daily basis, the average waiting time across the country is about 21 minutes. If we're not funded properly and we don't have replacement staff, those waiting times are going to go up significantly.

The other effect would be the processing of our disability claims and the backlogs that would occur. If funding is not provided, there would be delays in that. Potentially, the hearings backlog progress would be reversed.

Our telephone calls coming into the offices, there's a tremendous volume. Last year, I mentioned, 100 million telephone calls that SSA handled. My office alone receives about 4,000 telephone calls in a month. It's very difficult to get to those folks, and we try to do the best job that we can——

Senator HARKIN. Four thousand phone calls. How many employees?

Mr. DIRAGO. We have 30 employees in Newburgh.

Senator HARKIN. But, not all those would be employees who would be representatives that could handle a phone interview, are they?

Mr. DIRAGO. Well, there's four management employees and the rest of the folks are on the front lines.

Senator HARKIN. So, that's 26, yeah?

Mr. DIRAGO. Yeah.

Senator HARKIN. For——

Mr. DIRAGO. And we do——

Senator HARKIN [continuing]. 3,000 calls.

Mr. DIRAGO [continuing]. The best job we can. But, sometimes—you know, it—the resources are very short.

The other impact that I would mention specifically is the program-integrity workloads. They're tremendously important. Last year, we did about 2.4 million in the agency. And that has a huge benefit. We already talked about the potential of $1 to $7 savings—$1–$7 in savings for every $1 invested. My office does in excess of 2,000 redeterminations. And again, if we don't have the resources, and if the staffing is not replaced, then we're not going to get to those workloads. And then the long-term effect would be negative.

Senator HARKIN. Someone told me also about the phone calls coming into your offices, that these are not usually 30-second phone conversations.

Mr. DIRAGO. No, generally, the phone calls that come in, that are to the field offices, are often in regards to claims development, which could be to resolve issues on their disability applications; could be complex issues in the Supplemental Security Income Program, where you have to go into development of income and resources. So, oftentimes those telephone calls are 5 to 10 minutes, or even more. The telephone calls that go into the teleservice center sometimes can be resolved very quickly, where they may be just a request for location of an office or a request for a benefit verification. So, generally when folks call the local field office, they want to speak to someone in the local field office because they have an issue that needs to be addressed, with a particular claims representative, about their claim.

Senator HARKIN. And, while I'm very supportive of technology and putting more things online—Commissioner Astrue talked about that—as I travel around my State of Iowa, and I go to so many small towns and places, where we have a lot of elderly people that live by themselves—in many cases, in small houses, and the only thing they have is Social Security; that's all they've got—they just aren't too proficient online. And a lot of them don't even have online services. In rural areas, they just don't have it. And so, while technology's okay, it just doesn't reach, I think, a big segment of the population out there that are elderly. Now, that may change as the Baby Boomers start to retire and people who are used to using online services retire. But, I'm saying, for the present generation out there, I mean, some of them have never used computers before, have never gone online.

Mr. DIRAGO. Yes. We've—in terms of the agency, right now we're at about 34 percent online, in terms of the claims filed, between a combination of retirement, survivors, and disability, which is very good. It's a significant improvement over prior years.

The Commissioner's fiscal year 2012 goal is 50 percent in retirement and 38 percent in disability. But, you are correct, there's—rural counties, there's issues, in terms of access to the Internet; there's issues, oftentimes, with people's ability to handle the difficult process of processing——

Senator HARKIN. Right.

Mr. DIRAGO [continuing]. A claim online, particularly disability claims. That's the large challenge.

The one point I'd like to make—the agency is in the process of improving its disability online application, and that's an important initiative, and would be very helpful, because if more claims are taken online the—what we have to work on, in terms of the offices—we'd be better able to handle that. Because every one of those online claims still has to be handled within the office. So, the local field office reviews the claim, makes the decision, in terms of any entitlement factors, may pursue other development. In terms of the disability, they have to basically clean up the entire application so that the product that's sent to the disability determination services is accurate and so they can make a good decision.

Senator HARKIN. All right. Thank you. My time's up.

Senator SHELBY. Thank you, Mr. Chairman.

Mr. Hammond, I'll direct the first question to you, if I could.

In your testimony, you note that, while funding for Social Security Administration administrative expenses is critical, AARP has equal concern for many other vital programs. Specifically, you note the importance of sufficient funding to help seniors afford to pay Medicare premiums, for senior nutrition, and job-training programs, and the Low-Income Energy Assistance Program. Funding for these initiatives also falls within this jurisdiction of this subcommittee.

As we work to craft a bill in these tough economic times, and to balance funding priorities for programs that serve our aging population, do you think a 9.4-percent increase for the Social Security Administration's administrative expenses is the best use of limited resources, especially, given substantial buildup of Social Security's reserve funds, which you know that this funding may take from other programs you believe are vital to seniors?

Mr. HAMMOND. Sir, I think—pardon me, I forgot the microphone again.

Senator SHELBY. Go ahead.

Mr. HAMMOND. I think it's very important for us to understand that Social Security is a real safety-net program for this country. We have millions of Americans who are now on Social Security. We have more millions of Americans who will be on Social Security within the next 10 to 15 to 20 years. Unless we provide a viable system that can take applicants, process their claims, and do it accurately and efficiently and quickly, we're going to have longer lists than we have now, waiting for some help. And, as Senator Harkin mentioned, many of those folks have Social Security as their only means of income. So, we need to beef up the Social Security Administration program to the point where it can handle these new applicants and the other applicants that are coming through SSI and through the disability claims department, and give them the resources that they need.

Certainly, those other programs are very important to us. But, we think there needs to be bipartisan support to find solutions to those programs, too.

Senator SHELBY. Absolutely. What recommendations, specifically, would you make to the Social Security Administration to attain its goal of improving service to the public? That's very important to all of us.

Mr. HAMMOND. I'm not here with any specific recommendations this morning, Senator, but I'd be happy to have staff——

Senator SHELBY. Could you do——

Mr. HAMMOND [continuing]. Talk with you about that.

Senator SHELBY [continuing]. Some for the record? Would you——

Mr. HAMMOND. Yes.

Senator SHELBY [continuing]. You or AARP——

Mr. HAMMOND. Yes, we can do something——

Senator SHELBY [continuing]. So we can consider them.

But—because we're interested in spending the money wisely, being efficient for the people who need assistance. Not to waste money, but to do it timely; as you are, I'm sure.

Mr. HAMMOND. We can have staff do something on that regard.

Senator SHELBY. Ms. Ford, I've got a question for you, if I could.

Ms. FORD. Sure.

Senator SHELBY. It's my understanding that the majority of the Social Security Administration's administrative expenses are attributed to the Disability Insurance Program. Given your work with the Consortium for Citizens with Disabilities, could you discuss briefly the impact of the Social Security Administration's efforts, to date, to fast-track disability claims? Specifically, has the disability community noted an improvement in the time to approve claims of those with severe disabilities through Social Security's fast track initiatives, known as Compassionate Allowances and Quick Disability Determinations? Is that program working? And, if it is, good; if it's not, how can we suggest they improve it, if you have some suggestions?

Ms. FORD. Yes, Senator, we have been watching that and have worked with the administration, and note that those two programs have been working. The Quick Disability Determination, I believe that they are still able to decide cases in well under the 20 days. I can't cite, chapter and verse, the exact number of days. And the Compassionate Allowance Program has been able to choose certain types of impairments, where they can determine that the evidence is there and the type of impairment, and the evidence with it, will lead them to a quick decision. And they are——

Senator SHELBY. The right decision, right?

Ms. FORD. The right decision quickly. And they are moving slowly, not too quickly. I think it's important not to move too quickly, so that they do it properly. And we believe that that is working.

We want that to work well, because we think it's important that it not—I don't think it would be good to move too fast and have it work improperly. But, there is good promise there that the administration can move cases——

Senator SHELBY. Is it more——

Ms. FORD [continuing]. Quickly, when the——

Senator SHELBY [continuing]. Efficient than it——

Ms. FORD [continuing]. Evidence is there.

Senator SHELBY [continuing]. Used to be?

Ms. FORD. Pardon?

Senator SHELBY. Is it a lot more——

Ms. FORD. Oh, absolutely.

Senator SHELBY [continuing]. Efficient?

Ms. FORD. Much more efficient.
Senator SHELBY. That's what I was saying.
Ms. FORD. I wish I could cite you the——
Senator SHELBY. Okay.
Ms. FORD [continuing]. The times, but I can't.
Senator HARKIN. If you can get some of that for the record——
Ms. FORD. Yes. I'm sure——
Senator HARKIN [continuing]. It would be good.
Ms. FORD [continuing]. And I'm sure the administration will be able to give that to you——
Senator HARKIN. Okay.
Ms. FORD [continuing]. But we can get that for you.
[The information follows:]

LETTER FROM THE CONSORTIUM FOR CITIZENS WITH DISABILITIES

JULY 27, 2011.

Hon. TOM HARKIN,
*Chairman, Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education and Related Agencies, Washington, DC.*

Hon. RICHARD C. SHELBY,
*Ranking Member, Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education and Related Agencies, Washington, DC.*

RE: Information for the record, Senate Committee on Appropriations, Labor-HHS Subcommittee hearing on the Social Security Administration budget, March 9, 2011

DEAR CHAIRMAN HARKIN AND RANKING MEMBER SHELBY: Thank you for the opportunity to testify on March 9, 2011 on behalf of the Consortium for Citizens with Disabilities (CCD) regarding funding for the Social Security Administration (SSA) in fiscal years 2011 and 2012. At the hearing, the Committee asked for additional information for the record regarding three topics.

*Compassionate Allowance and Quick Disability Determination*

Senator Shelby asked for additional information on efficiencies under SSA's Compassionate Allowance (CAL) and Quick Disability Determination (QDD) initiatives. Through CAL and QDD, cases receive expedited processing within the context of the existing disability determination process. I testified that these programs are working and provide an efficient way for SSA to arrive at accurate, timely determinations for people with some of the most serious impairments in cases where evidence can be quickly and easily obtained, and there is a high likelihood that they meet disability eligibility criteria.

In fiscal year 2010, SSA identified 4.6 percent of all initial disability claims as CAL or QDD; SSA reports that it can "complete these disability claims in days compared to months." [1] Unfortunately, statistics that quantify this are unavailable: SSA collects, but does not report, CAL and QDD processing times. The SSA Office of the Inspector General recently recommended adding data on CAL and QDD processing times and allowances to SSA's annual Performance and Accountability Report, and providing more detailed data on each program.[2] Such data would help policymakers and the public better understand the efficiency and effectiveness of the CAL and QDD initiatives.

*Social Security Beneficiaries With Disabilities*

Senator Shelby also asked how many people with disabilities receive Social Security. As of May, 2011 approximately 15,611,000 people received Social Security Old Age, Survivors, and Disability Insurance (OASDI), Supplemental Security Income (SSI), or both, on the basis of their own disability.[3]

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[1] Social Security Administration (November, 2010). Performance and Accountability Report for FY 2010. http://www.ssa.gov/finance.

[2] Office of the Inspector General, Social Security Administration (April, 2011). Performance Indicator Audit: The Social Security Administration's Fiscal Year 2010 Performance Indicators. A–02–10–11076.

[3] Social Security Administration (May, 2011). Monthly Statistical Snapshot, May 2011. Accessed July 1, 2011 at http://ssa.gov/policy/docs/quickfacts/stat__snapshot/index.html.

*Amendment 195 to H.R. 1*

Senator Harkin asked for additional information regarding Amendment 195 to H.R. 1. This amendment would prohibit any Federal funds appropriated for the rest of fiscal year 2011 from being distributed under the Equal Access to Justice Act, 28 U.S.C. § 2412 ("EAJA").

The EAJA was signed into law by President Reagan in 1980 after receiving broad bipartisan Congressional support. The EAJA provides attorneys' fees to individuals, small businesses, and nonprofits who prevail in claims against the Federal Government and who can prove that the Federal Government was not "substantially justified" in bringing or defending the case.

The EAJA allows low-income and middle-income people who cannot otherwise afford an attorney to bring their claims. For example, the EAJA allows people with disabilities and seniors to appeal denials of Social Security benefits to Federal court, and veterans to appeal decisions to the Board of Veterans' Appeals and to the Court of Appeals for Veterans Claims. The fees paid under the EAJA are assessed against the Federal agency involved and, as a result, do not reduce the past due benefits received by the plaintiff/claimant.

As discussed in my written testimony, CCD is concerned that by making legal representation less available, Amendment 195 would make it more difficult for people whose disability claims have been denied to pursue their claims in Federal court. For that reason, my testimony urged the Subcommittee to oppose inclusion of similar language in the fiscal year 2011 and 2012 spending packages.

On May 25, 2011, legislation that would have a similar effect as Amendment 195 was introduced in both the House and Senate (Government Litigation Savings Act; H.R. 1996 and S. 1061). As more information and analysis on this legislation becomes available, we will forward it to you. Additionally, for more information about how the legislation may affect Social Security claimants, you may wish to contact Nancy Shor, Executive Director of the National Organization of Social Security Claimants' Representatives, at 201–567–4228 or nosscr@att.net.

In closing, thank you for the opportunity to testify and for your leadership in considering the needs of people with disabilities. Please do not hesitate to contact me if you require any additional information.

Sincerely,

MARTY FORD,
*Consortium for Citizens with Disabilities,*
*Co-Chair, Social Security Task Force.*

Ms. FORD. I think it—they are both good programs. We like to watch this carefully, because we want to be sure that the cases are being handled properly. But, yes, there is great promise there in making——

Senator SHELBY. Good.

Ms. FORD [continuing]. Sure that cases can move more quickly.

Senator SHELBY. I also noted in your testimony that you expressed support for the administration's proposed Disability Work Incentives Simplification Pilot Program, which would provide beneficiaries with the flexibility to return to work without fear of losing their benefits. Could you elaborate on the concerns that beneficiaries have on trying to return to work? And what additional recommendations would you make? Because some people are temporarily disabled, and they might get better, but they've got to get back in the workforce, and it's hard.

Ms. FORD. There are a lot of concerns that people with severe disabilities have about returning to the workforce. One is the issue of whether or not they're going to be able to maintain the medical care that they need. Once they become conditioned to the—you know, their new life with the impairment that they may have acquired, do they have the medical treatment and support that they need? And will they be able to maintain work? Some people find that they will be able to, and therefore they won't need the program anymore. Some people find that, in attempting to work, they may not be able to maintain that. Those experiences are what peo-

ple are worried about. Will they be able to get back into the Social Security——

Senator SHELBY. Sure.

Ms. FORD [continuing]. System if they need it? And——

Senator SHELBY. That's very critical, though——

Ms. FORD. Yeah.

Senator SHELBY [continuing]. To someone that's been out of the workforce. They don't want to use—lose their benefits; yet, if they could take a step toward work, and without losing them——

Ms. FORD. Right.

Senator SHELBY [continuing]. It would be helpful, would it not?

Ms. FORD. But—it would. But, if it took you 2 to 3 years to get into the program——

Senator SHELBY. I understand.

Ms. FORD [continuing]. That's one of the problems. And so, if you knew that, once you were in the program, you could attempt work without having to go back——

Senator SHELBY. Sure.

Ms. FORD [continuing]. Through that 2- or 3-year process, that you could just simply come back in, and that risk of having to reenter would——

Senator SHELBY. Sure.

Ms. FORD [continuing]. Be gone, and you had an easy on-and-off. You could take those risks and attempt work. And that's what we would like to——

Senator SHELBY. Without fear of——

Ms. FORD [continuing]. See happen.

Senator SHELBY [continuing]. Losing everything at once.

Ms. FORD. Yes.

Senator SHELBY. To——

Ms. FORD. Yes.

Senator SHELBY. In other words, try and see if they can swim——

Ms. FORD. Right.

Senator SHELBY [continuing]. In the water, huh?

Ms. FORD. Have a good connection to the medical—to the Medicare. And have a good connection to the——

Senator SHELBY. Sure.

Ms. FORD [continuing]. Cash benefit, if you need it. And those are the things that we think could happen in the work incentive simplification (WIS) program, and that's why we would like to work with SSA——

Senator SHELBY. Well, that would help——

Ms. FORD [continuing]. On that.

Senator SHELBY [continuing]. Help the program and help——

Ms. FORD. Yes.

Senator SHELBY [continuing]. The people, would it not?

Ms. FORD. I think it would help immensely.

Senator SHELBY. We worked on that.

Ms. FORD. Yes.

Senator SHELBY. Mr. Dirago—is that right?

Mr. DIRAGO. Yes.

Senator SHELBY. Your administration is the frontline service provider for the Social Security Administration in communities all

over the Nation. Would you elaborate on the legislative and regulatory actions that you recommend in your written testimony, and to—as to simplify the work incentive process, to improve the Social Security Administration program efficiencies? That's very important.

Mr. DIRAGO. Okay.

Senator SHELBY [continuing]. Because we've got a lot of people working at this. The Social Security has been a good program, but to say we can't improve it, is nonsense. You know? You just cited how we could improve it.

Mr. DIRAGO. And I would just elaborate on the work incentive simplification, as well. That's probably the most significant legislative change that's included in the fiscal year 2012 budget request.

The complexity of the—of disability work-incentive development is just beyond belief. You have trial work period, you have substantial gainful activity, you have extended period of eligibility. It's an extremely complex area for our technicians to resolve when individuals attempt to return to work. The proposal would greatly simplify that and make it more of an earnings test, as opposed to these complex decisions. And, as Ms. Ford just indicated, we would support it significantly, because it would reduce administrative costs, in terms of developing these cases.

It would also overcome the fear that individuals have of returning to work, because, as was stated, individuals once—it takes them sometimes 2 years to get on the program; and, when they're on, they just don't want to try to go back to work, because they're fearful of losing the little economic security that they have. So, we would strongly encourage that.

We also encourage—there's some wage matching that we encourage, in terms of windfall elimination provisions in Government pension offsets, where there could be some kind of automatic——

Senator SHELBY. What do you mean by that?

Mr. DIRAGO. Well, in terms of if individuals receive some form of a public benefit, a Government retirement payment, so that there would be matching with Social Security records so that we can resolve any payment issues. So, that if there's more interfaces——

Senator SHELBY. Well, that's a question of information technology, isn't it?

Mr. DIRAGO. Yes, it is.

Senator SHELBY. And the database you have——

Mr. DIRAGO. Right.

Senator SHELBY. And that can be done.

Mr. DIRAGO. Right. And there's also—Federal wage reporting would be something else, in terms of reporting wages on a quarterly basis; that would help us significantly.

Senator SHELBY. About how many people, roughly, are on Social Security disability in the Nation? Just roughly.

Mr. DIRAGO. I don't want to misstate the number. I will get——

Senator SHELBY. Well, just roughly.

Mr. DIRAGO [continuing]. It for you.

Senator SHELBY. Just give a ballpark figure.

Mr. DIRAGO. Wow.

Senator SHELBY. Is it in the millions?

Mr. DIRAGO. Oh, definitely in the millions.
Senator SHELBY. Is it 5 million, 10 million?
Mr. DIRAGO. Hold on——
Ms. FORD. Is it approximately 11?
Mr. DIRAGO [continuing]. One second, here.
Ms. FORD. I'm thinking 11 million. But, I——
Senator SHELBY. Eleven million? Could you furnish it for the record?
Mr. DIRAGO. Absolutely.
[CLERK'S NOTE.—The information was provided in the July 27, 2011 letter from the Consortium for Citizens With Disabilities.]
Senator SHELBY. Let's assume it's just 10 million—that's a lot of people.
Now, in going back to what Ms. Ford said, if some of those people, statistically, will get better—some of them have different problems; some will never get better, we know that, and—but, if we could ferret out who is getting better.
Mr. DIRAGO. Yeah, and that's part——
Senator SHELBY [continuing]. Who could work, and would like to work—and without throwing them in a ditch, to help them to get out, that would help vitalize this program, would it not? And for others that maybe are much more in need.
Ms. FORD. Help—to give them the opportunities to——
Senator SHELBY. You see what I mean, Ms. Ford?
Ms. FORD [continuing]. To try work and to get a——
Senator SHELBY. Absolutely.
Ms. FORD [continuing]. Foothold in the workforce, without the fear of losing the support system that they've had to depend on.
Senator SHELBY. I know it's not a total analogy, but in welfare reform, I know, myself, people that were drawing benefits, especially single mothers, a lot of them, and dropped out of school and we didn't knock out their benefits. And a lot of them have gone and finished high school. I know some that have gone on—I know one that's an electrical engineer right now. But, if we had knocked out their benefits, their props, they would never have made that step toward the marketplace. And I think—isn't that what we want to do, where people are able and want to work again, Ms. Ford?
Ms. FORD. Yes, absolutely.
Senator SHELBY. Okay.
Ms. FORD. We need to give them an opportunity.
Senator SHELBY. Absolutely.
Mr. Chairman, I thank you for your indulgence on your time.
Senator HARKIN. No, it was a good exchange.
Now, that's what the President's proposal is going to, hopefully, going to try to do, is to test a new system out on this. And I'm looking forward to working with the administration on the implementation of this pilot program, starting next year. See if it works.
I would hasten to add, though, that a lot of this information is—mentioned about the information technology, but I'm quick to point out that, in addition to the cuts in H.R. 1, it rescinds $500 million in reserves that we have for information technology upgrades in the Social Security Administration. So, on the one hand, we want to use information technology to help us do the work better and more efficiently; and then we take $500 million from the reserve

fund for information technology upgrades and expenses. So, I just wanted to point that out, that that's another little whack out there that might happen.

I just had one follow up question, Ms. Ford. In your testimony, you mention an amendment—an amendment to H.R. 1, I guess, was adopted, I guess—that will adversely impact the ability of disability claimants to obtain legal representation in Federal court. Could you discuss that a little bit more, and its impact on people with disabilities?

Ms. FORD. It was the—let me find my copy, here.

Senator HARKIN. You said—mentioned amendment 195 or something? I don't——

Ms. FORD. Yes, it was the—it would make it difficult for people whose claims have been denied to take their claims to Federal District Court, since no funds would be available for payment of fees or expenses, under the Equal Access to Justice Act. And we are fearful that that could make legal representation unavailable to claimants who need to pursue their claims in Federal court. And so, we just wanted to bring that to the subcommittee's and the full committee's attention to ensure that no such language would enter into the Senate bill.

Senator HARKIN. Do we have any—if you don't have the information now, maybe we could get it for the record, about how many claimants actually seek to take their cases to Federal court. I don't know if we know that, or not.

Ms. FORD. When you mention Nancy Shor, she might have that. Do you have any idea?

Ms. SHOR. About 20,000.

Ms. FORD. About 20,000 a year.

Senator HARKIN. About 20,000 a year actually seek to go to Federal—actually go to Federal court, or—actually go to Federal court.

Ms. FORD. Currently, actually go to Federal court, yes.

Senator HARKIN. And what you're saying is that there's something in H.R. 1 that says that we don't provide legal representation any longer?

Ms. FORD. That this would not allow them to receive—have their fees paid under the Equal Access to Justice Act, yes.

Senator SHELBY. Can I ask a question?

Senator HARKIN. We can——

Senator SHELBY. Are the fees paid out of the—say, if they had a back reward, and it depends on their work——

Ms. FORD. As——

Senator SHELBY [continuing]. Say, an attorney's work. And they have to approve a fee?

Ms. FORD. That's the case, as long as you're still in the administrative——

Senator SHELBY. Okay.

Ms. FORD [continuing]. System. As long as you're still working your way through the Social Security system.

Senator SHELBY. Okay.

Ms. FORD. But, once you've finished, at the appeals level of SSA, and then you head into Federal District Court, you're no longer working in that——

Senator SHELBY. Okay.

Ms. FORD [continuing]. System. Correct?
Ms. SHOR. Close.
Ms. FORD. Close.
Nancy knows this better than I do.
Senator SHELBY. Okay.
Ms. FORD. Should we submit something that describes that in more detail?
Senator HARKIN. Well, I might want to get more information on that, because I don't think that we ought to be in the business of denying access to court for people who have no money and they have a legitimate—or they feel they have a legitimate reason to go to Federal court to contest an administrative decision. I was not aware of that in the—in H.R. 1—not aware that that provision was in there.
Did you have something?
Senator SHELBY. Mr. Chairman, I just want to follow up——
Senator HARKIN. Yes.
Senator SHELBY [continuing]. On that, if I may.
Senator HARKIN. Yes.
Senator SHELBY. Do you have some statistics—and, if you don't have it, I'm sure you could get it and furnish it for the subcommittee record—on—if 20,000—just roughly, 20,000 cases are appealed from the——
Senator HARKIN. ALJ.
Senator SHELBY [continuing]. Is it the—the appeal on the Supreme——
Senator HARKIN. Probably ALJ.
Senator SHELBY. Yes.
Senator HARKIN. Yes.
Senator SHELBY [continuing]. To the Federal court—Federal District Court—what's the—are the statistics on overturning the decision and everything? We'd be curious about that, too.
Ms. FORD. I think——
Senator HARKIN. Well, you know what?
Ms. FORD [continuing]. We'd have to get that——
Senator HARKIN. I think——
Ms. FORD [continuing]. For the record.
Senator HARKIN. I think I'm going to call Ms. Shor up to the table. No reason we can't.
Senator SHELBY. Good idea.
Senator HARKIN. What the heck.
So, we have a new witness here on this panel. Nancy Shor, the executive director of the National Organization of Social Security Claimants' Representatives.
So, Ms. Shor, welcome to the subcommittee.
Ms. SHOR. Thank you very much.
I did want to respond to the question you had, Senator Shelby, about the availability of a claimant's past-due benefits to pay the attorney's fee. That can be available for Federal court cases, as well as fees, pursuant to the Equal Access to Justice Act. And there's an offset so that it's not a double recovery.
Senator SHELBY. Okay.
Ms. SHOR. In response to your question about the statistics for outcome in Federal court, about 40 percent of cases annually are—

the Commissioner's denial is affirmed—a handful are dismissed, a handful are paid outright, about 50 percent of the cases go back to the agency on——

Senator SHELBY. Are remanded back for a hearing.

Ms. SHOR. And about two-thirds of those cases—in about two-thirds of those cases, the claimant is successful.

Senator SHELBY. Okay. A lot of this could be prevented if you had all the information at the initial hearing, where you'd save money, but it'd also bring justice if somebody was really disabled.

Ms. SHOR. No question about it.

Senator SHELBY. Is that right?

Ms. SHOR. You're absolutely correct.

Senator SHELBY. That's—looks to me like that's where we ought to be working.

Ms. SHOR. Absolutely correct.

Senator SHELBY. Either, somebody's got merit or they don't, sometimes it's in between. Because the other is costly to the person who's denied, also costly to the person who—if the person's rewarded and they're really maybe not that disabled. I don't—I can't determine that.

Okay.

Senator HARKIN. So, why do so many cases, 20,000 a year, go through this whole system and stuff if—I mean, is it just an interpretive question, or is it a question of judgment, how disabled a person is? Why is there so much difficulty, at the beginning, in ascertaining whether they quality or not, Ms. Shor?

Ms. SHOR. Senator, I think there are a variety of reasons. Some of it has to do with inadequate development of the case throughout the process, that there are impairments that this individual presents with that are never really researched and never adequately presented.

I think there are also instances where the improper legal standards are applied throughout the process, and it isn't til a Federal judge steps in and directs the agency to correct an error that they've been making.

There are people whose conditions worsen. They've got a degenerative type of disease so that, at the very beginning of the process, they are—their prognosis doesn't look so great, but, the day they apply, there could certainly be a contested question about whether they're disabled, that day. And, as the process proceeds, their conditions will deteriorate and additional evidence will become available.

Senator HARKIN. Complicated system.

Ms. SHOR. Complicated system.

Senator HARKIN. Not every case is the same. They're all different, and that's why sometimes people have to appeal these to ALJs and then on to Federal court, I guess. But, I did not know that there was this provision in H.R. 1 that would take that away.

But, I just want to be clear that, with that provision in H.R. 1, are you saying that there are still funds available through the passthrough?

Ms. SHOR. The Equal Access to Justice Act provides an offset so that a claimant doesn't have to pay the entire fee that a—that is awarded for the court. In other words, if there were a $5,000 attor-

ney fee awarded for the attorney's work, there could easily be a $3,000 or $4,000 fee awarded, under the Equal Access to Justice Act. That money goes to the claimant, the now successful beneficiary. And, of course, is desperately needed, because, almost by definition, this person has been out of work for probably 5 years, with the pace of processing of claims at the Social Security Administration. So, the Equal Access to Justice Act is an extremely important statute that defrays the cost of legal expenses for claimants who find themselves having to go to Federal court.

Senator HARKIN. I don't understand that. Let me rephrase it.

If, in fact, $500 million was rescinded—$500 million was taken from the Special Reserve Fund for—no, no. I'm sorry, that's not it.

If, in fact, the language, that was in H.R. 1, that says that these funds cannot be used for appeals to District Court—I don't have the exact language——

Ms. SHOR. No.

Senator HARKIN [continuing]. In front of me.

Ms. SHOR. Senator, the language in amendment 195——

Senator HARKIN. Yes.

Ms. SHOR [continuing]. Would stop the payment of Equal Access to Justice Act fees, Government-wide. So, it includes Social Security, but it includes all the other Federal agencies where plaintiffs are potentially eligible for Equal Access to Justice Act fees.

Senator HARKIN. Oh.

Ms. SHOR. So, although Social Security cases are the largest number of cases in which Equal Access to Justice Act fees are awarded, the per-case fee is tiny, compared to the amounts of Equal Access to Justice Act fees that are awarded in litigation having to do with a lot of other Federal agencies.

So, amendment 195 doesn't contain the words, "Social Security," it only talks about a prohibition on payment of any fees, in any type of case, pursuant to the Equal Access to Justice Act.

Senator HARKIN. How much money do we—are we talking about, do we know?

Ms. SHOR. I'm sorry, I don't. But, I could certainly supply it.

Senator HARKIN. Well, maybe I can get my staff to get it. Do we know?

Senator SHELBY. Can you get it for the record, then?

Ms. SHOR. Certainly.

Senator SHELBY. That would be good.

Ms. SHOR. Absolutely.

Senator HARKIN. Okay. Well, we'll get that for the record.

Senator SHELBY. Good.

[CLERK'S NOTE.—The information was provided in the July 27, 2011 letter from the Consortium for Citizens With Disabilities.]

Senator HARKIN. Anything else?

Senator SHELBY. No, nothing.

Senator HARKIN. Well, listen. Thank you all very much.

Thank you, Ms. Shor, for adding to our deliberations here.

Senator SHELBY. Our fourth panelist.

Ms. SHOR. Thank you very much.

Senator HARKIN. Yeah, yeah. But again, we wanted to have this hearing, to highlight the problems confronting the Social Security Administration, that we have jurisdiction over, only in terms of the

administrative aspect of it. We don't have jurisdiction over policies, we don't have jurisdiction over solvency, and all that kind of stuff. That's another committee, that's not this committee. We just have a responsibility to make sure that the Social Security Administration gets enough money to fulfill its obligations, and to do so in a timely manner, to make sure that, you know, it's efficient and effective.

So, I guess we're going to have votes today, on H.R. 1 and the alternative, at 3 p.m. today. And again, I just wanted to have this hearing, again, to highlight what might happen if, in fact, the H.R. 1 was enacted. And I think we've got some interesting testimony on the record.

I would just state that, in administrative funding—I just want to be clear that—here's the data—for fiscal year 2010, we enacted $11.447 billion, from this subcommittee. The President's budget for fiscal year 2011 is $12.379 billion. The House continuing resolution has $11.322 billion. The Senate continuing resolution has $11.822 billion. And the fiscal year 2012 President's budget is $12.522 billion. I just wanted to make sure all those figures are out there.

Anybody else—do you have anything else at all?

Senator SHELBY. No.

Senator HARKIN. Okay.

SUBCOMMITTEE RECESS

Thank you all very much. The subcommittee will stand recessed.

[Whereupon, at 11:15 a.m., Wednesday, March 9, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

# MATERIAL SUBMITTED SUBSEQUENT TO THE HEARING

[CLERK'S NOTE.—The following testimonies were received subsequent to the hearing for inclusion in the record.]

## PREPARED STATEMENT OF THE AMERICAN FEDERATION OF GOVERNMENT EMPLOYEES, AFL–CIO

Chairman Harkin, Ranking Member Shelby, and members of the Senate Appropriations Subcommittee on Labor, Health and Human Service, Education and Related Agencies, I thank you for the opportunity to present this statement regarding the Limitation on Administrative Expenses (LAE) for the Social Security Administration.

As the President of the American Federation of Government Employees, National Council of SSA Field Operations, AFL–CIO, I speak on behalf of approximately 29,000 Social Security Administration (SSA) employees in over 1,300 facilities. These employees work in Field Offices, and Teleservice Centers throughout the country where retirement and disability benefit applications and appeal requests are received, processed, and reviewed.

AFGE thanks the Senate Appropriations Committee for calling this important hearing, at a very critical time, to examine the SSA's budget needs for this year and next year, in order to support the proper administration of our programs. Our employees are very concerned about prospects for furloughs, loss of staff and overtime hours needed to keep up with rapidly expanding workloads, and general deterioration in service delivery. They care deeply about the public they serve, and the continuing uncertainty about future staffing and resources is generating high levels of stress.

*Background*

During the past 3 years, with increased staffing and funding, we have substantially reduced disability hearing backlogs and processing times, and turned more of our attention to long-neglected program integrity workloads. However, working without a budget for the past 5 months, we have been struggling to keep up with rapidly growing requests for face-to-face and telephone service, and we could easily slip back. We are constrained by continuing resolutions that have been funding SSA operations at fiscal year 2010 levels, with a freeze on hiring in most parts of the Agency. Our clients are having more difficulty accessing service, waiting times are increasing, and backlogs have developed in initial disability benefit applications. Field Representatives who serve clients who are mobility-impaired or live in remote areas have all but disappeared. SSA Spokesman Mark Hinkle recently acknowledged that budget pressures have slowly done away with 1,500 of the 2,000 contact stations that existed in the 1980s.[1] The recession and the aging of the population have created unprecedented demands upon the employees we represent. We are concerned that, if there are further cuts in employee work years, we may be unable to keep up with record numbers of new claims for retirement, survivor, and auxiliary benefits. No matter how people access service, whether face-to-face, by telephone, or via the Internet, our employees need to be on the job to process new applications for benefits, and to ensure that payments are made to the right people, in the right amount, and on time.

*Budget Battles*

The President proposed $12.379 billion to fund SSA administrative expenses for fiscal year 2011, and $12.522 billion for fiscal year 2011. AFGE supports both requests.

[1] "Social Security ends visits to seniors", Boston Globe, January 12, 2011.

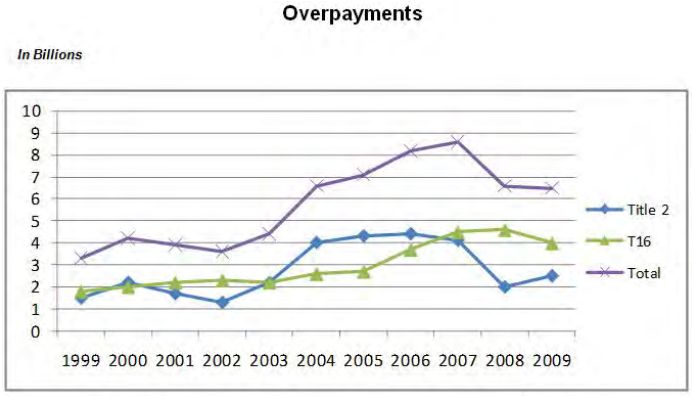
The Agency is limited to spending $11.447 billion, the fiscal year 2010 level with a carryover of $480 million for a total of $11.927 billion, under the current continuing resolution.

The House recently passed H.R. 1, which would cut full year funding to $11.321 billion. Additionally, H.R. 1 also includes rescissions of $500 million from the SSA reserve fund and from a special IT appropriation of $118 million for the National Computer Center. This would provide SSA with $10.7 billion in overall spending for fiscal year 2011. This represents about a 5.5 percent decrease from fiscal year 2010 spending levels and would require $743 million in cuts before October 1, 2011. Such reductions would most likely cease all hiring at the Office of Disability and Adjudicative Review (ODAR), which is currently exempt from the present hiring freeze under the continuing resolution. Backlogs would escalate very rapidly, improper payments would grow, and furloughs of employees could be implemented for up to a month per employee. Public service will be devastated.

The Senate has proposed a fiscal year 2011 budget of $11.822 billion, which includes rescissions of $400 million of the agency reserve fund. This is essentially the same funding level as fiscal year 2010. This budget would most likely prevent the furloughing of Social Security workers and allow SSA "to keep the lights on." However, SSA would most likely be forced to operate under an agency wide hiring freeze for the remainder of fiscal year 2011, which would result in the loss of approximately 3,500 SSA and DDS employees by the end of the fiscal year. This will cause understaffing in offices around the country. Backlogs will continue to grow and decisions on benefit claims will take longer. Access to field offices and the 800 number would take much longer and waiting times would be expected to increase.

SSA Commissioner Astrue and President Obama have determined the funding level that is required to maintain service, and to make needed improvements. The wide differences between the House and Senate proposals for fiscal year 2011 domestic discretionary spending have raised the specter of one or more Government shutdowns and budget-driven employee furloughs during the rest of this fiscal year. The adverse impact of a shutdown or furloughs on Social Security's clients, and on the hard-working employees dedicated to serving them, would be very serious. One week ago today, during their lunch breaks, Social Security employees in 96 facilities across the country joined with members of their communities to make the public aware of these threats. It is imperative that Congress pass a responsible budget for the rest of this year that allows SSA workers to continue to provide high quality service to the public, and avoid any interruption of services caused by shutdowns and/or furloughs.

*Penny Wise is Pound Foolish*




Constraints on spending and on front-line staffing have damaged the integrity of the programs themselves. Continuing disability reviews are not being conducted on schedule, and Supplemental Security Income (SSI) eligibility reviews are being done too infrequently. With insufficient staff to handle the work, SSA is forced to rely too much on self-reporting by mail, rather than on a full examination of eligibility factors through an interview by a trained SSA employee. Continuing disability reviews save about $10 for every $1 spent on them, and SSI reviews about $8 for every $1 invested in them. The President's requests for 2011 and 2012 would provide dedicated funds to conduct more Supplemental Security Income (SSI) eligibility

redeterminations, and more continuing disability reviews for Social Security and SSI beneficiaries. Both the House and Senate are silent regarding this targeted funding, and both have rescinded the vast majority of the Agency reserves, funds that could have been used to support these critical workloads and others.

Setting the work aside because of insufficient staff and funding is penny-wise and pound-foolish, but SSA has little choice because the disability claims and appeals crisis demands attention. These neglected workloads have contributed to record overpayments, nearly 9 billion in fiscal year 2007 [2], and many of the overpayments are uncollectible, which has captured the interest of the Government Accountability Office. The last 2 fiscal years, SSA has been successful in reducing the overall amount of overpayments. However, with congressional proposals to reduce Government agency budgets and staffing, this success may be very short lived. Without adequate staff and budget, AFGE expects to see a new record number of overpayments, which may actually exceed SSA's annual administrative expense budget within the next few years. To make matters worse, the amount of funds lost to overpayments over the last 10 years exceeded $55 billion. These lost funds would have funded SSA's administrative expenses for at least 4 years.

*The Off Budget Solution*

The Omnibus Reconciliation Act of 1990 provided that SSA FICA taxes and benefits payments were "off budget." Congress later interpreted that SSA's Limitation on Administrative Expenses (LAE) was not covered by the Omnibus Reconciliation Act of 1990, although the Social Security Act stipulates that administrative costs for the Social Security program must be financed by the Social Security Trust Fund. Since the SSA LAE (e.g., staffing, office space, supplies, technology, etc.) is "on budget," Congress decides on a yearly basis the amount that will be authorized and appropriated to administer SSA programs. Often SSA is left with insufficient staff and limited overtime due to a combination of competing interests within the Labor, Health and Human Services, Education and Related Agencies appropriation and the congressional budget scoring system. These circumstances make it next to impossible to appropriate adequate administrative funds to enable SSA to complete the tasks assigned by Congress in a timely manner. Such shortages adversely affect disability appeals processing time and cause severe integrity problems.

The Social Security Trust Funds, projected to run a $113 billion surplus this year, and over $128 billion next year, pay for the great majority of the operating costs for the programs we administer. AFGE proposes that the Congress take SSA's administrative accounts off budget now. We are very efficient, spending just 0.9 percent of income in Social Security program administration. The Agency would still be required to justify its budget requests to Congress, and receive approval to spend money, but there is no reason why SSA should have to compete for funding with the many other agencies in the Labor/HHS appropriation package, when our source of funding is almost entirely off budget.

In an "off budget" environment Congress would continue to maintain spending authority but would be unencumbered by artificial caps and budgetary scoring rules. However, Congress would continue to appropriate SSA administrative expenses to ensure integrity and efficiency. Legislation should require SSA's Commissioner to document (in performance reports mandated under the Government Performance and Results Act) how funds have been and will be used to effectively carry out the mission of the Agency, to meet expected levels of performance, to achieve modern customer-responsive service, and to protect program integrity.

Most importantly, GAO must annually inform Congress regarding SSA's progress in achieving stated goals. Congress should also mandate that SSA's Commissioner submit the proposed budget directly to Congress as is now only optional in the independent agency legislation (Public Law 103–296, § 101). This requirement to submit the SSA budget directly to Congress may also be a provision of "off-budget" legislation and would be endorsed by AFGE.

Without sufficient funding of Social Security, the LAE will not go far enough to put the agency on a clear path to provide its mandated services at a level expected by the American public. SSA must receive enough funding to make disability decisions in a timely manner and to carry out other critical workloads. AFGE strongly urges Congress to separate SSA's LAE budget authority from the section 302(a) and (b) allocations for discretionary spending. The size of SSA's LAE is driven by the number of administrative functions it conducts to serve beneficiaries and applicants. Congress should remove SSA's administrative functions from the discretionary budget that supports other important programs.

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[2] Source of verification of all overpayments found in each respective OIG Annual Audit and SSA Performance Plans for each fical year listed.

AFGE does not believe the American public deserves poor service from SSA. Some claimants while waiting for a disability hearings decision lose their homes, declare bankruptcy, and die. Their families suffer tremendous financial hardships; some lose everything during the prolonged wait for a decision. The public deserves efficient, expeditious service. Now is the time to make the correction, so that there is stability to run SSA programs that are so vital in providing family insurance and income security to 54 million beneficiaries.

In closing, AFGE urges the Senate to do whatever is necessary to insure that SSA receives full funding to do the work that Congress demands from the Agency.

AFGE thanks the Subcommittee for its time and consideration of the concerns addressed in this statement. AFGE is committed to serve, as we always have, as the employees' advocate AND a watchdog for clients, taxpayers, and their elected representatives.

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## PREPARED STATEMENT OF THE NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE

As President and Chief Executive Officer of the National Committee to Preserve Social Security and Medicare, I appreciate the opportunity to submit this statement for the record. With millions of members and supporters across America, the National Committee is a grassroots advocacy and education organization devoted to the retirement security of all citizens.

Chairman Harkin, Ranking Member Shelby and members of the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, the National Committee appreciates your holding this hearing to examine funding for the Social Security Administration in fiscal year 2011 and fiscal year 2012.

The National Committee is committed to preserving and strengthening Social Security. This includes ensuring a strong and stable Social Security Administration that delivers high-quality, prompt service to the public. We are certainly concerned about the tremendous funding challenges facing the Social Security Administration for the remainder of fiscal year 2011 and for fiscal year 2012. It is crucial that SSA be provided with adequate funding so that they are able to provide the American people with the level of service they expect and deserve, one that also prevents workloads from spiraling out of control.

As you know, 54 million Americans receive Social Security benefits each month. The benefits they receive from this program constitute a vital lifeline that is critical to their economic well-being. Given the essential nature of Social Security, and the increasing demands of an aging population, I believe it is extremely important that the Social Security Administration be provided sufficient funds for operating expenses so it can meet the needs of the American people.

In fiscal year 2010, the last time Congress enacted an appropriation for SSA, a total of $11.5 billion was made available for administering the Social Security program. The President, in his fiscal year 2011 budget, requested an appropriation of $12.4 billion. Instead, Congress has enacted a series of continuing resolutions that essentially freeze the Agency's funding at the fiscal year 2010 level.

The House of Representatives recently passed a continuing resolution for the remainder of the fiscal year that proposes significant reductions in funding, including elimination of funds for vital systems improvement projects. The fiscal year 2011 continuing resolution being considered by the Senate increases funding over the House-passed amount, providing needed resources to this important Agency. While the President's fiscal year 2011 budget request would minimize service reductions and continue the Agency's progress toward reducing processing backlogs in the disability program, the Senate proposed funding level is a dramatic improvement over the funding cuts passed by the House.

Staying within the reduced spending levels authorized in previously enacted continuing resolutions has been challenging for the Social Security Administration. The hiring freeze imposed on the Agency's field offices has resulted in significant staffing imbalances that have stretched the capability of the staff to provide timely and effective levels of public service.

Further cuts would exacerbate these problems, resulting in longer waiting times for appointments to file for benefits, or for processing address changes or direct deposit information, delays in receiving Agency decisions, and busy signals at the Agency's toll-free 800 number. In addition, we understand that further cuts may mean employee furloughs or even office closures, resulting in even greater reductions in service to America's seniors.

While we believe the President's funding request would best serve the American people, we believe the funding levels proposed in the Senate's continuing resolution

would provide the Agency with sufficient funding to avoid major service disruptions. We therefore urge all Senators to show their commitment to Social Security by providing the SSA with the resources it needs to do its job.

Going forward, in order for SSA to fully meet its multitude of responsibilities, the agency will require no less than the $12.667 billion recommended in the President's budget for its fiscal year 2012 administrative funding. This level of funding is necessary due to the increase in requests for assistance from the American public due in large part to the economic downturn. SSA teleservice centers, hearing offices, Disability Determination Services (DDSs), and the nearly 1,300 field offices are in critical need of adequate resources to address their growing workloads. Without this level of funding, SSA will be unable to cope with the continued increase in demand for services and maintain the progress it has already made in providing satisfactory service delivery to senior citizens, people with disabilities and others who rely on Social Security.

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2012

**WEDNESDAY, MARCH 30, 2011**

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 10:03 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senator Harkin, Reed, Pryor, Mikulski, Brown, Shelby, Johnson, Kirk, and Moran.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### OFFICE OF THE SECRETARY

**STATEMENT OF HON. KATHLEEN SEBELIUS, SECRETARY**

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Labor, Health and Human Services Appropriations Subcommittee will come to order.

We welcome back Madam Secretary to the subcommittee. I want to first start by commending you for the outstanding work that you are doing to implement our healthcare reform law. It has been just 1 year since President Obama signed the Affordable Care Act into law, and already millions of Americans are reaping major benefits. Those benefits include very strong consumer protections. No longer can large health insurers use technicalities to cancel your policy if you get sick or impose lifetime limits on your benefits. No longer can children be denied coverage because of a preexisting health condition. Americans have greater access to preventative care than ever before, and of course, young adults can now stay on their parents' plan until age 26.

In the past year, your Department has also awarded the first grants from the Prevention and Public Health Fund, a new fund that will not only improve the health of the American people but also help bend the cost curve on healthcare. This fund is already being used to help Americans stop smoking, as well as to reduce obesity and prevent costly chronic diseases like diabetes.

Your plan for fiscal year 2011 expands on all of this work and adds an investment in childhood immunization which data shows saves about $6.30 for every dollar that we spend.

Your Department is implementing these reforms with great skill and dedication, and I thank you for your leadership.

I also want to assure you that as chairman of both this Appropriations subcommittee and the authorizing committee, the HELP Committee, your Department will continue to receive the resources you need to implement the Affordable Care Act. The American people will not allow the hard-earned protections and benefits in this law to be taken away. And neither will we.

Reforming healthcare is not only the right thing to do, it will save taxpayers money and reduce the deficit by $210 billion in the first decade and more than $1 trillion in the next. And those are not my estimates. They are from the nonpartisan Congressional Budget Office.

I am well aware that some opponents of healthcare reform say they intend to use the Labor, HHS appropriations bill, our bill, as a vehicle for defunding the Affordable Care Act. That will not happen.

Our topic today is the President's fiscal year 2012 budget request for the Department of Health and Human Services. Unfortunately, as we all know, Congress still has not closed the books on fiscal year 2011. That uncertainty makes it harder than usual to evaluate the President's request. For example, the House has proposed major reductions to key programs like community health centers, Head Start, and the National Institutes of Health. We do not yet know the outcome of negotiations to complete a budget for fiscal year 2011, but one of the things I want to cover in this hearing is what the impact of those potential cuts would be, that is, on community health centers, Head Start, and the National Institutes of Health (NIH).

Overall, the President's proposed budget for fiscal year 2012 is a good start. It is a tight budget. Total funding for the Department is almost flat compared with fiscal year 2010, but it does include some significant increases for key priorities like NIH, child care, Head Start, and of course, rooting out fraud and waste in Medicare and Medicaid.

I also applaud the administration for proposing a new early learning challenge fund which is intended to improve the quality of early childhood education programs. The money for this new fund would go through the Education Department, but HHS would be a partner in that effort.

However, some provisions in the President's budget are a cause for concern. I recognize that we are operating under significant fiscal constraints, but I am greatly disappointed by the proposed 50 percent cut to the community services block grant program. This funding is critically important for community initiatives that provide a safety net for millions of low-income people across the country, and I will do whatever I can to oppose that cut in any bill that comes out of this subcommittee.

I am also concerned by the proposed $2.5 billion cut to the Low-Income Home Energy Assistance Program, as well as the small but important $30 million cut—that would be a 72 percent cut—to the Child Traumatic Stress Network.

But as I said, overall the budget is a good start.

Madam Secretary, I look forward to hearing your testimony.

First, before I yield to Senator Shelby for his opening remarks, I have received statements from the full committee chairman, Senator Inouye and the vice chairman, Senator Cochran. Their statements will be inserted into the record at this point.

[The statements follow:]

PREPARED STATEMENT OF CHAIRMAN DANIEL K. INOUYE

Secretary Sebelius, given the unique geographic challenges in Hawaii it is imperative that we continue to work together to address the healthcare needs of our population. I would like to take this opportunity to thank you for your support in addressing the medical needs of the people in Hawaii. I will provide questions for the record.

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PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, thank you for chairing this hearing to review the President's fiscal year 2012 budget for the Department of Health and Human Services. We are pleased to welcome the Secretary of Health and Human Services, Kathleen Sebelius to her third appearance before our Subcommittee, and we look forward to working with her to support our Nation's investment in healthcare, social services programs, medical research and disease prevention.

I am pleased that your budget includes a $745 million increase for the National Institutes of Health. These additional dollars are essential if we are to continue to make scientific discoveries in cancer, autism, heart disease and the many other maladies that plague so many Americans.

This subcommittee will be challenged to balance the competing needs of the programs contained in your $79 billion budget. We look forward to working with you to maintain our commitment to fiscal restraint while providing much needed increases for high priority programs.

I am very sorry I cannot stay for the duration of this important hearing due to another hearing that requires my attention, but I am submitting questions for the record and I look forward to a response.

Senator HARKIN. Senator Shelby.

STATEMENT OF SENATOR RICHARD C. SHELBY

Senator SHELBY. Thank you, Mr. Chairman.

Welcome, Secretary Sebelius.

I look forward to hearing your testimony today on the 2012 budget request.

In this austere economic environment, Congress is struggling with difficult budget decisions. We all understand the valuable role that healthcare plays in the lives of our citizens, and we all want to make healthcare more affordable, more accessible, and on the cutting edge of scientific discoveries.

However, in times of economic uncertainty when every Department should be exercising fiscal restraint, I am disappointed that the administration has not significantly reduced healthcare spending. In fact, on top of the 9 percent increase in the entire Department of Health and Human Services' budget request, the 2012 bill includes $4.2 billion in mandatory spending for the Affordable Care Act, ACA. This is $4.2 billion that, due to Senate rules, this subcommittee cannot reduce or rescind. It is simply more spending for another entitlement program.

One of the most troubling aspects of the ACA is the Community Living Assistance Services and Supports (CLASS) Act. The CLASS Act we call it. The CLASS Act is a new voluntary Federal insurance program. Its goal is twofold: to provide a cash benefit to individuals with either a functional or equivalent cognitive limitation

that become too disabled to work and to create a voluntary insurance program for healthy individuals looking to hedge against the risk of needing long-term care in the future. However, the CLASS Act's poor design attempts to accomplish these two incompatible goals with a single program. The result will be that the cost of serving disabled workers will push premiums to unacceptably high levels for those looking to purchase insurance, and they will decline to buy. I think this will quickly push the program to insolvency.

The Congressional Budget Office predicts the CLASS Act will "add to budget deficits by amounts on the order of tens of billions of dollars." The Department of Health and Human Services actuary states and says, "There is a very serious risk that the program will be unsustainable." Even you, Madam Secretary, testified at the Senate Finance Committee hearing early this year and said, "The bill as written is totally unsustainable."

In addition to the $4.2 billion included in mandatory spending for the ACA, the budget submission includes $450 million in discretionary funding. Specifically, the budget proposes to spend $120 million on the financially unsustainable CLASS Act, $236 million for health insurance exchange operations, $38 million for healthcare.gov, and $28 million to help consumers navigate the private insurance market. Secretary Sebelius, we fundamentally disagree on the implementation of the ACA. However, one area of the ACA we should agree on is that $38 million to fund one website is unacceptable.

Further, I am concerned that many important programs, such as the Community Health Center Fund, are moved to the mandatory side of the ledger and funded under the ACA. The question is, what happens if the ACA is repealed and agencies' baseline funding levels are too low to cover the cost of these programs?

Finally, as we continue to review the 2012 budget, I believe we need to ensure that our entire Nation, not just population-rich urban areas, is reaping the benefits of healthcare programs. There are numerous consolidations in the budget that eliminate formula-funded grants which will result in the redirection of critical Federal funds from smaller, rural States to urban areas. I think we must continue to make certain that programs that are deemed competitive actually allow all States to compete on a level playing field.

Mr. Chairman, the level of Federal spending, I believe, is unsustainable. We must make steps to reduce the deficit that burdens our Nation today and will continue to in the future. Every Federal program should be reviewed to ensure it is working effectively and efficiently and is a valuable use of taxpayer dollars. However, I remain cautious about arbitrary or across-the-board cuts to agencies and programs simply to score a political point. Congress needs to carefully examine programs to ensure that we are sustaining those that are effective and cutting those that are not.

In particular, one of the most results-driven aspects of our entire Federal budget I believe is the National Institutes of Health. Research conducted at NIH reduces disabilities, prolongs life, and is an essential component to the health of all Americans. NIH programs consistently meet their performance and outcome measures, as well as achieve their overall mission.

For example, in February, NIH research led to the announcement of a very promising cystic fibrosis therapy that targets the genetic defect that causes cystic fibrosis as opposed to only addressing its symptoms. The preliminary success of this drug, for instance, underscores the importance of the NIH whose innovative work on human genetics and other areas of basic science could potentially lead to treatments and even cures for some of our most devastating diseases.

Mr. Chairman, I look forward to working with you to craft a bill that balances the needs of our healthcare system with our fiscal realities.

Senator HARKIN. Thank you very much, Senator Shelby.

Now we will turn to our distinguished Secretary of Health and Human Services. Kathleen Sebelius became the 21st Secretary of the Department of Health and Human Services on April 29, 2009. Prior to that, of course, in 2003 she was elected as Governor of Kansas and served in that capacity until her appointment as the Secretary.

Prior to her election as Governor, the Secretary served as the Kansas State insurance commissioner.

She is a graduate of Trinity Washington University and the University of Kansas.

I believe this will make the Secretary's fourth appearance before this subcommittee since her appointment.

Madam Secretary, we welcome you again. Your statement will be made a part of the record in its entirety, and please proceed as you so desire.

SUMMARY STATEMENT OF HON. KATHLEEN SEBELIUS

Secretary SEBELIUS. Thank you, Mr. Chairman. Chairman Harkin, Ranking Member Shelby, members of the subcommittee, I need to do a special shout out to my fellow Kansan, Senator Moran, who is a new member of your subcommittee, Mr. Chairman. But I had the privilege of working with the Senator for years on Kansas business and now look forward to working with him in his new capacity here in the Senate.

It is good to be with you and discuss the President's 2012 budget for the Department of Health and Human Services.

In the President's State of the Union Address, he outlined a vision of how the United States can win the future by out-educating, out-building, and out-innovating the world so we give every family and business the chance to thrive.

Our 2012 budget is a blueprint for putting that vision into action. It makes investments for the future that will grow our economy and create jobs.

But the budget recognizes we cannot build lasting prosperity on a mountain of debt. Years of deficits have put us in a position where we need to make some tough choices. In order to invest for the future, we need to live within our means.

In developing our budget, we looked closely at every program in our Department. We cut waste when we found it, and when programs were not working well enough, we redesigned them to put a new focus on results. And, in some cases, we cut programs that would not have been cut in better budget times.

Now, I look forward to answering your questions on the budget, but first I want to share some of the highlights that fall under the jurisdiction of this subcommittee which oversees more than $72 billion of our Department's $80 billion budget.

Last week, as the chairman said, was the 1-year anniversary of the Affordable Care Act. Over the last 12 months, we have worked around the clock with partners in Congress and States to deliver on the promise of the law to the American people.

Thanks to the new law, children are no longer denied coverage because of their preexisting health conditions. Families have new protections under the Patient's Bill of Rights. Businesses are beginning to get some relief from soaring healthcare costs, and seniors have lower cost access to prescription drugs and preventive care.

We are building on this first year's progress by supporting innovative new models of care that will improve patient safety and quality while reducing the burden of rising health costs on families, businesses, cities, and States.

We are also making new, important investments in our healthcare workforce and community health centers to make quality, affordable care available to millions more Americans and create hundreds of thousands of new jobs across the country.

To make sure America continues to lead the world in innovation, our budget also increases funding for the National Institutes of Health. New frontiers of research like cell-based therapies and genomics have the promise to unlock transformative treatments and cures for diseases ranging from Alzheimer's to cancer to autism. Our budget will allow the world's leading scientists to pursue these discoveries while keeping America at the forefront of biomedical research.

And because we know, Mr. Chairman, there is nothing more important to our future than the healthy development of our children, our budget includes significant increases in funding for child care and Head Start. Science shows that success in school is significantly enhanced by high quality early learning opportunities, which makes these some of the wisest investments we can make in America's future.

But the budget does more than provide additional resources. We are also aiming to raise the bar on quality by supporting key reforms to transform the Nation's child care system into one that fosters healthy development and gets children ready for school. The budget proposes a new early learning challenge fund, a partnership with the Department of Education that helps promote State innovation in early education. These initiatives, coupled with the quality efforts already underway in Head Start, are an important part of the education agenda that will help every child reach their academic potential and make America more competitive.

Our budget also recognizes that at a time when so many Americans are making every dollar count, we need to do the same. That is why we are providing new support for President Obama's unprecedented push to stamp out waste, fraud, and abuse in the healthcare system, an effort that well more than pays for itself. Last year, we returned a record $4 billion to taxpayers. The key part of this effort is empowering seniors to recognize and report fraud, and we have appreciated the support of Congress and espe-

cially Senator Harkin for the Senior Medicare Patrol Program, which is one of our best tools for doing that.

In addition, the budget includes a robust package of legislative proposals to root out waste and abuse within Medicare and Medicaid. These proposals enhance prepayment scrutiny, expand auditing, increase penalties for improper actions, and strengthen CMS' ability to implement corrective actions. We address State activities that increase Federal spending. Over 10 years, on the conservative side, they will deliver at least $32 billion in savings.

Across our entire Department, Mr. Chairman, we have made eliminating waste, fraud, and abuse a top priority, but we know that is not enough. Over the last few months, we have also gone through our Department's budget, program by program, to find additional savings and opportunities where we can make our resources go further.

The President's 2012 budget makes tough choices and smart, targeted investments today so that we can have a stronger, healthy, and more competitive America tomorrow. That is what it takes to win the future and that is what we are determined to do.

PREPARED STATEMENT

Again, thank you, Mr. Chairman, for having me here today and I look forward to our discussion.

[The statement follows:]

PREPARED STATEMENT OF KATHLEEN SEBELIUS

Chairman Harkin, Senator Shelby, and Members of the Subcommittee, thank you for the invitation to discuss the President's fiscal year 2012 budget for the Department of Health and Human Services (HHS).

In President Obama's State of the Union address he outlined his vision for how the United States can win the future by out-educating, out-building and out-innovating the world so that we give every family and business the chance to thrive. His 2012 budget is the blueprint for putting that vision into action and making the investments that will grow our economy and create jobs.

At the Department of Health and Human Services this means giving families and business owners better access to healthcare and more freedom from rising health costs and insurance abuses. It means keeping America at the cutting edge of new cures, treatments and health information technology. It means helping our children get a healthy start in life and preparing them for academic success. It means promoting prevention and wellness to make it easier for families to make healthy choices. It means building a healthcare workforce that is ready for the 21st century health needs of our country. And it means attacking waste and fraud throughout our department to increase efficiency, transparency and accountability.

Our 2012 budget does all of this.

At the same time, we know that we can't build lasting prosperity on a mountain of debt. And we can't win the future if we pass on massive debts to our children and grandchildren. We have a responsibility to the American people to live within our means so we can invest in our future.

For every program we invest in, we know we need to cut somewhere else. So in developing this budget, we took a magnifying glass to every program in our department and made tough choices. When we found waste, we cut it. When we found duplication, we eliminated it. When programs weren't working well enough, we reorganized and streamlined them to put a new focus on results. When they weren't working at all, we ended them. In some cases, we cut programs we wouldn't in better fiscal times.

The President's fiscal year 2012 budget for HHS totals $891.6 billion in outlays. The budget proposes $79.9 billion in discretionary budget authority for fiscal year 2012, of which $72.4 billion is within the jurisdiction of the Labor, Health and Human Services, Education, and Related Agencies Subcommittee.

The Department's discretionary budget is slightly below the 2010 level. Within that total we cover the increasing costs of ensuring the safety of our food supply,

providing medical care to American Indians and Alaska Natives, managing our entitlement programs, investing in early childhood, and advancing scientific research. We contribute to deficit reduction and meet the President's freeze to non-security programs by offsetting these investments with over $5 billion in targeted reductions. These reductions are to real programs and reflect tough choices. In some cases the reductions are to ineffective or outdated programs and in other areas they are cuts we would not have made absent the fiscal situation.

The budget proposes a number of reductions and terminations in HHS.

—The budget cuts the Community Services Block Grant in half, a $350 million reduction, and injects competition into grant awards.

—The budget cuts the Low Income Home Energy Assistance Program by $2.5 billion bringing it back to the 2008 level appropriated prior to energy price spikes.

—The budget eliminates subsidies to Children's Hospitals Graduate Medical Education focusing instead on targeted investments to increase the primary care workforce.

—The budget reduces the Senior Community Services Employment Program by $375 million, proposes to transfer this program from the Department of Labor to HHS, and refocuses the program to train seniors to help other seniors.

The budget also stretches existing resources through better targeting.

—The budget redirects and increases funding in CDC to reduce chronic disease. Rather than splitting funding and making separate grants for heart disease, diabetes, and other chronic diseases, the budget proposes one comprehensive grant that will allow States to address chronic disease more effectively.

—The budget redirects prevention resources in SAMHSA to fund evidence-based interventions and better respond to evolving needs. States and local communities will benefit from the additional flexibility while funds will still be competed and directed toward proven interventions.

These are the two goals that run throughout this budget: making the smart investments for the future that will help build a stronger, healthier, more competitive, and more prosperous America, and making the tough choices to ensure we are building on a solid fiscal foundation.

The budget documents are available on our website. But for now, I want to share an outline of the budget, including the areas of most interest to this Committee, and how it will help our country invest in, and win, the future.

That starts with giving Americans more freedom in their healthcare choices, so they can get affordable, high-quality care when they need it.

TRANSFORM HEALTHCARE

*Expanding Access to Coverage and Making Coverage More Secure*.—The Affordable Care Act expands access to affordable coverage to millions of Americans and strengthens consumer protections to ensure individuals have coverage when they need it most. These reforms create an important foundation of patients' rights in the private health insurance market and put Americans in charge of their own healthcare. As a result, we have already implemented historic private market reforms including eliminating pre-existing condition exclusions for children; prohibiting insurance companies from rescinding coverage and imposing lifetime dollar limits on coverage; and enabling many adult children to stay on their parent's insurance plan up to age 26. The Affordable Care Act also established new programs to lower premiums and support coverage options, such as the Pre-Existing Condition Insurance Plans Program and the Early Retiree Reinsurance Program. The Act provides Medicare beneficiaries and enrollees in most private plans access to certain covered preventative services free of charge. Medicare beneficiaries also have increased access to prescription drugs under Medicare Part D by closing the coverage gap, known as the "donut hole," by 2020 so that seniors no longer have to fear being unable to afford their prescriptions. The Act also provides for an annual wellness visit to all Medicare beneficiaries free of charge.

Beginning in 2014, State-based health insurance Exchanges will create affordable, quality insurance options for many Americans who previously did not have health insurance coverage, had inadequate coverage, or were vulnerable to losing the coverage they had. Exchanges will make purchasing private health coverage easier by providing eligible consumers and small businesses with "one-stop-shopping" where they can compare a range of plans. New premium tax credits and cost-sharing reductions will also increase the affordability of coverage and care. The Affordable Care Act will also extend Medicaid insurance to millions of low-income individuals who were previously not eligible for coverage, granting them access to affordable healthcare.

*Ensuring Access to Quality, Culturally Competent Care for Vulnerable Populations*.—The budget includes $3.3 billion for the Health Centers Program, including $1.2 billion in mandatory funding provided through the Affordable Care Act Community Health Center Fund, to expand the capacity of existing health center services and create new access points. The infusion of funding provided through the Affordable Care Act, combined with the discretionary request for fiscal year 2012, will enable health centers to serve 900,000 new patients and increase access to medical, oral, and behavioral health services to a total of 24 million patients.

*Reducing Health Care Costs*.—New innovative delivery and payment approaches will lead to both more efficient and higher quality care. For example, provisions in the Affordable Care Act designed to reduce healthcare acquired conditions and preventable readmissions will both improve patient outcomes and reduce unnecessary health spending. The Innovation Center, in coordination with private sector partners whenever possible, will pursue new approaches that not only improve quality of care, but also lead to cost savings for Medicare, Medicaid, and CHIP. Rate adjustments for Medicare providers and insurers participating in Medicare Advantage will promote greater efficiency in the delivery of care. Meanwhile, new rules for private insurers, such as medical loss ratio standards and enhanced review of premium increases, will lead to greater value and affordability for consumers.

*Combating Healthcare Associated Infections*.—HHS will use measures related to heathcare-associated infections (HAIs) for hospital value-based purchasing beginning in fiscal year 2013, as called for in the Affordable Care Act. The fiscal year 2012 budget includes $86 million—of which $20 million is funded in the Prevention and Public Health Fund Prevention Trust Fund—to the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and the Office of the Secretary to reduce healthcare-associated infections. In fiscal year 2012, HHS will continue research on health-care associated infections and tracking infections through the National Healthcare Safety Network. HHS will also identify and respond to new healthcare-associated infections by conducting outbreak and epidemiological investigations. In addition, HHS will implement, and ensure adherence to, evidence-based prevention practices to eliminate healthcare-associated infections. HHS activities, including those that the Innovation Center sponsors, will further the infection reduction goals of the Department's Action Plan to Prevent Healthcare-Associated Infections. HHS has made progress in reducing HAIs. For instance, in 2009, an estimated 25,000 fewer central line-associated blood stream infections (CLABSIs) occurred among patients in ICUs in the United States than in 2001 (a 58 percent reduction). Progress in reducing CLABSIs highlights the preventability of these infections, and HHS will continue to support HAI prevention in collaboration with States and facility partners.

*Health Services for 9/11 Terrorist Attacks*.—To implement the James Zadroga 9/11 Health and Compensation Act, the fiscal year 2012 budget includes $313 million in mandatory funding to provide medical monitoring and treatment to responders of the September 11, 2001 terrorist attacks and initial health evaluations, monitoring, and treatment to others directly affected by the attacks. In addition to supporting medical monitoring and treatment, HHS will use funds to establish an outreach program for potentially eligible individuals, collect health data on individuals receiving benefits, and establish a research program on health conditions resulting from the terrorist attacks.

ADVANCE SCIENTIFIC KNOWLEDGE AND INNOVATION

*Accelerating Scientific Discovery to Improve Patient Care*.—The budget includes $32 billion for the National Institutes of Health (NIH), an increased investment of $745 million over the fiscal year 2010 enacted level, to support innovative basic and clinical research that promises to deliver better health and drive future economic growth. In fiscal year 2012, NIH estimates it will support a total of 36,852 research project grants, including 9,158 new and competing awards.

Recent advances in the biomedical field, including genomics, high-throughput biotechnologies, and stem cell biology, are shortening the pathway from discovery to revolutionary treatments for a wide range of diseases, such as Alzheimer's, cancer, autism, diabetes, and obesity. The dramatic acceleration of our basic understanding of hundreds of diseases; the establishment of NIH-supported centers that can screen thousands of chemicals for potential drug candidates; and the emergence of public-private partnerships to aid the movement of drug candidates into the commercial development pipeline are fueling expectations that an era of personalized medicine is emerging where prevention, diagnosis, and treatment of disease can be tailored to the individual and targeted to be more effective. To help bridge the divide between basic science and therapeutic applications, NIH plans to establish in fiscal

year 2012 the National Center for Advancing Translational Sciences (NCATS), of which one component would be the new Cures Acceleration Network. With the creation of NCATS, the National Center for Research Resources will be abolished and its programs transferred to the new Center or other parts of NIH.

*Advancing Patient-Centered Health Research*.—The Affordable Care Act created the Patient-Centered Outcomes Research Institute to fund research and get relevant, high quality information to patients, clinicians and policy-makers so that they can make informed healthcare decisions. The Patient-Centered Outcomes Research Trust Fund will fund this independent Institute, and related activities within HHS. In fiscal year 2012, the budget includes $620 million in AHRQ, NIH and the Office of the Secretary, including $30 million from the Trust Fund, to invest in core patient-centered health research activities and to disseminate research findings, train the next generation of patient-centered outcomes researchers, and improve data capacity.

*Advancing Health Information Technology*.—The budget includes $78 million, an increase of $17 million, for the Office of the National Coordinator for Health Information Technology (ONC) to accelerate health information technology (health IT) adoption and promote electronic health records (EHRs) as tools to improve the health of individuals and transform the healthcare system. The increase will allow ONC to assist healthcare providers in becoming meaningful users of health IT.

ADVANCE THE HEALTH, SAFETY, AND WELL-BEING OF THE AMERICAN PEOPLE

*Enhancing the Quality of Early Care*.—The budget provides $6 billion in combined discretionary and mandatory funding for child care. These resources will enable 1.7 million children to receive child care services. The Administration also supports reforms to the child care program to serve more low-income children in safe, healthy, and nurturing child care settings that are highly effective in promoting early learning; supports parental employment and choice by providing information to parents on quality; promotes continuity of care; and strengthens program integrity and accountability Additionally, the President's budget includes $8.1 billion for Head Start, which will allow us to continue to serve 968,000 children in 2012. The Administration is also working to implement key provisions of the Head Start Reauthorization, including requiring low-performing programs to compete for funding, that will improve program quality. These reforms and investments at HHS, in conjunction with the Administration's investments in the Early Learning Challenge Fund, are key elements of the broader education agenda designed to help every child reach his or her academic potential and improve our Nation's competitiveness.

*Preventing and Treating HIV/AIDS*.—The budget supports the goals of the National HIV/AIDS Strategy to reduce HIV incidence, increase access to care and optimize health outcomes for people living with HIV, and reduce HIV-related health disparities. The request focuses resources on high-risk populations and allocates funds to State and local health departments to align resources to the burden of the epidemic across the United States. The budget includes $2.4 billion, an increase of $85 million, for HRSA's Ryan White program to expand access to care for persons living with HIV/AIDS who are otherwise unable to afford healthcare and related support services. The budget also includes $858 million for domestic HIV/AIDS Prevention in CDC, an increase of $58 million, which will help CDC decrease the HIV transmission rate; decrease risk behaviors among persons at risk for acquiring HIV; increase the proportion of HIV infected people who know they are infected; and integrate services for populations most at risk of HIV, sexually transmitted diseases, and viral hepatitis. In addition, the budget proposes that up to one percent of HHS discretionary funds appropriated for domestic HIV/AIDS activities, or approximately $60 million, be provided to the Office of the Assistant Secretary for Health to foster collaborations across HHS agencies and finance high priority initiatives in support of the National HIV/AIDS Strategy. Such initiatives would focus on improving linkages between prevention and care, coordinating Federal resources within targeted high-risk populations, enhancing provider capacity to care for persons living with HIV/AIDS, and monitoring key Strategy targets.

*Addressing the Leading Causes of Death and Disability*.—Chronic diseases and injuries represent the major causes of morbidity, disability, and premature death and contribute to the growth in healthcare costs. The budget aims to improve the health of individuals by focusing on prevention of chronic diseases and injuries rather than focusing solely on treating conditions that could have been prevented. Specifically, the budget includes $705 million for a new competitive grant program in CDC that refocuses disease-specific grants into a comprehensive program that will enable health departments to implement the most effective strategies to address the leading causes of death. Because many chronic disease conditions share common risk

factors, the new program will improve health outcomes by coordinating the interventions that can reduce the burden of chronic disease. In addition, the allocation of the $1 billion available in the Prevention Fund will improve health and restrain the growth of healthcare costs through a balanced portfolio of investments. The fiscal year 2012 allocation of the Fund builds on existing investments and will align with the vision and goals of the National Prevention and Health Promotion Strategy under development. For instance, the CDC Community Transformation Grants create and sustain communities that support prevention and wellness where people live, learn, work and play through the implementation, evaluation, and dissemination of evidence-based community preventive health activities.

*Preventing Substance Abuse and Mental Illness*.—The budget includes $535 million within the Substance Abuse and Mental Health Services Administration (SAMHSA) for new, expanded, and refocused substance abuse prevention and mental health promotion grants to States and Tribes. To maximize the effectiveness and efficiency of its resources, SAMHSA will deploy mental health and substance abuse prevention and treatment investments more thoughtfully and strategically. SAMHSA will use competitive grants to identify and test innovative prevention practices and will leverage State and Tribal investments to foster the widespread implementation of evidence-based prevention strategies through data driven planning and resource dissemination.

*Supporting Older Adults and their Caregivers*.—The budget includes $57 million, an increase of $21 million over fiscal year 2010, to help seniors live in their communities without fear of abuse, and includes an increase of $96 million for caregiver services, like counseling, training, and respite care, to enable families to better care for their relatives in the community. The budget also proposes to transfer an Older Americans Act program that provides community service opportunities and job training to unemployed older adults from the Department of Labor to HHS. As part of this move, a new focus will be placed on developing professional skills that will enable participants to provide services that allow fellow seniors to live in their communities as long as possible.

*Pandemic and Emergency Preparedness*.—While responding to the H1N1 influenza pandemic has been the focus of the most recent pandemic investments, the threat of a pandemic caused by H5N1 or other strains has not diminished. HHS is currently implementing pandemic preparedness activities in response to lessons learned from the H1N1 pandemic in order to strengthen the Nation's ability to respond to future health threats. Balances from the fiscal year 2009 supplemental appropriations are being used to support recommendations from the HHS Medical Countermeasure Review and the President's Council of Advisors on Science and Technology. These multi-year activities include advanced development of influenza vaccines and the construction of a new cell-based vaccine facility in order to quickly produce vaccine in the United States, as well as development of next generation antivirals, rapid diagnostics, and maintenance of the H5N1 vaccine stockpile.

The HHS Medical Countermeasure Review described a new strategy focused on forging partnerships, minimizing constraints, modernizing regulatory oversight, and supporting transformational technologies. The request includes $665 million for the Biomedical Advanced Research and Development Authority, to improve existing and develop new next-generation medical countermeasures and $100 million to establish a strategic investment corporation that would improve the chances of successful development of new medical countermeasure technologies and products by small and new companies. The budget includes $70 million for FDA to establish teams of public health experts to support the review of medical countermeasures and novel manufacturing approaches. Additionally, NIH will dedicate $55 million to individually help shepherd investigators who have promising, early-stage, medical countermeasure products. Finally, the budget includes $655 million for the Strategic National Stockpile to replace expiring products, support BioShield acquisitions, and fill gaps in the stockpile inventory.

### STRENGTHEN THE NATION'S HEALTH AND HUMAN SERVICE INFRASTRUCTURE AND WORKFORCE

*Strengthening the Health Workforce*.—A strong health workforce is key to ensuring that more Americans can get the quality care they need to stay healthy. The budget includes $1.3 billion, including $315 million in mandatory funding, within HRSA, to support a strategy which aims to promote a sufficient health workforce that is deployed effectively and efficiently and trained to meet the changing needs of the American people. The budget will initiate investments that will expand the capacity of institutions to train over 4,000 new primary care providers over 5 years.

*Health Workforce Diversity*.—As part of these health workforce investments, the budget also includes $163 million at HRSA for Health Workforce Diversity programs to improve the diversity of the Nation's health workforce and improve care to vulnerable populations. This funding will support training programs and scholarship opportunities to students from disadvantaged backgrounds enrolled in health professions and nursing programs.

*Expanding Public Health Infrastructure*.—The fiscal year 2012 budget supports State and local capacity so that health departments are not left behind. Specifically, the budget requests $73 million, of which $25 million is funded in the Prevention Fund, for the CDC public health workforce to increase the number of trained public health professionals in the field. CDC's experiential fellowships and training programs create an effective, prepared, and sustainable health workforce to meet emerging public health challenges. In addition, the budget requests $40 million in the Prevention Fund to support CDC's Public Health Infrastructure Program. This program will increase the capacity and ability of health departments to meet national public health standards in areas such as information technology and data systems, workforce training, and regulation and policy development.

INCREASE EFFICIENCY, TRANSPARENCY, AND ACCOUNTABILITY OF HHS PROGRAMS

*Strengthening Program Integrity*.—Strengthening program integrity is a priority for both the President and myself. The budget includes $581 million in discretionary funding, a $270 million increase over fiscal year 2010, to expand prevention-focused, data-driven, and innovative initiatives to improve CMS program integrity. The budget request also supports the expansion up to 20 Strike Force cities to target Medicare fraud in high risk areas and other efforts to achieve the President's goal of cutting the Medicare fee-for-service error rate in half by 2012. The proposed 10 year discretionary investment yields $10.3 billion in Medicare and Medicaid savings, a return of about $1.5 for every dollar spent. In addition, the budget includes a robust package of program integrity legislative proposals to expand HHS program integrity tools and produce $32.3 billion in savings over 10 years. We appreciate the support of Congress, particularly Chairman Harkin, on efforts to fight Medicare fraud. I look forward to working with the Subcommittee on this issue.

In addition, the Affordable Care Act provides unprecedented tools to CMS and law enforcement to enhance Medicare, Medicaid, and Children's Health Insurance Program (CHIP) program integrity. The Act enhances provider screening to stop fraudsters from participating in these programs in the first place, gives the Secretary the authority to implement temporary enrollment moratoria for fraud hot spots, and increases law enforcement penalties. Additionally, the continued implementation of the Secretary's Program Integrity Initiative seeks to ensure that every program and office in HHS prioritizes the identification of systemic vulnerabilities and opportunities for waste and abuse, and implements heightened oversight.

*Implementing the Recovery Act*.—The American Recovery and Reinvestment Act provides $138 billion to HHS programs as part of a government-wide response to the economic downturn. HHS-funded projects around the country are working to achieve the goals of the Recovery Act by helping State Medicaid programs meet increasing demand for health services; supporting struggling families through expanded child care services and subsidized employment opportunities; and by making long-term investments in health information technology (IT), biomedical research and prevention and wellness efforts. HHS made available a total of $118 billion to States and local communities through December 31, 2010; recipients of these funds have in turn spent $100 billion by the same date. Most of the remaining funds will support a signature Recovery Act program to provide Medicare and Medicaid incentive payments to hospitals and eligible healthcare providers as they demonstrate the adoption and meaningful use of electronic health records. The first of these Medicaid incentive payments were made January 5, 2011. More than 23,000 grantees and contractors of HHS discretionary programs have to submit reports on the status of their projects each calendar quarter. These reports are available to the public on Recovery.gov. For the quarter ending December 31, 2010, 99.6 percent of the required recipient reports were filed timely. Recipients that do not comply with reporting requirements are subject to sanction.

CONCLUSION

This budget is about investing our resources in a way that pays off again and again. By making smart investments and tough choices today, we can have a stronger, healthier, more competitive America tomorrow. This testimony reflects just some of the ways that HHS programs improve the everyday lives of Americans.

Under this budget, we will continue to work to make sure every American child, family, and senior has the opportunity to thrive. And we will take responsibility for our deficits by cutting programs that were outdated, ineffective, or that we simply could not afford. But, we need to make sure we're cutting waste and excess, not making across the board, deep cuts in programs that are helping our economy grow and making a difference for families and businesses. We need to move forward responsibly, by investing in what helps us grow and cutting what doesn't.

My department can't accomplish any of these goals alone. It will require all of us to work together. I look forward to working with you to advance the health, safety, and well-being of the American people. Thank you for this opportunity to speak with you today. I look forward to our conversation.

Senator HARKIN. Thank you very much, Madam Secretary.

We will start a round of 5-minute questions and recognize people in order of appearance at the subcommittee. So I will start, and then Senator Shelby, then we will go by order of appearance at the subcommittee.

HEAD START

Madam Secretary, I want to focus on early childhood programs, the impact of H.R. 1, the House-proposed bill, which would cut over $1 billion from Head Start and the child care programs. This would go well beyond whatever we did in the Recovery Act. It actually would cut the funding below the level where they stood prior to the Recovery Act.

I just visited a Head Start center in Iowa, talked to parents there and the Head Start program people and the teachers, and the impact in my own State would be pretty severe. They estimate about 1,800 kids in Iowa would lose their Head Start program.

Can you just tell us for the subcommittee what do you see as the impact of H.R. 1 on Head Start, what changes are you making to Head Start to ensure that children receive high quality services, and just a little bit about the early learning challenge fund and the purpose of it?

Secretary SEBELIUS. Mr. Chairman, I share your interest and focus on early childhood education as being an investment that pays huge dividends in the long run. If H.R. 1 were to become the law, the budget for Head Start would be cut about $1.1 billion below 2010 funding, and we think about 218,000 children across the country who are currently being served would lose those slots both in Head Start and in Early Head Start.

The President, by contrast, has proposed an increase in Head Start, feeling that that is an investment that is important to make. Even though our budget is flat-lined, he has chosen to make an increase in that area, or recommend an increase.

We have looked across the range of programs at Head Start and since studies have been done to indicate there has not been enough progress made as children become school-eligible and continue on in school, we are relooking at all kinds of features with the Department of Education in terms of school readiness. The programs are currently being upgraded and updated in great collaboration and partnership with the Department of Education.

We are also, Mr. Chairman, recompeting the 25 lowest-performing quadrant of the programs, feeling that automatic ongoing funding has not provided an incentive to update and upgrade the quality.

Senator HARKIN. By the way, I commend your Department and your leadership in that area.

Secretary SEBELIUS. Well, I think parents need to be assured that whatever out-of-home placement they choose for their child, whether it is a child care setting or Head Start or a school-based early education program, that the same goals are in place. And that is really what the early learning challenge grant is about.

States—and I will take some credit for what we did in Kansas—are frankly a bit ahead in this. A lot of States have been very innovative in early child care and early education opportunities, putting all the placement folks at the table and insisting that the same kind of quality standards be in place.

The early learning challenge grant would be a partnership with HHS and Department of Education who together run the scope of the child care programs and make sure that we are putting incentives in place to drive higher quality because children who enter school less prepared than their peers, often, by the third grade, are so far behind that they will never catch up. We know that having not only developmentally ready children but educationally ready children is a way to really open those doorways of opportunity, and that is what the focus has been.

Senator HARKIN. Thank you, Madam Secretary.

COMMUNITY HEALTH CENTERS

My last question—I am running out of time—has to do with community health centers. I happen to think the community health center has been one of the great underpinnings of our health system in America, 1,100 of them nationwide providing the kind of healthcare that low-income people need when they walk in that door. Could you explain the impact of the proposed cuts in H.R. 1, what that would do, and how many patients we might lose?

Secretary SEBELIUS. The billion dollars that would be, again, cut from the community health center funding below 2010 would serve—we are calculating that about close to 3 million of the people currently served in community health centers would lose that opportunity, and 10 million who are looking forward to having access to community health centers would also not have those sites available. Along with the health center sites themselves are the healthcare providers, doctors, nurses, nurse practitioners, mental health professionals. So, with the Recovery Act, the Affordable Care Act, and the budget investments, the community health center footprint is scheduled to go from serving about 20 million Americans to serving 40 million Americans in the most underserved areas, rural and urban, throughout the country.

Senator HARKIN. Thank you very much, Madam Secretary.

Senator Shelby.

CLASS ACT

Senator SHELBY. Secretary Sebelius, the CLASS Act attempts to address an important public policy concern, that is, the need for non-institutional long-term care, but it is viewed by many experts as financially unsound. The President's Fiscal Commission recommended reform or repeal of the CLASS Act. You stated to health advocacy groups—and I will quote you—that "it would be irrespon-

sible to ignore the concerns about the CLASS program's long-term sustainability in its current form."

The President's budget proposal includes a request of $120 million for the CLASS Act which would be the first discretionary appropriation for the program. If you are unable to certify that it will be sustainable absent a massive taxpayer infusion of funds, why should Congress want to appropriate the requested $120 million in taxpayer funds for a program that a lot of the experts project will fail? And what will prevent the Department from subsidizing this alleged self-sustaining program with taxpayer funds once it is implemented and then fails? Is that a concern of yours?

Secretary SEBELIUS. Senator, the law as written has some pretty clear directions that we have to be able to certify before benefits would become available to promote to the public for their voluntary enrollment that the program is not only sustainable short-term but sustainable long-term. It needs a 20-year and a 75-year actuarial projection of sustainability.

There also is a very clear directive in the law that prohibits any taxpayer dollars being spent to subsidize what may be a program that is on shaky financial ground.

So those are the two guardrails that we are looking at very closely.

We are working with actuaries. In fact, the head actuary from GenWorth, who has probably the biggest footprint in this space, has become our chief actuary on the CLASS modeling program. But looking at the flexibility that we have, frankly, to look at work requirements, premium indexing, and enrollment—three of the elements that are really critical to making sure you have a solvent program in the future, if indeed only the disabled community enrolls—this program is immediately insolvent in a fiscal manner because there will not be enough income to pay for the benefits.

The money that you have referred to in the budget, which is being requested as an initial outreach and enrollment feature, is designed to make sure we have a solvent program, which means you need to reach into a younger, healthier population, market benefits——

Senator SHELBY. In other words, it is taxpayers' money you are asking for here. Right? $120 million.

Secretary SEBELIUS. It is budgeted money that could make the CLASS program sustainable into the future. Yes, sir.

Senator SHELBY. The budget proposal for the CLASS Act also includes $93.5 million in new Federal spending for, "information and education to ensure that an adequate number of individuals would enroll in the program." While I do not agree myself with Congress appropriating $120 million for an insolvent program, it makes even less sense to me to spend $93.5 million of that funding to promote a program that we know is structured currently to fail.

How do you justify, Madam Secretary, spending such a large sum of money on promotion efforts, given you will be promoting a program that is not quite defined?

Secretary SEBELIUS. Well, again, Senator, we would not promote a program that could not be sustained, and I am prohibited by law from doing that. So it is our intent to—and we are engaged in extensive outreach to look at the elements of the program that need

to be adjusted in order to make sure it is sustainable. I have just mentioned three of them: the work requirements, the premium indexing issues, and the outreach efforts.

The outreach is absolutely essential to engage the employer community and engage citizens who right now—frankly, most think that Medicare provides long-term care, which it does not. Most think that that is a benefit that they have to look forward to, and there really is no private market opportunity right now for the kind of residential assistance that most people want and need.

Senator HARKIN. We will do other rounds.

Senator SHELBY. I will come back.

Senator HARKIN. We have a lot of people here. I want to make sure everyone gets a chance.

I will recognize in order now Senator Pryor, Senator Johnson, Senator Moran, Senator Reed, Senator Brown, and Senator Mikulski. Senator Pryor.

WASTE, FRAUD AND ABUSE

Senator PRYOR. Thank you, Mr. Chairman.

And thank you, Madam Secretary, for being here.

Let me follow up on something that we actually talked about 1 year ago in this subcommittee, and we were talking about waste, fraud, and abuse. You had a request in I think for $110 million to do a 2-year process, I guess you can say, to try to get all the Medicare payment data sets in one system. And I understand we have had some budget issues in the meantime, but I am curious about where you are in that process. I guess you got some of the money appropriated, but tell me where you are in that process?

Secretary SEBELIUS. Well, Senator, there is a broad-based effort underway to put together what is called in the private market "predictive modeling," the kind of data checks that credit card companies use to find if there is an aberrant billing pattern. So, if 10 flat screen TVs end up on your credit card, you are likely to get a call saying did you purchase 10 flat screen TVs before they actually send the money out the door. We have never had that ability with Medicare data in five or six different systems and not integrated.

We are building that database. We are well down the line to modeling now what we can do, and with the Affordable Care Act, we were given new tools to actually be much more nimble in stopping payments before they go out the door. So the opportunity to go from the old "pay and chase" model, where the money went out and then we tried to put back together the scheme of the crooks and find them at some point, to actually stopping that from ever happening in the first place, using the very effective tools that the private sector has used for years, is well underway and we hope to be up and running. We do have a request in the budget that would continue not only that but the strike force opportunities and building that data system, enforcing scrutiny as providers come into the system, all of which we think will be very effective. Last year alone, Senator, we got about a 7 to 1 return on dollars out/dollars in, which I think just gives a prelude to what could be effective in terms of building some firewalls at the very front end.

Senator PRYOR. Great. At one point you had, I think, a deadline of trying to get this up and running at least in some measure maybe at the end of 2011. Are you still on track there?

Secretary SEBELIUS. I think we have been a little bit frozen in terms of our capabilities of moving ahead. So there are some new assets in the Affordable Care Act that we are continuing to mobilize. We are still working on 2010 assumptions in our budget, and as you know, one of the things that the House continuing resolution would do to our budget is take an additional $500 million out of CMS administrative overhead, reducing us to a level that is about 2006. So we are a little uncertain what the funding would be, but this is definitely a program that well pays for itself.

CHILDREN'S HOSPITAL GRADUATE MEDICAL EDUCATION

Senator PRYOR. In the President's budget, it eliminates funding to children's hospitals for graduate medical education. And I am concerned about that because pediatricians really are the primary care providers for our children. So when I see something like that, it makes me concerned that, in effect, we are going to harm the ability to train physicians to be primary care physicians for children.

So what assurance can you give me today that this budget is not going to harm our ability to train more qualified pediatricians?

Secretary SEBELIUS. Well, I share your concern, Senator, and can assure you that in rosier budget times this would not have been a proposal to take that $317 million out of the budget. There are some exclusive children's hospitals that have that funding. I would tell you that there is $40 million in our block grant for maternal and child health that trains pediatricians and pediatric residents across the country, as well as Medicaid training of about $3.89 billion, again some of which comes to pediatricians. So this is not the sole source of funding for pediatricians. But I share your concerns that primary care docs and particularly those who deal with children are critical.

Senator PRYOR. And I do not have time to ask the question, but there is a Government Accountability Office (GAO) report that came out this month. It is GAO–11–318SP, and it looks for opportunities to reduce potential duplication in Government programs, save tax dollars, and enhance revenue. And I notice that your Department is mentioned in here many, many times on ways that hopefully we can save money and stop duplication. We do not have time to really ask because other Senators are waiting, but I hope you will look at that——

Secretary SEBELIUS. We are.

Senator PRYOR [continuing]. And take their recommendations to heart.

Secretary SEBELIUS. Thank you.

Senator HARKIN. Thank you, Senator Pryor.

And now we will turn to Senator Johnson. I want to welcome our new member to the committee and the subcommittee. As a matter of fact, I was just checking with my staff. This may be a unique situation where we have two Senators from the same State on the same subcommittee on the Appropriations Committee. So welcome to the subcommittee, Senator Johnson.

Senator JOHNSON. Well, thank you, Mr. Chairman. It is a privilege to serve on the subcommittee with you.

Madam Secretary, it was a pleasure meeting you earlier.

I want to center on the Affordable Care Act or law I guess. First of all, obviously your background is pretty impressive, being a health commissioner and Governor of the State. You obviously understand health insurance pretty deeply.

Have you ever purchased, though, a healthcare plan for a group of individuals, other than the State? I mean for 50 employees, 100 employees.

Secretary SEBELIUS. Yes, sir. I ran the State health insurance program which was the largest covered group in Kansas for 90,000 covered lives. We negotiated 10 or 12 various competitive plans, kind of the exchange that we are looking to set up in States around the country. It is exactly that model.

Senator JOHNSON. Again, that is a very large group, obviously. Just so you understand my background, I am an accountant by training, a business owner for the last 31 years, and I have been buying healthcare for the people that work with me for 31 years. So I understand fee-for-service. I understand a self-insured plan where you are buying inspector general coverage and specific coverage. I know about PPO's and HMO's. Obviously, with the background with my daughter, having to seek out the best surgical technique for her, I always made sure that the employees that worked with me had that exact same freedom in a fee-for-service type of plan to be able to go anywhere in the country to do that. So basically what I do is I bring the perspective of a business owner, a business manager who will be making the kind of decisions on healthcare coverage under this Affordable Care Act.

So from my standpoint, this is a very complex bill, 2,700 pages. We have another 6,200 pages, what I was reading, in terms of additional regulations that have been written since that point in time. So I try and simplify things. I am trying to look at the bigger picture. And so I would like to start by just asking some basic questions we can kind of agree on some figures here because I am a very reality-based guy. I want to look at facts and figures.

So is it true that about 163 million people in America get their healthcare through an employer-sponsored plan? Is that about the correct number?

Secretary SEBELIUS. I think it is about 180 million.

Senator JOHNSON. The Congressional Budget Office (CBO) has issued a study, a report that claims that under the healthcare law now, that by 2016 the average cost of a family plan will be in excess of $15,000. Is that pretty much your——

Secretary SEBELIUS. I assume that is accurate.

Senator JOHNSON. It is. We will stipulate that.

Is it also true that under the healthcare law now, if an employer with more than 50 employees does not provide, I guess, affordable coverage, the penalty to that employer will be $2,000 per employee?

Secretary SEBELIUS. It is an employer responsibility. If that employee qualifies for the taxpayer subsidy that is in the bill, then there is, yes, a payment into the fund so that that cost is not shift-

ed on to other taxpayers who are, indeed, providing coverage for their employees and paying for the subsidy.

Senator JOHNSON. So the CBO has also estimated now that they are thinking—it is starting, I think, at 2.6 million rising to about 3.6 million employees will lose their coverage, will be dropped from their employer-sponsored care into the Government exchange. Is that about the right figure?

Secretary SEBELIUS. Well, I know there were all sorts of studies done by all kinds of people, sir, during the course of the debate, and I think before we have a framing of a plan and the opportunity to look at how affordable these plans are, one of the directives, as you know, with the State-based plan is that it be affordable coverage. So I think there is not at all a firm number on how many employers will or will not do what they are voluntarily doing now.

Senator JOHNSON. But that is how this thing has been scored dollar-wise in terms of the cost estimate. Around 3 million people.

The average subsidy, according to CBO, per person in those exchanges will rise from about $4,500 to over $7,000 by the year 2021. Is that largely correct?

Secretary SEBELIUS. The average subsidy—it is based on an income level to——

Senator JOHNSON. Per person. I understand, but what has been budgeted is almost $7,000 by the year 2021. My concern is taking a look at the big picture here. I think we have grossly underestimated the number of employees that will lose their employer coverage plan under this healthcare act, be put in the exchanges under extremely high subsidy levels. If I am right, if my fears come true, we could be looking at tens of millions of people put in the exchanges at the tune of $5,000 to $7,000 in subsidies. We could be doubling, tripling, quadrupling the cost of this healthcare bill. Rather than $150 billion, it could be easily one-half a trillion dollars per year. That is my concern.

Secretary SEBELIUS. Well, Senator, I think, as you know and as a business person participating in the market, the market is entirely voluntary now for employers. I think the most cynical view is that employers will just dump all their employees, discontinue employee benefits, and I guess move people into some other option. I don't share that kind of cynical view. I think the voluntary marketplace, in fact, is going to be far more attractive. A lot of small business owners who now are paying 18 to 20 percent more for identical coverage to large business owners will have, for the first time, affordable options within an exchange to purchase coverage. I think that the opportunity for individuals, entrepreneurs, farm families, and others who right now are on the edge of the market or often outside the market will have affordable options. And I think the large employers who we talked to who will not see much difference in their choices, except they will stop paying the approximately $1,000 per policy tax for everyone who is accessing the healthcare system without affordable coverage that gets shifted onto everybody who has coverage.

I guess I think that while there is a scenario that says everybody would voluntarily walk out of the market and dump their employees, I think just the opposite is going to happen. We have not seen that in the one State that is really up and running—in Massachu-

setts. Employers have not dropped their coverage, have not dumped employees. They, in fact, are continuing, and Massachusetts is now at about a 97 percent coverage rate. So I think that is an encouraging at least precursor of what may be coming.

Senator JOHNSON. Thank you.

Senator HARKIN. Thank you, Senator.

Senator Moran.

Senator MORAN. Mr. Chairman, thank you.

Senator HARKIN. Again, welcome to the subcommittee. Senator Moran and I have done a lot of work in the past on farm issues. Now we can work on health issues.

RURAL ACCESS HOSPITALS

Senator MORAN. I look forward to continuing that working relationship, and I am honored to serve Kansas in the United States Senate by the side of my colleagues here today and honored to have my former Governor with us this afternoon so that I can ask a few questions.

Secretary, my thoughts for questioning you today really revolve around some pretty significant Kansas issues related to healthcare and your role. And they are, of course, related to the issue of healthcare in a rural setting.

The IPAB at the moment fails to account for critical access hospitals. Congress carved out exceptions to the payment mechanism that we have in place but did not carve out critical access hospitals, and I would like your reaction to that related to that because I am fearful that if that carve-out does not occur and decisions are made by those policymakers not responsible to rural America, those critical access hospitals could easily be a target for reduced spending which in my view causes the demise of access to healthcare in rural America.

Related to that is the budget item for providing the doc fix. In so many instances today, our rural hospitals are now employing physicians. And they do that out of necessity. The ability to track a physician to a rural community is restricted, is limited. And so in many instances, our rural hospitals pay the salaries of physicians. Their ability to do that will be greatly damaged if we lose the ability to be reimbursed as we are currently as critical access hospitals. But it is compounded by the problem that in the 29.5 percent reduction in payments to physicians under Medicare, if we do not put a doc fix in place. So we have the circumstance in which many hospitals will have declining revenues and increasing costs. Of course, a hospital has little viability if there are not physicians in that community admitting patients to those hospitals.

So my question is—I have only been in the Senate 2 months, but I have learned that I have to ask more than one question in the one question in the 5 minutes that I am allowed. But my two questions that are related to each other is what is the plan for the carve out for critical access hospitals and what is the administration's plan in regard to the so-called doc fix, the sustainable growth rate problem that we face. There is a fix in the President's budget for the next couple of years, but nothing beyond that. And it is significant amounts of dollars that we need to figure out how we are

going to pay and I very much would welcome your input on both those items.

Secretary SEBELIUS. Well, thank you, Senator, for those questions. I do want to tell the chairman that you are not only an expert now on rural agricultural issues but rural health issues because Senator Moran started when he was a Kansas senator working on rural health issues and has continued that interest. So I look forward to the opportunity to work on some of these enormous challenges.

The rural access hospitals, as you know, Senator, are paid at a different rate. So they are paid, I think it is now, 101 percent of costs, and that does not change with anything with IPAB. The other hospitals are negotiated rates. And so I think that the lack of a carve out was due to the fact that there is a different payment structure.

But I share your concern that somehow being focused on by recommendations in the future with the Independent Payment Advisory Board is precarious territory. And I would look forward to working with you on how to look at that structure going forward. But I do think the differential in the payment rates was one of the areas that the drafters of the Affordable Care Act looked at.

In terms of the sustainable growth rate and the ability to pay Medicare providers adequately and commit to that payment into the future, I think it is one of the most significant looming issues. As you know, it well predates the Affordable Care Act. This has been a discussion for the last decade. The President has, as you said, in his budget proposed about a 2½ year offset for the fix going forward.

But there is no doubt that we need, on a very bipartisan basis, to sit down and look at what is the long-term ability to make sure that doctors do not have this looming crisis. I have now been in my job slightly longer than you have been in yours, but I can tell you that it is certainly the single most raised topic by physicians dealing with Medicare. And I do think it is something that while we have proposed offsets for the next couple of years, we need to at least have a 10-year or permanent fix which could be part of the ongoing deficit conversations or into the future. But there is no question that that has to be solved long term.

I would tell you, though, also that the Affordable Care Act has a couple of features that are particularly focused on rural areas where Medicare providers are paid. Starting this year, an enhanced rate for serving in underserved areas where there are access issues that are particularly addressed in terms of not only the health service corps, but nurse practitioners, and nurse-provided health centers, that are again, targeted for rural and underserved areas that I think also are going to be critically important as you look at healthcare delivery because it is not only affordable, it is available healthcare.

Senator HARKIN. Thank you very much, Senator.

Senator MORAN. Thank you, Mr. Chairman.

Senator HARKIN. And now Senator Reed.

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

Senator REED. Thank you very much, Mr. Chairman.

Thank you, Madam Secretary, for your service.

Let me begin also by thanking you for the investment in the budget for health professions. We had a chance to talk about the need for primary care physicians and nurse practitioners, and the budget represents a good step forward. I know we have to do more, but thank you for what you have done.

I want to focus quickly on two areas. One was alluded to by the chairman. That is the cuts in LIHEAP. When the budget was being prepared, prices in the oil markets were a little tamer. They are now seemingly out of control. I know there have been some long-term reductions, at least moderation in the natural gas market, but up our way we depend heavily on heating oil and together with the 12 percent unemployment rate, we are anticipating a huge, huge crisis next winter in terms of heating. And so these LIHEAP cuts are going to be very difficult to bear.

Can you talk about how you got to this recommendation? And two, is there any way going forward that you have the flexibility to adapt to these increased prices?

Secretary SEBELIUS. Well, again, Senator, you and I have had this conversation, and I know that you are not only concerned, but have been a real leader in the low energy assistance area. What this budget does—and again, I can assure you this is not an easy choice for anyone—is return the LIHEAP funding to the historic traditional levels. The LIHEAP budget more than doubled in fiscal year 2009 and continued that in 2010 and 2011. This goes back to what was the historic rate. And it cuts $2.5 billion which is a very significant cut in the LIHEAP funding. I would not say that I have flexibility, if it is moving money from somewhere else into LIHEAP, probably not unless the direction of the Congress is aimed in that area.

So again, I do not think there is an easy answer for this. It was traditionally the level of funding before there was a dramatic increase, but will it leave a lot of people who have relied on that help and support for the last couple of years in much more difficult circumstances? No question.

Senator REED. Well, just to reemphasize the point, we are looking at over 11 percent unemployment in my State. That was one of the reasons I think for the increase, the recognition of the difficult times. But the new factor is not a stable but potentially accelerating price for particularly heating oil, and we will have to revisit this again, unfortunately, I think, as we go forward, Madam Secretary.

IMMUNIZATION—SECTION 317 FUNDS

Let me switch to a second area in the remaining time I have, and that is the section 317 funds for immunization. Immunization is such a critical part of healthcare. We do not have to state the benefits. When children are immunized, they are protected and they save tremendous amounts of—billions of dollars in avoided health care problems.

The 317 funds as proposed—there seems to be a tradeoff now between the 317 funds and the prevention trust fund which was incorporated in the new healthcare act. The prevention trust fund is designed, at least in your proposal, for infrastructure improve-

ments, but that will take away money from the actual acquisition of the vaccines that are necessary. Unfortunately, what we have seen in Rhode Island is a slippage in coverage for children. We have gone down from almost 90 percent to less than that. I have less than a moment for you to comment on that.

Secretary SEBELIUS. Well again, Senator, this is a critical area, and Chairman Harkin already mentioned it. What the budget proposes is the same funding level that we have had in the 317 program, and then, as you noted, an additional $100 million that would be spent out of the prevention fund for what are more likely to be sort of one-time investments whether it is school vaccination clinics or outreach efforts that States can employ.

One of the challenges, as you well know, is that not only in Rhode Island but in States across the country, the health staff, the infrastructure to distribute vaccines, to do outreach to have kids vaccinated across the country has been severely hampered in cuts. So we are really trying to calibrate our resources and make them flexible to States, and I think that additional $100 million for fiscal year 2011 is a critical component. Up to 50 percent could be used for vaccination purchase or for actually immunizing kids. And we think States can use that to really make sure that they are filling the holes in their own strategies.

Senator REED. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Reed.

Senator Brown.

CHILDREN'S HOSPITAL GRADUATE MEDICAL EDUCATION

Senator BROWN. Thank you, Mr. Chairman.

I wanted to mention that I appreciate Senator Pryor's concern about children's GME. I also am concerned. I know Senator Harkin is. For 10 years, he and I have worked on this issue and it began when I was at Akron Children's Hospital some years ago and saw that we had no way with the squeeze of managed care to fund particularly children's pediatric specialist training. I appreciate your answer. I appreciate just about everything you do. But I think that these other ways of funding graduate medical education for children for training pediatricians is far too inadequate. So I hope that you will revisit this issue as it comes forward.

Thank you for coming to Columbus on the patient safety issue. My State has done some remarkable things in patient safety in hospitals, and I think that is going to bring a lot of cost savings that I think opponents to the healthcare bill have not recognized. None of that was scored as we know, the work that Senator Mikulski did and Senator Harkin and others. But that kind of preventive care, that kind of patient safety, everything from the Pronovost checklist to so much else will clearly help us restrain healthcare costs that the opponents to healthcare really barely addressed. And I am really proud to have been part of that.

MAKENA, KV PHARMACEUTICAL

Two issues I want to bring up. One is a conversation that we had last week on the Makena, KV Pharmaceutical. For my colleagues who do not know the background, a drug, a progesterone, that was administered once a week for 20 weeks at a cost of about $10 a

shot for high-risk pregnant women who had typically had a low birth weight or a preterm birth in their past, was making such a difference in cutting the rate of low birth weight babies.

This drug company, KV Pharmaceutical, out of St. Louis that really spent some money to do the clinical trials, although the Government had done them 7 or 8 years earlier and paid for it, raised their price once they got FDA approval from $10 a shot, $200 for the whole regimen of treatment, to $1,500 a shot, or $30,000 for the regimen of treatment, which will mean terribly high costs and burden for those women, for Medicaid, for insurance companies, for businesses and will also clearly result in an increased number of low birth weight babies.

So I just wanted you, if not in the hearing today, to recommend administrative or legislative strategies that we can employ to do something about this. We have tried, frankly, to embarrass the company. We have tried to look at the Food and Drug Administration (FDA) when Dr. Hamburg testified to our subcommittee not too long ago to another subcommittee here about that. And we are looking for answers legislatively, administratively. If you would speak to that.

Secretary SEBELIUS. Well, Senator, as you know, the FDA is really prohibited from considering price in terms of drug approval, which I think is an appropriate policy.

Having said that, one of the things that the company has done is to actively notify pharmacists that the FDA will be enforcing a noncompounding rule. We have put out a statement today saying that is not the case. The FDA will not be conducting any enforcement action over the opportunity for pharmacists to continue to do what they have been doing, which is compounding this treatment and having it available to patients throughout the country unless there is some specific safety issue, which has not come to our attention yet. And we are continuing to work on what other options we may have, but we wanted pharmacists throughout the country to understand that in spite of the drug company's warning, that is not really the policy of the Food and Drug Administration.

## PEDIATRIC CANCER

Senator BROWN. Thank you. And we will continue on that.

A low birth weight baby in the first year of life costs on the average $51,000, putting aside the human cost to the child, to the baby, the family, and everyone else. And we know what that is going to do to costs of Government, and I would hope that people very bipartisanly would go to work on this.

Last point, Mr. Chairman, in the brief time I have. There is no comprehensive pediatric cancer registry, which makes it difficult to compare State by State statistics. Ohio is, unfortunately, home to what we think of as five different sorts of cancer clusters. There is one in Clyde, Ohio where many children have been afflicted and several died. Caroline Pryce Walker, named after Ohio Congresswoman Deborah Pryce's daughter, Childhood Cancer Act was signed into law in 2008. It authorizes $30 million annually over 5 years for pediatric cancer clinical trials. I would just ask you to work with us on this whole Clyde, Ohio cancer cluster. The cause has not been determined. We are looking to HHS to work with

other agencies to research this and other kinds of cancer clusters around the country.

Secretary SEBELIUS. Well, Senator, I would welcome that opportunity because this question has come up a couple of times in committee and I know you are trying to parse your way through. But again, one of the very troubling features of H.R. 1 in the House would have a huge detrimental effect on NIH trials because not only does it cut a significant amount of resources, $1.6 billion, but it also has a lot of language that would micromanage trials. And we feel that many of the clinical trials now underway dealing with cancer, dealing with autism, dealing with others would have to stop taking any additional patients immediately if that language were to be adopted. So just to put a little warning on the radar screen.

Senator HARKIN. Senator Mikulski.

Senator MIKULSKI. Thank you, Mr. Chairman.

Madam Secretary, I really just want to welcome you to the subcommittee. Before I go to my questions, I just want you to know I think you are doing a great job. You have one of the largest, most complex agencies within our Federal Government, and we want to salute you on what you are doing and also the fact that you are even in public service. Someone with your background could certainly be in the private sector. One of those insurance companies would snap you up in a minute and multiply your salary over and over again.

Secretary SEBELIUS. Maybe not.

IMPACT OF A FEDERAL GOVERNMENT SHUTDOWN

Senator MIKULSKI. Well, maybe not now.

But anyway, I just wanted to say that, because I think there is a lot of intensity involved in these hearings.

This is a very quiet hearing, and I am surprised because we are on the brink of a shutdown. Whether you call it a shutdown or a slowdown, we are on the brink I think of a catastrophic situation. And we are only 10 days away from it. My question to you as Secretary of HHS is the implications and the operational consequences if we go to a shutdown. With the people who work at HHS, could you tell me how many work at HHS, and in the event of a shutdown, how many would be deemed nonessential and how many would be possibly furloughed?

Secretary SEBELIUS. Senator, I am not sure I can give you the precise numbers right now. We do have a look-back to 1995 when a shutdown occurred and have looked at some of the services and operations that were slowed down or even stopped. It has a pretty widespread effect on healthcare delivery and human service availability throughout the country because we do touch lives each and every day.

Senator MIKULSKI. Well, let me jump in. I have major iconic agencies from the Federal Government and beneficiaries in my State. And they are also globally recognized and globally envied. They have names like the National Institutes of Health, the Food and Drug Administration, beneficiaries of HHS funds, Nobel Prize winning institutions like Johns Hopkins, important institutions like the University of Maryland.

Let us go to NIH. If there was a shutdown, could you tell me the consequences on NIH either both in terms of the employees who would be nonessential, what would be the impact on clinical trials, what would be the impact on grant beneficiaries like at Johns Hopkins?

Secretary SEBELIUS. Well again, Senator, I hesitate to give you specifics because I do not have them here. I can tell you there are conversations going on, and our best indication is the look-back.

But having said that, we know that critical trials are underway. Research goes on day in and day out. Thousands of people are affected not only on the campuses that you referred to but certainly in grant programs throughout this country which provide jobs and economic opportunity.

Senator MIKULSKI. If there is a shutdown, would grant beneficiaries continue to get their funds?

Secretary SEBELIUS. Dubious. I do not know what the funding cycle would be.

Senator MIKULSKI. I think this is really a big deal. So if you are in the midst of a clinical trial, whether it is cancer or autism, even if we looked at the "A" words, AIDS, autism, arthritis.

Secretary SEBELIUS. I can tell you, having met with Dr. Collins as recently as 3 days ago, he currently, because of the uncertainty just of the 2011 budget and the numbers he has to work with, has given information to grantees all over the country that he cannot assure them that ongoing funding is available, and has given a very cautionary note about what they should do in the future. So we are operating under extremely uncertain territory right now.

Senator MIKULSKI. Well, how will you proceed?

Secretary SEBELIUS. We continue to be hopeful that there will be a resolution which will give us at least a framework for the remainder of this fiscal year which, as you know, we are halfway through. But certainly we have given great notice to all of our 11 agency directors and everyone throughout the Department that we are operating on 2010 estimates but to prepare for the possibility of significant differences.

Let me just give you a snapshot outside of NIH.

Senator MIKULSKI. Go to any agency. I mean, I raised it——

Secretary SEBELIUS. We are two-thirds of the way through a school year with Head Start. If indeed there were to be a cut right now, we are not sure the programs even have enough money to make that cut. So, there would be programs that would be shut down immediately across the country because they literally do not have enough in their budgets to take the possible cuts. So we are trying to model scenarios that are very difficult to try and administer.

Senator MIKULSKI. Well, Madam Secretary, I know my time is up.

But, Mr. Chairman, you know, there is this belief that somehow or another a shutdown will only occur in Washington with people who ostensibly are overpaid or the lights will go out on the Washington Monument. I am terrified that the lights will go out at Johns Hopkins, the University of Maryland. I am concerned that the lights will go out in my Head Start programs in the rural parts of my State where they are needed. So, Mr. Chairman, I think we

might have to ask Senator Inouye. We need to have maybe an all-hands-on-deck hearing on what are the consequences to this.

Anyway, I exceeded my time. Thank you.

Thank you very much, Madam Secretary.

Senator HARKIN. Thank you, Senator.

Senator Kirk.

Senator KIRK. Thank you.

CHILDREN'S HOSPITAL GRADUATE MEDICAL EDUCATION

With all respect, I hope we can reject the administration's proposal to zero out children's graduate medical education. And you just head about that as well. I think for, obviously, like Children's Memorial Hospital in Chicago, La Rabida, et cetera, I hope we go with regular order on this because the current system—I do not have faith that the proposal would adequately provide the trained physician needs in pediatrics. And I hope the subcommittee goes in that direction.

Senator HARKIN. I can assure the gentleman that I share his concern.

Senator KIRK. Thank you.

WASTE, FRAUD, AND ABUSE IN MEDICARE

I would say, Madam Secretary, you have about a $580 million request to root out Medicare waste, fraud, and abuse, and you are running around an 8 to 1 ratio of dollars provided to dollars saved, which is good.

Another thing that with Ranking Member Shelby and the chairman that we are working on is to upgrade the very outdated Medicare card. This is the Medicare card as it currently exists, and it has none of the standard upgrades that is available on ID's that are available today.

Now, the Department has funded a pilot project for DME equipment in Indianapolis, but it is totally outdated. It is only providing a mag swipe which for $30 can be completely counterfeited and I think does not represent the technology that is used by the Federal Government.

This is a common access card of the U.S. military, and 20 million of these have been issued at a cost of approximately $8 each. What I just saw, because I was alert and had a lot of coffee at the time, is Transportation Security Administration (TSA) agents have common access cards. So that whole 70,000-man agency now has this. The critical thing is not just the enhanced bar code, the optical variable ink, the picture, the signature, and the chip, but it is all on the back as well.

As far as I know, the Department of Defense (DOD) reports not a single CAC card has been counterfeited, whereas this card is pretty easy to counterfeit and the Social Security card being almost no barrier to counterfeit.

We have agreed to team up and look at how we can use what is commonly available, and I am hoping you take a look at—and I would ask you to reach out to Secretary Gates and his team because I think if we had legislation that went forward to say to seniors, if you want to protect your ID and help root out waste, fraud, and abuse, for an $8 fee you can get an enhanced Medicare card.

And I hope we do not reinvent the wheel. I hope that in fact we reinvent nothing. We just expand the CAC card to 40 million seniors.

But I wonder if you could explore that.

Secretary SEBELIUS. Well, Senator, I would love to have our team work with you on this issue. I do know that there has been concern that DOD's card is generations ahead of what we are looking at. It is, as you might understand, a slightly different universe. They have a closed network system. We have about 1 million providers. So, it is a challenge of different proportions. But we do have a new administrator who is specifically charged with program integrity at CMS, a position never created before. He is helping to build the new system and look at ways—and I would love to ask him to follow up with you and your staff because we would love to take a look at what you are talking about.

Senator KIRK. I am going to be very much in train with the chairman and ranking minority here. But I think that a lot of seniors in this age of identity theft would be pretty reassured.

Secretary SEBELIUS. Well, and we are trying, among other things, to establish the fraudulent card database, because it is not only seniors losing their card, but it is providers. So we have got the challenge on both fronts. But I agree with you. Things that could prevent that in the front end are what we are looking at. So, I will have Dr. Budetti follow up with you right away. Thank you.

Senator KIRK. Thank you, Mr. Chairman.

Senator HARKIN. I will exercise a little chairman's prerogative here. I will just back up to what Senator Kirk said. Senator Kirk brought this up when Mr. Budetti testified here a few weeks ago. So it would be good for you to contact him and have him start closing this loop. I concur wholeheartedly with Senator Kirk. I think this is something that we just have not paid much attention to and we should. I hope we can close the loop on this this yearμ—

Secretary SEBELIUS. You bet.

Senator HARKIN [continuing]. And move head on it very aggressively.

Secretary SEBELIUS. It sounds like a great bipartisan proposal. All for it.

Senator HARKIN. Actually a great proposal.

Madam Secretary, we will start a second round here of questions for 5 minutes.

CLASS ACT

The CLASS Act was raised by my good friend, Senator Shelby. I remember when we discussed this in the healthcare debate and in developing the legislation. I can tell you, as the chief sponsor of the Americans with Disabilities Act, now in its 21st year, and the chief sponsor of the Americans with Disabilities Act amendments which were just signed into law by President Bush in 2008, I was very concerned about the CLASS Act and how it would work. Too many people in our country simply have no recourse, have no way of setting aside some funds really for a possible disability that could happen to them or for long-term care as they grow older.

Right now, one out of six people who reach the age of 65 will spend more than $100,000 on long-term care. Yet, only about 8 to

10 percent of Americans have private long-term care insurance coverage. Medicaid now pays more than $110 billion—$110 billion—annually for long-term care for both the elderly and the disabled.

So I was one of those. I was very cautiously supportive of the CLASS Act. I was concerned about whether it would work or not and how viable it would be. That is why we put into the legislation the language that would give authority to you, to the Secretary, to change the program to make sure that it is financially solvent.

So again, I guess my question to you, Madam Secretary, is simply that. Are you confident enough that under the legislation you have the authority to make any changes in the program to make it financially solvent in the long term?

Secretary SEBELIUS. Yes, Mr. Chairman, I do think that the concern about actuarial solvency in the future is one that is very real, and I have stated that on earlier occasions. Both as an insurance commissioner working on solvency issues but also setting up the framework for what an HMO has to have in reserve and how you model that into the future is something that I take very seriously. And I think the legislation is very clear that we cannot turn the switch on in this program unless we can effectively demonstrate through actuarial models that this is a solvent program.

Part of the challenge—and Senator Shelby referred to this earlier—is what the outreach looks like and what the take-up rate is. If the premiums are too high, the take-up rate will be very low and only accessed by those who desperately need it. If indeed there is a broader education effort—and I have to tell you part of the education effort is directly tied to the fact that most Americans believe that Medicare covers long-term care. That is a commonly held belief and often not until they get close to needing long-term care is there a realization that really the only program covering long-term care is Medicaid and that is only if your income is eligible.

So part of the outreach which would have to be done early on and again to younger, healthier workers is the opportunity to set aside some income. And again, we are not talking about competing on long-term care insurance policies. That market would stay in place. This is really for a range of residential services. What we also know is that people want to age in place. They want opportunities to have assistance to stay in their own homes for a longer period of time, to have care around areas that they may not be able to do as readily as they could have years ago and not have a nursing home as the only option.

But it would need a broad take-up rate, competitively priced policies, and if that cannot be modeled successfully, we will not turn the switch on.

Senator HARKIN. Thank you very much, Madam Secretary.

Senator Shelby.

### CHRONIC DISEASE GRANT PROGRAM

Senator SHELBY. Madam Secretary, the President's budget proposes the elimination of the preventative health services block grant and proposes a new consolidated chronic disease grant program at the Centers for Disease Control and Prevention (CDC). The budget justification in my understanding says this new grant program will not be a formula grant structure but, rather, it will

be competitive. Rural areas and States without capacity will be, I believe, disproportionately affected by competition.

I am concerned that the new chronic disease grant program will create a scenario where the rich get richer and the poor get poorer. What are your plans to ensure that State health departments have the capacity to compete for funds at the Centers for Disease Control?

Secretary SEBELIUS. Well, Senator, I——

Senator SHELBY. Is that a concern of yours?

Secretary SEBELIUS. I share the concern that often some of the, I would say, more underserved areas are also those with the higher levels of chronic disease. So the worst of all worlds would be to have a situation where the revenue does not follow the disease patterns.

The new CDC proposal is to consolidate a series of separately funded disease programs. Not only does the budget propose an increase in funding—about $72 million above what the current level is—but I would suggest gives States the flexibility of really directing these resources to their target areas. Every State would get resources. Let me make that clear. This is not 100 percent of the funds are competed for and there could be losers and winners. So every State would have a level of funding, and over and above that, there would be some additional competition, but it would very much tie I think the disease profiles in often some of the most underserved areas to the resources.

But we have heard this proposal was greatly informed by State health officers who asked us—often they are dealing with heart disease and diabetes and three or four chronic conditions that have the same underlying causes. And so rather than having that funding channeled through separate silos, they said give us the flexibility of really addressing our State profile, our situations in a more strategic manner. So that information with the State health officers is part of what informed this proposal to have a chronic disease program and get rid of the separate silos.

## CONGRESSIONAL REQUESTS FOR INFORMATION

Senator SHELBY. On another subject, Madam Secretary. You have evidenced a commitment to work with Congress—you have said this before—to implement the Affordable Care Act. However, some of my colleagues on the HELP authorizing committee, specifically Senator Enzi and Senator Hatch have talked to me, and have many outstanding requests for information from your Department. I know it is a big Department. It is very important that the Committees on Appropriations work with their authorizing committees to conduct oversight and assess the impact that the law is having on patients, employers, States, and taxpayers.

To ensure that the Congress has the necessary information to make informed decisions about the implementation of the new law going forward, Madam Secretary, would you commit—and have you committed before—to have your Department respond to congressional requests, including letters and hearing questions for the record within 30 days of the request? It is my understanding from Senators Enzi and Hatch there have been 52 requests and 67 per-

cent no response or incomplete response. Is that a concern to you? It is to them.

Secretary SEBELIUS. Senator, we are committed to responding thoroughly and as timely as possible. We have delivered hundreds of boxes, thousands of pages of materials. I have had two hearings in the Senate Finance Committee, and I can assure you we are trying to get the information as quickly as possible. The level of requests is significant and takes an enormous amount of time and energy to gather the materials, but we are working as fast as we possibly can to be responsive and as timely as possible.

Senator SHELBY. So you are basically committing to be responsive to their requests.

Secretary SEBELIUS. Yes, sir.

Senator SHELBY. Thank you.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Shelby.

Senator Johnson.

AFFORDABLE CARE ACT

Senator JOHNSON. Thank you, Mr. Chairman.

Madam Secretary, I would like to kind of go back to the earlier questions I was asking about what I consider just really understated cost estimates for the healthcare act. You know, back in the 1960s when they passed Medicare, they projected out 25 years and said that Medicare would cost $12 billion in 1990. In fact, it ended up costing $110 billion, almost 10 times the original estimate. My concern is our Federal Government has not gotten any better at estimating costs.

So you had mentioned, when I started talking, a little bit about the incentives embedded in this bill for not only employers to drop coverage but now it is for employees to want to get into the exchanges because there are such high levels of subsidies. You talked about that being cynical. I am trying to be realistic, and I am not the only one I think that has that same viewpoint.

Douglas Holtz-Eakin, a former CBO director, has issued a pretty good study where he is talking about a very detailed decision matrix that pretty well shows that it is in the employer's best interest and the employee's best interest for about 35 million people to take advantage of those subsidies and the exchanges.

Yesterday I believe The Hill reported that Joel Ario, I believe—I am not sure I am pronouncing that right, but he is the head of the health insurance exchange office within your agency—was quoted by saying that if exchanges worked pretty well, then the employer can say this is a great thing. I can now dump my people into the exchange and it would be good for them and good for me.

And that is just what I want to explain. The decision that an employer is going to be going through is I can pay $15,000 a year to provide healthcare coverage or I can pay a $2,000 penalty, and by doing that, I am making my employee eligible for, in some cases, in excess of $10,000 in subsidies. Right now, in 2018, according to the way the healthcare bill is written, a family that earns $64,000 will be eligible for a $10,000 subsidy. And you know, let us face it. When the Federal Government offers subsidies, they are generally taken advantage of. So I think it is totally unrealistic to expect

only 3 million out of 180 million people to take advantage of those subsidies.

And my question is what happens if I am right. What if Douglas Eakin is right and it will be at least 35 million or even higher? For every 10 million additional people, it is going to cost $50 billion in additional costs, and that is 33 percent higher than the original cost estimate for this healthcare act.

Secretary SEBELIUS. Well, Senator, first of all, the Affordable Care Act has a ban on large employers even considering exchanges for at least their first 3 years. So your scenario in 2018 for large employers is not a possibility because they would not be eligible to enter into an exchange. And I think the ban is written in such a way that Congress will reconsider at the end of 3 years whether that should indeed be extended, and the vast majority right now who have stable coverage at least in the employer market is in the large employer area.

Second, I think that while there are a whole variety of scenarios, what I know about the existing market is that small employers have been abandoning the market altogether. The trend rate for the last 10 years has been sharply downward. So employees who either are self-employed or farm families or who are working for a small employer are less and less and less likely to have any affordable options and therefore are shopping on their own in what is a very fragile individual market. So the trend rate is not good at all.

I think there are, again, some very optimistic opportunities in creating State-based exchanges where small employers for the first time will have the pooling flexibility that their large competitors have. They will have an opportunity to essentially shop without a very sophisticated human resources (HR) department in a predesigned marketplace and will have the benefit right now of tax credits that we are seeing for the first time in a very long time bringing some of those folks back into the market.

So I think the large employee marketplace will stay relatively stable and stay fairly much the same, although hopefully their costs will go down as the CBO predicts, and the small marketplace, which has been disintegrating dramatically over years, will again be stabilized.

Senator JOHNSON. What is the definition of a large employer? What is the definition that will be excluded from these exchanges?

Secretary SEBELIUS. I think the large employer is 100 or more employees.

Senator JOHNSON. Thank you.

Senator HARKIN. Senator Moran.

## INDEPENDENT PAYMENT ADVISORY BOARD

Senator MORAN. Mr. Chairman, thank you again.

I want to go back to a couple of topics that we visited about earlier, Secretary, and then add a third one.

Back to the IPAB. I want to make sure I understand that you indicated that there was a justification for not including critical access hospitals in the provisions that eliminate the potential for the independent board's decision. Does something need to be done now or are they safe for a while?

Secretary SEBELIUS. All I was suggesting, Senator, is that I am speculating that the reason that critical access hospitals were treated differently in the original proposal was that critical access hospitals are paid differently in the current system. So their payment protection stays in place. The law requires that they get paid based on cost. And that is not the case of other hospitals.

Senator MORAN. Do you support exempting critical access hospitals from the IPAB through 2019 like the other hospitals?

Secretary SEBELIUS. Well, I would be supportive of taking a look at what the proposal would look like. I share your concern that critical access hospitals are vitally important, and I just need to look at all the framework that protects them right now.

MEDICARE SUSTAINABLE GROWTH RATE

Senator MORAN. I actually think that because they are paid differently, they may be a greater target. But there is a justification that apparently you and I share for why they are paid differently.

On my other question about the so-called "doc fix," is my understanding that the administration has a plan for 2012–2013, but no concrete plan beyond that?

Secretary SEBELIUS. We have not proposed 10 years of offsets. As you know, up until probably 1 year ago, the doc fix was done in a limited fashion a year at a time and never paid for. I think the President has said it is important to pay for it. He has proposed in this budget to have what amounts to about 2½ years of pay-fors going forward and says we look forward to working with Congress on a permanent fix for this situation.

Senator MORAN. Well, I made my position clear on the Affordable Care Act, and that is known. But regardless of your position on that legislation, the system falls apart if we do not make the doc fix substantial and permanent.

Secretary SEBELIUS. There is no question and I have said that since the outset. As you noted, I mean, the Affordable Care Act is not what caused the gap in payment and it is not what will fix it. It really is, I think, something that needs to be discussed in the overall Medicare system.

Senator MORAN. I fear that part of the potential demise of our healthcare delivery system will be related to the Government's reimbursement of healthcare providers, that it is inadequacy, and we will potentially have more providers paid for by the Government under the Affordable Care Act, and if you add more people, more providers who are paid at a rate less than what it costs to provide the service, we lose the physicians who provide those services, we lose the hospitals that deliver those services. And so this seems to me to be an overriding consideration that we just have got to get to.

Finally, your successor's successor has asked for a waiver under the MOE.

Secretary SEBELIUS. My successor's successor.

Senator MORAN. Yes. Is that true?

Secretary SEBELIUS. Who is my successor's—I do not know what we are talking about.

Senator MORAN. It depends on what position you have got. That is true. You have held so many positions. The current Governor of

the State of Kansas has asked for a waiver. I am interested in knowing the status of that request and what criteria that you have in place or will put in place to make those determinations.

Secretary SEBELIUS. Well, it is my understanding, Senator—and I think this is the most updated information—that while there has been some suggestion by Governor Brownback that he would come to our office with some specifics, we do not have anything other than the notion that maybe a waiver would be a good idea. As far as I know, we have no paper. We have no proposal. We have no notion of what it is that he is talking about.

We are working actively around the country with States around not only what they can do to lower their pressing healthcare costs but ways that other States have taken advantage of the current law to deliver more effective services at a lower cost and would look forward to working on Kansas or any other State. But it is my understanding we really do not have anything other than a letter saying we are going to come to you with a proposal.

Senator MORAN. Thank you, Secretary. Appreciate our conversation this morning.

Mr. Chairman, thank you.

Senator HARKIN. Thank you, Senator.

Secretary SEBELIUS. My predecessor's predecessor. Okay. Successor. That is right. I had predecessors too.

Senator HARKIN. Do we need a more Kansas——

Secretary SEBELIUS. No, no, no. I am just sorting that title out.

Senator MORAN. There is very little good news in the Kansas world these days.

Secretary SEBELIUS. We are all bemoaning the Jayhawks.

Senator HARKIN. I watched that game. That was quite a game.

Secretary SEBELIUS. Painful for some of us.

Senator HARKIN. That is true.

Well, Madam Secretary, thank you again for your appearance here. Thank you for your stewardship of this vast and complex Department. Thank you so much for the clarity and the forthrightness of your responses here today.

## ADDITIONAL COMMITTEE QUESTIONS

The record will stay open for 10 days for other statements or inclusions of questions by other Senators.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

### QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

*Question.* Madame Secretary, your budget includes $765 million to fund the advanced development of the drugs and vaccines that we need to defend against bioterrorism or a public health emergency. The Department would like to fund this advanced development by means of transfers from the Project BioShield Special Reserve Fund (SRF). As you know, the purpose of BioShield is to provide a financial incentive to pharmaceutical companies by guaranteeing that the Federal Government will buy these drugs for the national stockpile. Unless adequate resources remain in BioShield, we may be calling into question the Federal Government's commitment to buy these products and therefore making it more risky for the private sector to remain in the countermeasure business.

Is there a risk of undermining the entire process of developing drugs and countermeasures for the stockpile if significantly more Project BioShield balances are used

for other purposes? What is the Department's plan to reauthorize BioShield and replenish the SRF when it expires at the end of fiscal year 2013?

Answer. Project BioShield and the Special Reserve Fund have provided a market guarantee to attract the interest of industry to medical countermeasures development, and in this they have succeeded. This market guarantee, however, does little to make drug development easier or faster. We are just beginning to see the fruits of our decade-long investment in medical countermeasure development. Initiatives—such as the Strategic Investor, the Centers of Innovation in Advanced Development and Manufacturing and additional support for regulatory science at the Food and Drug Administration—planned to be undertaken following the Medical Countermeasures Enterprise Review of last year are designed specifically to remove obstacles to success and to increase the flow of products through the pipeline, so that Project BioShield can realize its full potential.

The authorities added to the Public Health Service Act by the Pandemic All Hazards Preparedness Act have supported advancements in preparedness and response investments and capabilities. They have proven beneficial to the Project BioShield program by providing increased flexibility to support a more robust medical countermeasure pipeline to respond to chemical, biological, radiological, nuclear (CBRN) and other emerging threats. There are a number of expiring authorizations and authorities that should be reauthorized to ensure we can continue to adequately prepare for public health incidents.

In 2004, in the DHS Appropriations Act (Public Law 108–90), Congress provided advance appropriations of $5.593 billion for CBRN countermeasures acquisition from fiscal year 2004 to fiscal year 2013. Congress subsequently passed the Project BioShield Act (Public Law 108–276) to authorize the use of these funds for this purpose. The Special Reserve Fund (SRF), as the Project BioShield appropriation is called, was intended to serve as a statement of the U.S. Government's commitment to medical countermeasures development and a market guarantee to industry as it undertook the arduous process of developing novel medical countermeasures.

Since its inception, eight products have been acquired using Project BioShield funds and deliveries have been initiated or completed to the Strategic National Stockpile, at an aggregate expenditure of $2.192 billion. Additionally, since the creation of the SRF, $25 million has been rescinded, $995 million had been made available for the support of BARDA medical countermeasure advanced development, and $441 million has been transferred for NIH basic research and for BARDA and NIH pandemic influenza preparedness. Of the funds obligated to date for purposes other than medical countermeasure acquisition, the vast majority have contributed directly to maintenance and development of the medical countermeasure pipeline.

In May 2011, HHS anticipates an award of $433 million for the late-stage development of an antiviral drug to treat individuals infected with smallpox. The fiscal year 2012 President's budget requests $1.5 billion, including a request that another $665 million be made available for advanced research and development and that $100 million be made available to establish the proposed Medical Countermeasure Strategic Investor Initiative, which if enacted would leave $742 million for acquisitions between now and the end of fiscal year 2013.

Investments at BARDA have focused heavily on supporting advanced research and development in recent years, and Project BioShield acquisitions will also continue through the rest of fiscal year 2011 and into fiscal year 2012.

*Question.* Madame Secretary, there is a critical need to focus on drug abuse prevention. Specifically, we should provide sufficient funding for evidence-based programs that address the use and abuse of alcohol, marijuana and other illegal drugs. Our country is facing what the Office of National Drug Control Policy has called an "epidemic" of prescription drug abuse. Prescription drugs account for the second most commonly abused category of drugs, behind marijuana. For this reason I included language in last year's Senate Report 111–243 indicating my concern about efforts by the Substance Abuse and Mental Health Services Administration (SAMHSA) to blend mental health and substance abuse prevention funding:

"Given the paucity of resources for bona fide substance use and underage drinking prevention programs and strategies, the Committee instructs that money specifically appropriated to CSAP for substance use prevention purposes shall not be used or reallocated for other programs or initiatives within SAMHSA. In addition the Committee is instructing SAMHSA to maintain a specific focus on environmental and population based strategies to reduce drug use and underage drinking due to the cost effectiveness of these approaches."

Your Department recently issued a Request for Applications for the Strategic Prevention Framework State Prevention Enhancement Grants, funded through the Centers for Substance Abuse Prevention (CSAP). The first goal listed for potential

grantees is to: "With primary prevention as the focus, build emotional health, prevent or delay onset of, and mitigate symptoms and complications from substance abuse and mental illness." The third goal listed relates to suicide prevention.

*Question.* While I recognize that there are common risk and protective factors for substance abuse disorders and mental illness, substance abuse prevention programs are unique in focusing on the environmental strategies for preventing drug and alcohol abuse. Will the grants issued under this RFA be consistent with the intent of the language included in last year's Senate Committee report?

Answer. There is a critical need to focus on substance abuse prevention. As you point out, substance abuse prevention requires unique environmental and population-based approaches, but it also requires a focus on common risk and protective factors that put all the Nation's children at risk. SAMHSA has taken a leadership role, along with colleagues at NIH, CDC, and ACF, to consider the best way to encourage States and communities to work collaboratively on the prevention of substance abuse and on ways to build resilience that will help our young people, their families, and the systems that serve them.

As you note, a common set of risk and protective factors affects the development of certain mental and substance use disorders in youth. The scientific evidence supports an approach that addresses both substance abuse and mental health prevention in tandem. The 2009 Institute of Medicine Report Preventing Mental, Emotional, and Behavioral Disorders Among Young People provides evidence for these common factors. In addition, we know that youth with mental illnesses, such as depression, are much more likely to use/abuse alcohol or use substances. A high proportion of youth are under the influence of alcohol, illegal substances, or nonmedical use of prescription drugs when they attempt or die by suicide. These issues are not disconnected. For too long, we have focused on the unique aspects of prevention of mental illness and substance use/abuse when the evidence shows that both the substance abuse and the mental health fields can benefit from employing environmental strategies and supporting the emotional health of youth.

All SAMHSA grants and contracts are aligned with SAMHSA's Strategic Initiatives. The grants to be issued under the Strategic Prevention Framework State Prevention Enhancement Grants (SPE) request for applications (RFA) support SAMHSA's Strategic Initiative #1—Prevention of Substance Abuse and Mental Illness. These grants are intended to focus solely on substance abuse prevention and are strictly consistent with the intent of the language included in the fiscal year 2011 Senate Committee report. The language you reference in the RFA is a description of SAMHSA's Strategic Initiative, which addresses both substance abuse and the development of emotional health.

We have issued this RFA to assist States, Tribes, and U.S. Territories in conducting one intensive year of capacity building and strategic planning to strengthen and enhance their substance abuse prevention infrastructures to better support communities of high need throughout the Nation. Through stronger, more strategically aligned substance abuse prevention infrastructures, SPE grantees will be better positioned to apply the Strategic Prevention Framework (SPF) process to achieve more collaborative, cost-effective coordination of services and to implement data-driven, environmental, and population-based strategies to reduce substance abuse, including underage drinking.

The fiscal year 2012 President's budget for SAMHSA includes two separate State Prevention Grants, one for substance abuse and one for mental health, reflecting the highest priority of HHS on prevention generally and of SAMHSA on the prevention of both substance abuse and mental illness—with separate approaches for each. These programs will continue HHS/SAMHSA's priority to promote emotional health as well as supporting Congress' direction to focus on environmental and population-based strategies to reduce illicit drug use and underage drinking. Likewise, the fiscal year 2012 Budget continues separate funding to implement underage drinking prevention strategies under the Sober Truth on Preventing (STOP) Underage Drinking Act.

*Question.* Madame Secretary, since fiscal year 2002 this Committee has included funding for the embryo adoption public awareness campaign. The purpose of this program is to educate Americans about the existence of frozen embryos resulting from in-vitro fertilization and which may be available for adoption. In total, we've provided over $23 million for this program throughout its history.

Please provide an indication of how successful this program has been. For example, how many adoptions have been made since the start of the program?

Answer. Because it is a health awareness effort, the impact (and consequently the success) of the Frozen Embryo Donation/Adoption Public Awareness Campaign is difficult to directly link to the number of embryos "adopted" in a given year. The success is better measured by the level of public awareness of the issue among the

target population (in this case infertile couples). The first comprehensive and scientific attempt to assess the overall impact of the Frozen Embryo Donation/Adoption Public Awareness Campaign will be conducted in 2012 through the National Survey of Family Growth, which will survey a nationally representative sample of infertile couples about their level of awareness of the availability of frozen embryos for adoption. Estimates derived from the CDC's surveillance system of Assisted Reproductive Technology indicate that about 2,000 frozen embryos are adopted each year—a number that has been relatively static since 2004.

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## QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

### NINR'S ROLE IN THE NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

*Question.* Madam Secretary, scientific inquiry, planned and conducted by nurses, is a vital part of improving the health and healthcare of Americans. Nursing research has been a long time catalyst for many of the positive changes that we have seen in patient care over the years. The National Institute of Nursing Research (NINR) was given an fiscal year 2010 appropriation of $145.575 million and has requested $148.114 million for fiscal year 2012. That would be an increase of $2.539 million (1.7 percent), which is in line with the increases requested for many of the other NIH Institutes. The overall increase requested by NIH for fiscal year 2012 is 2.4 percent. About $1.2 million of the requested increase would support additional funding for NINR's research grants and training awards. About $1 million of the increase would support NINR's share of Institute contributions to several trans-NIH initiatives.

NIH has proposed the creation of a new National Center for Advancing Translational Sciences (NCATS) to provide the infrastructure and technologies to bring important discoveries from basic research to fruition through new diagnostics and therapeutics. What role might NINR have in working with NCATS?

Answer. Nursing science is historically grounded in the translation of research and science, and is an essential scientific nexus for these efforts across the United States and around the globe. NINR and its scientists, intramural and extramural, are leaders in the translation of research into health and healthcare interventions. NINR supports preclinical basic and applied research that integrates biological and behavioral sciences. NINR scientists are employing new scientific technologies from diverse fields including neuroscience, genetics and genomics, molecular biology, biochemistry, and physiology in order to improve quality of life through health promotion, disease prevention, and management of symptoms. NINR and nursing science invests in the infrastructure, resources, and scientific capacity building and training critical for the success of these efforts.

NINR would collaborate with the proposed National Center for Advancing Translational Sciences (NCATS) to maintain and enhance translational and interdisciplinary initiatives across the NIH, as well as with other government and nongovernment organizations. NINR currently leads and participates in several interdisciplinary collaborative programs and partnerships that support translational science including: the NIH Public Trust Initiative; the NIH Pain Consortium; and the Clinical and Translational Science Awards (CTSAs).

In particular, the Clinical and Translational Science Awards (CTSA) program is a major trans-NIH initiative that, since its launch in 2006, has proven to be a critical component in the NIH efforts to accelerate research translation. CTSA funded projects touch on all aspects of translational research including community-based participatory studies, implementation science, and health services research. Central to the CTSA program are multifaceted team science, broadly supported collaborations, and the training and mentoring of the next generation of interdisciplinary translational scientists—all of which are also central foci of nursing science.

NINR encourages its scientists to become leaders in the CTSAs. Working with NIH partners and groups such as the CTSA Nurse Scientists Special Interest Group, NINR co-sponsors CTSA-related workshops and symposia to identify research opportunities, highlight successful exemplars, and develop strategies to maximize the diverse disciplinary strengths of nursing science. While several current CTSA's include scientists from nursing specialties who are at the leading edge of translational and interdisciplinary research, NINR supports the goal of the CTSA Nurse Scientist Special Interest Group to elevate nurse scientists to leadership roles in future CTSAs.

ADOPTION OF BEST PRACTICES BY HEALTHCARE PROFESSIONALS AND THEIR PATIENTS

*Question.* NINR supports many activities to enhance the evidence base for healthcare decisions, including assessing the effectiveness of new therapies and healthcare interventions for individuals and within diverse populations. What are your successes and frustrations with seeing measurable changes in the adoption of such best practices by healthcare professionals and their patients?

Answer. NINR investigators and research efforts emphasize the development and use of evidence-based interventions with individuals in diverse, real-world settings. Nurses and nurse scientists play primary roles in the translation of research findings into standard practice because of their prominence in front-line health service provision across clinical settings. Currently, over 90 percent of NINR-supported projects are clinically focused.

As a science committed to the translation of evidenced-based research to the clinician, clinic, and community, nursing science shares the frustration of the translation-gap between research and clinical practice. Acknowledging this, nurse scientists are overcoming the barriers to translation and adoption of research findings through highly collaborative, interdisciplinary scientific efforts. NINR supports research efforts from a broad spectrum of disciplines, involving academic and clinical scientists in settings ranging from bench laboratories to hospital bedsides.

NINR has experienced successful translation and adoption of evidence-based programs in key areas such as transitional care, and patient and caregiver interventions. An NINR-supported program partnered an interdisciplinary group of caregivers with older heart failure patients to ease their transition from clinical to home care. In a randomized clinical trial, the program was successful in reducing re-hospitalization rates for this high-risk group of patients, and in addition, it reduced total costs by about 38 percent, or $3,500 per patient. Another NINR-supported program improved the knowledge and coping mechanisms for parents of premature infants by facilitating positive parenting behaviors and lowering parental stress. This intervention also decreased the length of NICU hospitalization by about 4 days and the associated hospital costs by about $4,800 per infant. NINR has also supported the development of a behavioral intervention that significantly reduced the incidence of post-stroke depression in stroke survivors, compared to patients who only received antidepressants. Immediate benefits, as well as sustainable improvements, remained for at least 1 year post-intervention. An intervention such as this one potentially can have a profound impact on the long term health outcomes of individuals who have survived a stroke.

NINR will continue supporting the adoption of evidence-based research into practice through such research programs as the NINR Centers Program. Across the United States, these Centers function as translational research hubs within schools of nursing. Promoting collaboration between disciplines and across institutions through the use of shared resources and expertise, this program is designed to increase research capacity, accelerate translational research, enhance mentorship of doctoral students and early career scientists, and expand the science of investigators working on multiple projects. NINR Centers provide the stable base needed to develop broad, interdisciplinary translational programs of research to speed the application of research into practice.

NINR'S PARTICIPATION IN PROGRAMS TO KEEP UP THE SUPPLY OF NURSE RESEARCHERS

*Question.* NIH has various grant and training programs that are meant to encourage young investigators to pursue research careers and try out innovative ideas. How does NINR participate in those programs to keep up the supply of nurse researchers?

Answer. NINR is committed to encouraging, supporting, and developing the next generation of nurse scientists. NINR training activities are designed to achieve the vision of creating an innovative, multidisciplinary, and diverse scientific workforce. In addition to supporting pre- and post-doctoral research fellowships and career development awards in the extramural community, NINR also leads and participates in a number of training programs through its Intramural Research Program (IRP).

NINR training activities support individual and institutional graduate and postgraduate research fellowships, as well as career development awards, including awards to trainees from under-represented and disadvantaged backgrounds. These programs provide the next generation of scientists with the necessary, interdisciplinary education and research skills that will enable them to improve clinical practice, enhance quality of life for those with chronic illness, and support preventative health. For example, NINR supports investigators under the NIH K99/R00 Pathway to Independence (PI) program, in which promising postdoctoral scientists receive both mentored and independent research support for up to 5 years.

The NINR IRP also supports several research training opportunities through programs such as the NINR Summer Genetics Institute, a 1-month program designed to increase the research capability in genetics among graduate students and faculty in nursing and to develop and expand the basis for clinical practice in genetics among clinicians. NINR also participates in the NIH Graduate Partnerships Program (GPP), in which doctoral students from schools of nursing with established NINR-supported training programs can complete their dissertation research within the IRP. NINR also sponsors the Pain Methodologies Boot Camp, which is a 1-week intensive research training course in pain methodology at NIH that is aimed at increasing the research capabilities of graduate students and faculty through distinguished guest speakers, classroom discussions, and laboratory training.

An expanded scientific workforce with expertise in these areas of research will significantly contribute to evidence-based improvements and reforms to the healthcare system in the coming years. Collectively, NINR training activities address the national shortage of nurses by contributing to the development of the nursing faculty needed to teach and mentor individuals entering the field.

NINR'S PLANS IN RESEARCH ON AUTISM, CANCER AND ALZEIMER'S DISEASE

*Question.* Does NINR have any particular plans that respond to the Presidential Initiatives in research on autism, cancer, and Alzheimer's disease?

Answer. NINR is committed to continuing efforts to support research that informs the provision of quality care and improving quality of life for persons with autism, cancer and Alzheimer's disease (AD) and other dementias, as well as supporting their informal caregivers. Recent efforts in autism at NINR include the examination of the effects of an intervention based on self-regulation human-animal interaction theory (e.g. therapeutic horseback riding) on children and adolescents with autism, as well as the development of a peer-mentored disaster-preparedness program for adults living with autism and other developmental disabilities. NINR is also cosponsoring an NIH funding opportunity to support research into the origins, causes, diagnosis, treatment, and optimal service delivery in autism spectrum disorders.

NINR's cancer research focuses on developing the evidence-base for enhancing the individual's role in managing disease, managing debilitating symptoms, and improving health outcomes for individuals and caregivers. Several NINR-supported scientists are examining how clinicians and patients work through the treatment and support decisionmaking process, across the trajectory from diagnosis to end-of-life and palliative care or illness remission. NINR currently supports numerous projects in the area of cancer pain research, including studies to investigate the underlying molecular mechanisms that cause cancer treatment-related pain, as well as a patient-controlled cognitive-behavioral intervention for cancer symptoms. Another study is developing and testing a physician-nurse team intervention to provide clear and timely end-of-life and palliative care communication to parents of children with brain tumors. NINR-supported research also focuses on cancer recurrence prevention and improved quality of life through such scientific efforts as the development of cancer screening programs for diverse populations, a genetic cancer risk assessment tool to improve screening efforts, and a psycho-educational telehealth intervention for rural cancer survivors. NINR also reaches directly to the public through such efforts as the development and dissemination of the NINR publication, "Palliative Care: The Relief You Need when You're Experiencing the Symptoms of Serious Illness" which has been downloaded from the NINR website nearly one million times.

NINR research on interventions for older adults with AD focuses on areas such as: alleviating symptoms such as pain, discomfort, and delirium; improving communication for clinicians; and memory support. For example, NINR is currently supporting a project to test the effectiveness of an activity-based intervention designed to increase quality of life by reducing agitation and passivity and increasing engagement and positive mood in nursing home residents with dementia. Another NINR-funded study involves an evidence-based, nurse practitioner-guided intervention for patients with AD or other dementia, as well as their family caregivers. The intervention is expected to improve overall quality of life by decreasing depressive symptoms, reducing burden, and improving self-efficacy for managing dementia in caregivers. NINR also emphasizes research on interventions aimed at improving quality of life and reducing burden for caregivers. Recognizing the challenges often experienced by caregivers, NINR supports research on strategies to improve the skills caregivers need to provide in-home care, to reduce stress and burden, and to maintain and improve their own health and emotional well-being. Together NINR and the National Institute on Aging are supporting the Resources for Enhancing Alzheimer's Caregiver Health (REACH) II program, a comprehensive, multi-site inter-

vention to assist AD caregivers by providing strategies to manage stress, maintain social support groups, and enhance their own health. Multiple efforts across the Federal Government are currently underway to implement REACH II in the community, such as through the Administration on Aging's Alzheimer's Disease Supportive Services Program.

*Question.* What is the current nursing shortage and how are current initiatives impacting that shortage?

Answer. Strengthening and growing the primary care workforce—including nurses and nurse practitioners—is critical to reforming the Nation's healthcare system. In fiscal year 2010, the ACA Prevention and Public Health Fund supported $31 million for the training of 600 new nurse practitioners and nurse mid-wives by 2015 and $15 million for Nurse-Managed Clinics, which provide primary care and wellness services to underserved and vulnerable populations. The fiscal year 2012 budget includes $20 million for these Clinics.

The fiscal year 2012 budget includes $333 million, an increase of $43 million over fiscal year 2010, to support the training of nurses and advance practice nurses. The fiscal year 2012 budget initiates a 5-year effort to fund the training of an additional 4,000 new primary care providers—including 1,400 advance practice nurses.

*Question.* Is the Department investing in any efforts to assure that nurses are available in the regions that need them the most?

Answer. The Administration supports several programs that encourage nurses to practice in underserved areas and facilities throughout our Nation. Applicants with initiatives benefitting rural and underserved areas are given preference for all Public Health Service Act Title VIII nursing workforce funding.

In addition, the Nurse Education Loan Repayment Program and Nursing Scholarship Program offer financial support for nurses who agree to serve in healthcare facilities facing critical shortages of nurses.

The Affordable Care Act provides $1.5 billion for the National Health Service Corps over the next 5 years, which will help bolster the supply of clinicians—including nurse practitioners—serving at rural health clinics, community health centers, and other primary care sites with a shortage of health professionals.

*Question.* H.R. 1 proposes to reduce funding for the Nurse Education and Loan Repayment program by two-thirds. Is this a good idea to reduce funding when there is such a well documented nursing shortage?

Answer. The Nursing Education Loan Repayment and Scholarship programs provide financial incentives to nurses who agree to work at healthcare facilities with a critical shortage of nurses. The proposed reduction in H.R. 1 would support approximately 850 fewer nurses than would otherwise be supported. The fiscal year 2012 budget includes $94 million, the same level as fiscal year 2010, for this program in recognition of the key role that it plays in supporting the recruitment and retention of nurses in underserved areas.

*Question.* How is it that HHS says we have a nursing shortage when I hear that graduating nursing can't find jobs?

Answer. While there remains an overall shortage of nurses, nursing shortages vary geographically and by sector (e.g., hospitals, nursing homes). More nurses are delaying retirement and increasing their hours due to the economic downturn, which has allowed for some temporary easing in the nursing shortage in some parts of the country. However, the shortage is still substantial in many parts of the country, and without sustained production of nurses, the situation will worsen.

*Question.* Will the funds appropriated from the Community Health Center Fund (Sec. 10503 of the Patient Protection and Affordable Care Act) be used to expand this program? If yes, what are the planned program expansions?

Answer. Native Hawaiian Health Care Programs are not eligible for funding under Section 10503 of the Patient Protection and Affordable Care Act.

*Question.* How would proposals to use some or all of the community health center fund in lieu of the annual health center appropriation affect: the program in general; the ability to sustain program investments made using American Recovery and Reinvestment Act (ARRA Public Law 111–5) funds; the ability to expand the program; and the Native Hawaiian healthcare system that is funded from the annual health center appropriation?

Answer. In fiscal year 2011 the combined resources from the Community Health Center Fund and discretionary appropriations will enable the program to sustain investments made using American Recovery and Reinvestment Act funds as well as create new health center sites. In total, the Health Center Program will receive a nearly $400 million increase in fiscal year 2011 above fiscal year 2010 levels.

*Question.* Secretary Sebelius, there are many different departments and agencies responsible for our Nation's preparedness and response to a natural or man-made disaster. Can you talk about the unique role EMSC plays in those efforts?

Answer. The Emergency Medical Services for Children (EMSC) Program under section 1910 of the Public Health Service Act (42 U.S.C. 300w–9) is the only Federal program that focuses specifically on improving the pediatric components of emergency medical care. The program was created to address gaps in the provision of quality emergency medical care to children, and to address the specific anatomical, physiological and developmental needs of children. The program focuses on improving the everyday pediatric readiness of the Nation's EMS system to provide the appropriate infrastructure for disaster preparedness. Furthermore, EMSC focuses on emphasizing pediatric specific issues in disaster care of a child in a non-pediatric facility, family reunification, surge capacity due to the increased vulnerability of children in disaster and transfer to other facilities for higher levels of care.

*Question.* Are our Nation's hospitals, ambulances, and first responders better prepared to treat pediatric patients as a result of the EMSC program?

Answer. During the 2010–11 assessment of performance measures, the 55 funded State Partnership grantees collected data from over 2,600 emergency departments, approximately 6,660 BLS/ALS agencies, and conducted an assessment of more than 22,000 vehicles that transport children in emergency situations.

Findings from select measures demonstrate improvement in the Nation's pre-hospital provider's access to pediatric medical guidance in the field, more Basic Life Support (BLS) and Advanced Life Support (ALS) transport vehicles carrying essential pediatric equipment and States supporting pediatric continuing education for BLS/ALS providers.

*Question.* How has the EMSC program helped States be better prepared for the disaster response and recovery of children?

Answer. The EMSC program is funding projects that will guide practice in the EMS field for which minimal evidence exist to guide appropriate delivery of care. Findings are translated into tool kits and resources that are readily available to States and local communities. The EMSC National resource center is working with multiple partner-agencies to develop a web-based resource tool with disaster related products, publications and resources. This will be available to States and local communities as they developed their disaster plans.

EMSC is also working with States to develop models of regionalized care where pediatric resources may be limited. State and Territory grantees in the Pacific Basin are working on an inter-island agreement for regionalized care for the pediatric patient. This type of model can be used in disaster planning as well in which specialty care is limited, geographical boundaries may require coordination of many agencies and a prior infrastructure will be essential.

EMSC collaborates with all agencies and systems involved in providing care to the pediatric patient and are active in contributing to the special situation of disaster. EMSC continues to provide important insight to disaster planning since issues of special equipment, surge capacity, regionalized care are integral to everyday readiness of pediatric emergency care.

*Question.* What would a cut along the lines of that proposed in H.R. 1 mean for the 127 health center sites that have opened within the past year and the almost 3.7 million new patients currently receiving care at a health center because of the investments through the American Recovery and Reinvestment Act?

Answer. Funding levels provided in H.R. 1 would impact the ability of the Health Center Program to fully fund the 127 new access point grants originally supported by the Recovery Act and would also impact the number of patients currently served at health centers, including the 3.7 million patients served through the Recovery Act.

*Question.* Can you tell us how many applications for new health centers HRSA has received?

Answer. Over 800 applications have been received for the fiscal year 2011 New Access Point funding opportunity.

*Question.* How many awards does HRSA intend to fund?

Answer. HRSA is in the process of determining how many Health Center New Access Points through Affordable Care Act funding in fiscal year 2011.

*Question.* How many awards would HRSA make if H.R. 1 is enacted?

Answer. Under H.R. 1, there would have been no new funding available to support Health Center New Access Points in fiscal year 2011.

*Question.* Can you describe the overarching impact on the healthcare system of the continued health center expansion, as outlined in the President's fiscal year 2012 budget request?

Answer. The President's fiscal year 2012 budget request for health centers, more high quality, cost-effective, preventive and primary healthcare services will be made available nationwide.

*Question.* Madam Secretary, what additional benefits do health centers bring to their local communities, in addition to the creation of jobs and generation of economic activity?

Answer. Health centers increase access to healthcare through an innovative model of community-based, comprehensive primary healthcare that focus on outreach, disease prevention, and patient education activities. For example, evaluations have found that:

—Uninsured people living within close proximity to a health center are less likely to have an unmet medical need, less likely to have postponed or delayed seeking needed care, and more likely to have had a general medical visit.[1]

—Health center uninsured patients are more likely to have a usual source of care than the uninsured nationally (98 percent versus 75 percent).[2]

Increasing access and reducing disparities in healthcare requires quality providers who can deliver culturally-competent, accessible, and integrated care. Health centers recognize this need and support a multi-disciplinary workforce designed to treat the whole patient. For example, evaluations have found that:

—Health center patient rates of blood pressure control were better than rates in hospital-affiliated clinics or in commercial managed care populations, and racial/ethnic disparities in quality of care were eliminated after adjusting for insurance status.[3]

—A high proportion of health center patients receive appropriate diabetes care.[4]

—Health center low birthweight rates continue to be lower than national averages for all infants. In particular, the health center low birthweight for African-American patients is lower than the rate observed among African-Americans nationally (10.7 percent versus 14.9 percent respectively).[5]

—Health centers play a critical role in providing healthcare services to rural residents who tend to have higher rates of chronic diseases, such as the 27 percent of rural residents suffering from obesity[6] and nearly 10 percent diagnosed with diabetes.[7]

—Over the past 4 years, cost increases at health centers have been at least 20 percent below national increases.[8]

—Rural counties with a community health center site had 33 percent fewer uninsured emergency room/department visits per 10,000 uninsured population than those without a health center.[9]

—The cost of treating patients with diabetes in health center settings was approximately $400 less than that experienced by other primary care settings.[10]

—In 2009, health centers generated over $11 billion in revenues and employed over 123,000 full-time equivalents.

*Question.* I noticed that the fiscal year 2011 Application and Guidance released in November of 2010 did not include pharmacist as part of the eligible participants in NHSC loan repayment program. Are there any plans in the near future to include pharmacists in the NHSC loan repayment program?

Answer. The National Health Service Corp (NHSC) program is currently conducting an analysis of the Loan Repayment Program (LRP) statute and program policies, which includes a review of the disciplines the NHSC supports.

The inclusion of pharmacists or other disciplines must be consistent with the statute that established the NHSC to recruit and retain primary medical, dental and mental healthcare providers to provide primary health services to underserved populations in health professional shortage areas. The Public Health Service Act, which

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[1] Hadley J and Cunningham P. Availability of Safety Net Providers and Access to Care of Uninsured Persons. Health Services Research 2004;39(5):1527–1546.

[2] Carlson, BL et al, "Primary Care of Patients without Health Insurance by Community Health Centers." April 2001 *Journal of Ambulatory Care Management* 24(2):47–59.

[3] Hicks LS, et al. The Quality of Chronic Disease Care in US Community Health Centers. Health Affairs 2006;25(6):1713–1723.

[4] Maizlish NA, Shaw B, and Hendry K. Glycemic Control in Diabetic Patients Served by Community Health Centers. American Journal of Medical Quality 2004;19(4):172–179.

[5] Shi, L., et al. America's health centers: Reducing racial and ethnic disparities in perinatal care and birth outcomes. Health Services Research, 2004; 39(6):1881–1901.

[6] Bennett, K. J., Olatosi, B., & Probst, J.C. (2008). "Health Disparities: A Rural—Urban Chartbook." South Carolina Rural Health Research Center.

[7] Pleis JR, Lethbridge-Çejku M. Summary health statistics for U.S. adults: National Health Interview Survey, 2006. National Center for Health Statistics. Vital Health Stat 10(235). 2007.

[8] Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group: National Health Expenditures: 2002–2005.

[9] Rust George, et al. "Presence of a Community Health Center and Uninsured Emergency Department Visit Rates in Rural Counties." Journal of Rural Health Winter 2009 25(1):8–16.

[10] Proser M, Deserving the Spotlight: Health Centers Provide High-Quality and Cost Effective Care. J Ambulatory Care Management, 2005; 28(4): 321–330.

authorized the NHSC, defines "primary health services" as "health services regarding family medicine, internal medicine, pediatrics, obstetrics and gynecology, dentistry, or mental health, that are provided by physicians or other health professionals" (42 U.S. Code Sec. 254d(a)(3)(D)). To date, pharmacists have not been considered an eligible discipline for participation in the NHSC program.

As part of the discipline review, the NHSC has also conducted a survey of Community Health Centers and other NSHC-approved sites to determine the demand for additional disciplines in the NHSC. The results of this survey are currently under review. Any updates to the eligible disciplines will be announced through program guidance.

*Question.* Currently, HRSA collects data on healthcare shortage areas for primary care. Given the poor outcomes in pregnancy in this country and the shortage of physicians and midwives, are there any plans to look at identifying maternity care shortage areas?

Answer. Health Professional Shortage Areas (HPSAs) are designated by the Department as those areas having shortages of primary medical care, dental or mental health providers. HPSAs may be geographic (e.g., a county or service area), demographic (e.g., low-income population) or institutional (e.g., federally qualified health center). Among the factors considered in the designation process are the numbers of healthcare providers in the area. For the primary care HPSA designation, Obstetricians/Gynecologists (OB/GYNs) are included in the provider count when the Department evaluates the number of primary care providers in an area. As you know, the Affordable Care Act required the establishment of a Negotiated Rulemaking Committee (Committee) to make recommendations regarding a revised methodology, criteria and process for making such shortage designations. The Committee is considering the role of OB/GYNs in the development of revised criteria for primary care shortage designation. There are not, however, current plans to separately identify maternity care shortage areas.

*Question.* In the remote islands of Hawaii women have few options for giving birth. We know that freestanding birth centers have improved access to care and made significant impact on disparities for mothers and babies. What plans, if any, are there to provide funding to develop more of these freestanding birth centers in underserved communities?

Answer. The Health Center Program does not provide funding specifically for the development of birthing centers. However, health centers may choose to address the primary healthcare needs of their target populations through a variety of services including obstetrics care and site locations within their approved Health Center Program grant.

*Question.* The Maternal and child health services block grant facilitate in planning, promoting, coordinating and evaluating healthcare for pregnant women, mothers, infants, and children, children with special healthcare needs, and families in providing health services for those populations who do not have access to adequate healthcare. I am concerned that decreased funding for this important program may have a negative impact on our Nation. Would you please describe the rationale behind decreasing funding for Maternal Child Block Grants in the fiscal year 2012 budget?

Answer. The fiscal year 2012 budget proposes a decrease to the Maternal and Child Health Block Grant. The proposed budget would reduce funding for categorical research grants and not from the MCH grants to States, in order to respond to the priorities in the fiscal year 2011 final appropriations.

*Question.* In 2000, Congress launched an important national program, the National Child Traumatic Stress Initiative, which focuses on a child traumatic stress, a critical public health problem. With over 130 funded and affiliate programs, this SAMHSA program addresses the specific needs of children and families who are exposed to a wide range of trauma, including physical and sexual abuse, violence in families and communities, natural disasters and terrorism, accidental or violent death of a loved one, refugee and war experiences, and life-threatening injury and illness. Over the past 10 years, this program has had strong bipartisan and bicameral support. The program has been shown to be extraordinarily effective in expediting science to service through a collaborative and systems change approach that is helping children and families recover by improving the treatment and services they receive. In Hawaii, we have a strong program through our Catholic Charities Center, and have seen firsthand the benefits of this initiative.

Secretary Sebelius, in fiscal year 2010 the funding for this program was $40,798,000. In fiscal year 2012, the funding drops to $11,300,000 a 72 percent cut from fiscal year 2010 funding levels. Would you please describe the rationale behind cutting funding to this valuable program?

Answer. SAMHSA is committed to developing and disseminating trauma-informed services by expanding efforts to infuse trauma-informed related activities and lessons learned from the 10-year history of the National Child Traumatic Stress Network (NCTSN) across its entire grant portfolio. SAMHSA's commitment to bring trauma-informed services to scale will reach beyond individual programs and grantees, build on the success of the NCTSN, and include a focus on a diverse mix of communities (e.g., military families) and trauma-related experiences (e.g., environmental, historic, economic) while allowing States to focus resources in communities with the greatest needs. SAMHSA is also working with the Administration on Children and Families (ACF) and the Department of Justice (DOJ) to provide technical assistance and share evidence-based practices and products garnered generated from the NCTSN. The fiscal year 2012 request for NCTSN does not terminate or reduce any existing grants.

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QUESTIONS SUBMITTED BY SENATOR HERB KOHL

*Question.* I am concerned about the timeline of implementing the physician sunshine provisions (section 6002) of the Affordable Care Act. Shining light on industry payments to physicians will help demonstrate the importance of proper research relationships, while exposing and eliminating conflicts of interest and providing important information to patients about their health choices.

As you know, the Department of Health and Human Services (HHS) has a deadline of this October to establish the procedures by which industry must report information. However, it would be helpful to release guidance as soon as possible. Businesses and industry will need time to develop their internal systems to comply with the disclosure deadline of March 31, 2013. As you develop the guidance, I encourage you to work closely with stakeholder groups to ensure that the data collected will be useful and consistent with the legislation's intent.

With these deadlines looming, what is HHS's plan for implementation of the sunshine regulations? Has your staff been meeting regularly with stakeholder groups? What is your timetable for proposing the scope of reportable information? Included in your response, please detail which office will be drafting and finalizing these rules and why that office was chosen.

Answer. HHS is moving forward with the implementation of the Affordable Care Act's requirements related to Section 6002, "Transparency Reports and Reporting of Physician Ownership or Investment Interests." After reviewing the responsibilities this provision delegates to the Department, I decided that the Centers for Medicare & Medicaid Services (CMS) would be the most appropriate agency to implement all of the requirements. CMS is currently in the process of rulemaking to establish procedures for reporting and more information will be forthcoming as the process moves forward. CMS' Center for Strategic Planning and the Center for Program Integrity have dual responsibility for developing these regulations. To prepare for rulemaking, they have individually met with at least seven different industry stakeholders, and consulted with State agencies from Minnesota and Massachusetts, which already have considerable experience with this type of data collection. In addition, on March 24, 2011, CMS held an open door forum to discuss the provision and to solicit feedback from almost 500 industry participants. CMS is working hard to meet the requirements and the deadlines of the physician sunshine provision, including providing industry with the information they will need to comply with it.

*Question.* An estimated 75 percent of all pregnant women use 4 to 6 prescriptions or over-the-counter drugs at some time during their pregnancy. I am concerned that a proposed rule to improve pregnancy labeling has been pending at the Food and Drug Administration (FDA) for nearly 3 years after comments were received in August, 2008. I have corresponded with HHS and Commissioner Hamburg about this rule and have not received an adequate response regarding a timeline for its finalization. I ask again, what is the status of this rule? Given the importance of this issue to safeguarding the health of pregnant women, I think getting this proposed rule finalized should be a priority. Is it a priority for HHS and the FDA?

Answer. Publication of the rule regarding drug labeling for pregnant and lactating women remains a priority within FDA. Earlier this year, my staff met with your staff to discuss the status of this rule, and as they made clear, FDA staff is actively working on the rule. After a rule is prepared, it undergoes a clearance process prior to publication. Because the timeframes for preparing the regulation and completing each step of the clearance process could be affected by various, unpredictable, factors, FDA cannot say for certain when the final rule will publish. Please be assured that FDA is committed to finalizing this rule as promptly as possible.

NCATS AND THE EFFECT ON CTSAS

*Question.* I am concerned about the reorganization within the National Institutes of Health (NIH) that will affect the Clinical and Translational Science Awards (CTSA) program, in which Wisconsin has a substantial stake. The NIH invested $42 million into the University of Wisconsin (UW) in a 5-year CTSA commitment. UW has successfully leveraged an additional $40 million in local resources. Together, over the past 4 years these dollars have enabled UW to: (1) train young scientists in clinical and translational research; (2) pursue clinical and translational research endeavors through a streamlined and more efficient research infrastructure; (3) create interdisciplinary research teams that can pursue diversified research more easily; (4) sustain a multi-disciplinary partnership across the State with other major Wisconsin institutions, including the Marshfield Clinic; and (5) partner with more than 100 community organizations to form research partnerships and perform collaborative research aimed at improving health in the community and eliminating health inequities.

The CTSA also promoted intrastate collaboration with UW, whose efforts have been complemented by independent and collaborative activities at the Medical College of Wisconsin, where a similar CTSA grant was awarded. These entities have all made major investments of resources and capital to deliver on their commitments to CTSA—in infrastructure, faculty, and research initiatives, to name a few.

Given the impact of CTSA in Wisconsin, I request clarity regarding the future of this program. The President's budget proposed that the CTSA program become part of the new National Center for Advancing Translational Sciences (NCATS) at NIH. However, the future of CTSA and its scope remains in question. With this in mind, I ask that you provide me with information about plans regarding CTSAs with respect to the following: (1) potential and/or planned changes in the CTSA mission or the scope of the CTSA program in 2011 and beyond, particularly the goal aimed at engaging communities in clinical research efforts; (2) potential and/or planned changes in the CTSA budget and in the number of institutions that may or are likely to receive CTSA funding in 2011 and beyond; (3) potential and/or planned changes in eligibility criteria for participants in the CTSA program; and (4) potential and/or planned changes in the process or rules for applicants to receive CTSA funding.

Answer. The Clinical and Translational Science Awards (CTSA) are slated to be moved into the proposed National Center for Advancing Translational Sciences (NCATS) in fiscal year 2012. We believe that this will be a natural fit; it will serve the CTSAs well to be in an institute that has a complementary mission to their own, which is to advance translational sciences.

The CTSAs conduct and support a wide range of translational research, including therapeutics discovery and development, community engagement, education and training, and regulatory sciences. Their contributions in these areas are critical to the mission of NCATS and the NIH as a whole. However, Director Collins understands the importance of a smooth transition of this program to a new center. His goal is to ensure that the CTSAs can continue their important work as we move to stand up NCATS by October 1. To meet that goal, in April 2011, he convened a trans-NIH working group (the NIH CTSA/NCATS Integration Working Group) to: (a) enumerate the roles and capabilities of the CTSAs that can support and enhance the mission of NCATS; (b) identify CTSA needs and priorities that should be understood and addressed by NIH and NCATS leadership; and (c) propose processes for ensuring a smooth transition from NCRR to NCATS.

This group, which is chaired by Dr. Stephen Katz, Director of the National Institute of Arthritis and Musculoskeletal and Skin Disorders (NIAMS) will consult with a group of CTSA principal investigators, the CTSA Consortium Executive Committee (CCEC), who have been involved in many discussions with the NIH working group as they carry out their charge. The working groups' recommendations will help Dr. Collins and his senior staff make informed decisions about the CTSAs that will ensure a smooth transition into NCATS. No decisions regarding the administration of the currently awarded CTSAs will be made until they have completed their work.

CTSA investigators who are not part of the CECC can engage with the NIH in a number of different ways: utilize the CECC as a conduit of information both from and to NIH; attend CTSA leadership meetings that will be held this summer; and provide input directly to NIH through CTSA staff or the website Feedback NIH.

*Question.* In 2009, I worked to ensure that long-term care facilities were eligible for health information technology (HIT) funding included in the American Recovery and Reinvestment Act by expanding the general definition of "healthcare provider" to also include nursing and other long-term care facilities. What is the status of pro-

viding HIT funds to long-term care providers? What has been done to help long-term care providers access these funds?

Answer. The Office of the National Coordinator for Health Information Technology (ONC) administers grant programs that support health information exchange within the long-term care community. ONC provided $265 million to Beacon communities across the Nation. For example, Bangor, Maine's Beacon community is bringing long-term care facilities together with hospitals and other physicians to coordinate care by using health IT.

Additionally, through the State HIE Challenge Grant, ONC awarded $6.8 million to four grantees for work in improving long-term and post-acute care transitions through health information exchange. Grant funding supports the following activities:

—Identification of the data elements for health information exchange that are relevant to acute to long-term care transitions.

—Determination of strategies to meet improved acute to long term care transition goals.

—Development of consumer friendly language for personal health records (PHRs), conversion of transfer forms to electronic format, and dissemination of best processes for ensuring safe care transitions—all of which will be integrated into health information exchange for acute to long-term care transitions.

—Implementation of pilot programs at local and/or regional levels to test health information exchange for acute to long-term care transitions, which can then be expanded to the State and national levels.

ONC is also engaging with the long-term care provider community in its efforts to establish a clinical electronic infrastructure and engaging long-term care providers in developing the Electronic Health Record (EHR) Incentive program's "Meaningful Use" definition.

*Question.* This year offers a prime opportunity to reshape and modernize aging services through the reauthorization of the Older Americans Act (OAA). As Chairman of the Senate Special Committee on Aging, I am looking forward to working with Assistant Secretary Greenlee to reauthorize the OAA. Has the administration set any priorities for OAA reauthorization? Please provide a timeline for when we might expect to receive an OAA proposal from the administration.

Answer. Over the past year, the Administration on Aging conducted the most open system for providing input on recommendations for reauthorizing the Older Americans Act in its history, convening and receiving reports from more than 60 reauthorization listening sessions held throughout the country, and receiving online input from interested individuals and organizations, as well as from seniors and their caregivers. This input represented the interests of thousands of consumers of the OAA's services, and we continue to receive input and work with advocates on a variety of issues.

Based in part upon this extensive public input process, we think that reauthorization can strengthen the Older Americans Act and put it on a solid footing to meet the challenges of a growing population of seniors. We look forward to working with you and the Special Committee on Aging on bipartisan reauthorization legislation.

The following are some examples of areas that we would like to discuss with the Committee as you consider legislation:

—Ensuring that the best evidence-based interventions for helping older individuals manage chronic diseases are utilized. A number of evidence-based programs have proven effective in helping participants adopt healthy behaviors, improve their health status, and reduce their use of hospital services and emergency room visits.

—Improving the Senior Community Service Employment Program (SCSEP) by integrating it with other seniors programs. The President's budget proposes to move this program from the Department of Labor to the Administration on Aging within HHS. The goal of this move is to better integrate this program with other senior services provided by AoA. We would like to discuss with you adopting new models of community service for this program, including programs that engage seniors in providing community service by assisting other seniors so they can remain independent in their homes.

—Combating fraud and abuse in Medicare and Medicaid by embedding the Senior Medicare Patrol Program (SMP) in the OAA as an ongoing consumer-based fraud prevention and detection program. The SMP program serves a unique role in the Department's fight to identify and prevent healthcare fraud by using the skills of senior volunteers to conduct community outreach and education so that seniors and families are better able to recognize and report suspected cases of Medicare and Medicaid fraud and abuse. In fiscal year 2009, the program educated over 215,000 beneficiaries in over 40,000 group education sessions and

one-on-one counseling sessions, resolving or referring for further investigation over 4,000 complaints of potential fraud, error, or abuse.

*Question.* The Elder Justice Act established the Elder Justice Coordinating Council to meet and make recommendations relating to elder abuse, neglect and exploitation. By law, this council is tasked with meeting twice annually and reporting to Congress by March, 2012. What is the status of and timetable for implementing the Elder Justice Coordinating Council?

Answer. As of March 30, 2011, we have accepted nominations to the Elder Justice Advisory Board, which makes recommendations to the Elder Justice Coordinating Council. The timetable for further action is under development.

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## QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

### TRAUMA FUNDING

*Question.* The Administration's fiscal year 2012 budget proposal includes $765 million "to enhance the advanced development of next generation medical countermeasures against chemical, biological, radiological and nuclear threats." The budget proposal also provides $655 million "to ensure the availability of medical countermeasures from the Strategic National Stockpile during a public health emergency."

Given this significant investment in biodefense, I am concerned that the Administration's budget does not similarly support our Nation's fragile trauma centers and systems, which will most certainly be called upon in the event of another terrorist attack or public health emergency. It is very concerning to note that 23 trauma centers have closed over the past decade and 45 million people lack access to a trauma center within 1 hour following injury during which definitive treatment can make the difference between life and death. In addition, $80 billion annually is attributed to trauma medical expenses and $326 billion is estimated for lifetime productivity losses for almost 50 million injuries that required medical treatment.

While the Administration's fiscal year 2011 budget includes funding, albeit decreased, for Public Health and Emergency Preparedness grants and Hospital Preparedness grants, these funds do not fully address the urgent needs of our trauma centers and systems.

Given these facts, what is the Administration doing to make the necessary investments in our Nation's trauma centers and systems?

Is the Administration working to fund the National Trauma Center Stabilization Act and the Trauma Care Systems Planning and Development Act (Public Health Service Act sections 1201–4, 1211–32, 1241–46 and 1281–2) so that all Americans have access to trauma care during every day traumatic events or in the event of another terrorist attack?

Answer. While there is no funding for the National Trauma Center Stabilization Act and the Trauma Care Systems Planning and Development Act in the HHS 2012 budget, the Secretary of Health and Human Services delegated to the Assistant Secretary for Preparedness and Response the authorities vested in the Secretary under sections 1201–1232 of title 12 of the Public Health Service Act, parts A through C of title 12, (42 USC § 300d through 300d-32), as amended, to administer grants and related authorities for trauma care. This also included the transfer of authority from the Health Resources and Services Administration to ASPR the authorities transferred in the affordable care act. These sections include four grant programs relating to trauma and emergency medical care. In addition, section 1201 also provides, among other things, the authority to sponsor workshops and conferences related to trauma and emergency care and to conduct and support research related to trauma and emergency care. This was an important first step in implementing provision of the Affordable Care Act relating to trauma programs. While these activities have not received funding, ASPR has undertaken a cooperative venture with CDC's National Center for Injury Prevention and Control to assist high-profile cities in improving their plans to respond to mass casualty events caused by major traumatic events such as terrorist bombing. Additionally, since the establishment of the Hospital Preparedness Program, over $3.3 billion has been provided to hospitals to improve overall surge capacity and strengthen the capability of hospitals and healthcare systems to plan, respond to, and recover from all hazard events.

### TITLE X FUNDING

*Question.* Title X is the Nation's cornerstone family planning program for low-income women. Each year approximately 5 million low-income individuals receive basic healthcare, including cancer screenings, birth control, and HIV testing, at clinics receiving funds under this program.

As we consider recommendations for the coming year, we're mindful that the House-passed fiscal year 2011 continuing resolution eliminates all $317 million in funding for the Title X program.

Given that 6 in 10 women who receive care at a Title X health center consider it their primary source of medical care, what would be the effects of zeroing out the program?

Answer. The Title X Family Planning program is the only Federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services. The program establishes the framework for the delivery of publicly funded family planning services in the United States, providing funding to more than 4,500 sites across the United States, including State and local health departments, freestanding clinics, hospitals, family planning councils, and Planned Parenthood agencies. At least 90 percent of Title X program funds are used to provide clinical services. Title X services include preventive health services such as cervical cancer screening, contraceptive counseling and supplies, pelvic exams, breast and cervical cancer screening, basic infertility counseling, clinical breast exams, HIV and STI tests, and other services related to reproductive health and family planning. Title X-funded agencies served an estimated 5 million individuals each year. At least 90 percent of the Title X clients served each year have family incomes at or below 200 percent of the Federal poverty level. For many, a family planning clinic is their entry point into the healthcare system and is considered to be their usual source of care. This is especially true for women with incomes at or below 100 percent of the Federal poverty level, who are uninsured, Hispanic, or black. One-quarter of all poor women who obtain contraceptive services do so at a site that receives Title X funding, as do 17 percent of poor women obtaining a Pap test or pelvic exam and 20 percent obtaining services for a sexually transmitted infection.

In fiscal year 2009, it is estimated that nearly 1 million unplanned pregnancies were averted by services provided at Title X agencies, including more than 233,000 among teens. In 2009, 2,035,017 female clients received screenings for cervical cancer. It is estimated that these screenings contributed to preventing approximately 670 cases of invasive cervical cancer. In 2009, more than 2.5 million clients were tested for Chlamydia and Gonorrhea, and nearly 800,000 were tested for syphilis. In 2009, nearly 1 million HIV tests were conducted. Services provided at Title X-supported clinics were estimated to account for $3.4 billion in savings in 2008 alone. Title X is also cost-effective—Title X-funded centers saved taxpayers an estimated $3.4 billion in 2008—or $3.74 for every $1 spent on contraceptive care. Unintended pregnancy has been linked with numerous negative maternal and child health outcomes. More broadly, contraception can enable women and couples to plan and space births, allowing them to invest in higher education and to participate more broadly in the Nation's workforce. Title X also provides a critical source of funding for our Nation's public healthcare infrastructure, which would look quite different in the absence of Title X funds. In short, in the absence of Title X, rates of unintended pregnancy, infertility and related morbidity, and abortion would be considerably higher. In addition, the public health infrastructure would be negatively impacted, at a considerable cost to the overall healthcare system.

FEDERAL FUNDING FOR PLANNED PARENTHOOD

*Question.* As you know, the House-passed fiscal year 2011 continuing resolution prohibits Planned Parenthood from receiving any Federal funds. Planned Parenthood operates approximately 575 health centers across the country that receive Title X funds to provide non-abortion-reproductive healthcare like pap smears, birth control, and cancer screenings.

Could you tell me what the impact of disqualifying Planned Parenthood from all Federal funds would be on women and families across the country, were this policy adopted for into next year's budget?

Answer. More than 800 Planned Parenthood clinics receive some portion of their funding through a variety of federally funded public health programs, including Title X and Medicaid. Medicaid is by far the largest source of funding. For some beneficiaries of these public health programs, Planned Parenthood serves as a critical source of services and supplies to prevent unplanned pregnancy, screen for cervical and breast cancer, vaccinate to prevent cervical cancer, and obtain pelvic exams and patient education and counseling. Barring Federal funding to Planned Parenthood agencies could create barriers to these services, many of which are critical to women's health. Planned Parenthood estimates that it serves 1.8 million clients with Federal funds, and provides nearly 4 million STI tests and more than

900,000 cervical cancer screening tests. Without access to these basic services, rates of STIs, unplanned pregnancy, and abortion could increase.

*Question.* Can you describe the overarching impact the continued health center expansion, as outlined in the President's fiscal year 2012 budget request, will have on the healthcare system, in terms of the cost-effectiveness and quality of services that health centers provide? And what about other benefits—like jobs generated and economic impact?

Answer. Through the President's fiscal year 2012 budget request for health centers, more high quality, cost-effective, preventive and primary healthcare services will be made available. Through the fiscal year 2012 budget request, health centers are projected to employ thousands of additional staff.

*Question.* As you know, the Balanced Budget Act of 1997 established that teaching hospitals may count, for the purposes of indirect (IME) post-graduate physician education payments, resident time spent in non-hospital settings, so long as certain conditions are met. One of these conditions set out in the legislation is that the "hospital must incur all or substantially all of the costs for the training program in the nonhospital setting . . .".

However, CMS, in its final rules for the Inpatient Prospective Payment System (IPPS) in 2004, interpreted the law to mean that the resident time is allowed only when one hospital sponsors the resident's participation in the non-hospital experience. This interpretation puts many shared residency rotation programs, including family medicine residency programs, in my State at risk, at a time when we should be encouraging more residency programs, not less.

Congress made clear that this was not the intention of the original legislation in Section 5504 of the Patient Protection and Affordable Care Act. This section modifies rules governing when hospitals can receive indirect medical education (IME) and direct graduate medical education (DGME) funding for residents who train in a non-provider setting so that any time spent by the resident in a non-provider setting shall be counted toward direct and indirect medical education if the hospital incurs the costs of the stipends and fringe benefits.

Are there discussions ongoing at HHS to alter the current interpretation of resident shared rotation and IME payments, particularly in light of provisions in the Affordable Care Act?

Answer. As you note in your question, section 5504 of the Affordable Care Act addresses the situation in which more than one hospital incurs the costs of training programs at non-provider settings. The provision allows hospitals to count, on a prospective basis only, a proportional share of the time that a resident spends training in such settings when more than one hospital incurs the costs. The Centers for Medicare & Medicaid Services (CMS) finalized its proposal to implement section 5504 in the CY 2011 Hospital Outpatient Prospective Payment System final rule, which was published in the Federal Register on November 24, 2010. The final rule allows hospitals to share the costs of resident training at non-provider sites, so long as those hospitals divide the resident time proportionally in accordance with a written agreement. In doing so, the final rule requires that hospitals have a reasonable basis for establishing the proportion and that the hospitals document the amount they are paying for the salaries and fringe benefits of the residents for the amount of time the residents are training at that site.

### FUNDING FOR THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH'S EDUCATION AND RESEARCH CENTERS

*Question.* The Administration's fiscal year 2012 budget request zeroed out all funding for the National Institute for Occupational Safety and Health's (NIOSH) Education and Research Centers.

What was the original programmatic intent for the National Institute for Occupational Safety and Health (NIOSH)-funded Education and Research Centers (ERCs)? As part of your reply to this question, please provide a copy of the original program announcement for the record.

Has HHS assessed whether this NIOSH program has fulfilled its statutory mandate under Section 21 of the Occupational Safety and Health Act of 1970 to provide an adequate supply of safety and health professionals?

Has HHS assessed the impact on ERCs from zeroing funding for the program in fiscal year 2012?

Answer. The original programmatic intent of the ERC program, which was established in 1977 in response to Section 21(a) of the Occupational Safety and Health Act, was to create "education programs to provide an adequate supply of qualified personnel to carry out the purposes of the Act". The program was envisioned as a commitment to training future professionals to work in industry, public health, and

academia. NIOSH has established partnerships with 48 academic institutions that comprise the academic network responsible for the Nation's occupational safety and health professional training infrastructure. Through university-based ERCs, NIOSH supports academic degree programs and research training opportunities in the core areas of industrial hygiene, occupational health nursing, occupational medicine, and occupational safety, plus specialized areas relevant to the occupational safety and health field. NIOSH also supports ERC short-term continuing education programs for occupational safety and health professionals and others with worker safety and health responsibilities. Please see attached program announcement from 1976.

[ERC Program Announcement, 1976]

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

PUBLIC HEALTH SERVICE

CENTER FOR DISEASE CONTROL

GRANTS FOR OCCUPATIONAL SAFETY AND HEALTH EDUCATIONAL RESOURCE CENTERS

PROGRAM GUIDELINES

The National Institute for Occupational Safety and Health is implementing a new national competition for training project grants to support a limited number of Occupational Safety and Health Educational Resource Centers. It is proposed to establish by 1980, subject to the availability of funds, at least 10 Center's—at least one in each Department of Health, Education, and Welfare Region.

*Authority*

Grants for Educational Resource Centers will be awarded under the Institute's basic training grant authority, the Occupational Safety and Health Act of 1970 (29 U.S.C. 670a). Except as otherwise indicated in these guidelines, the basic policies of the Public Health Service Grants Policy Statement (HEW Publication No. (OS) 77–50.000 (Rev.) October 1, 1976) are applicable to this program as are the HEW regulations on Grants for Educational Programs in Occupational Safety and Health (42 CFR Part 86).

*Background and Objectives*

In 1971, the Institute established training grant programs to assist public or private nonprofit educational institutions in establishing, strengthening or expanding graduate, undergraduate or special training of persons in the field of occupational safety and health in order to provide an adequate supply of qualified personnel to carry out the purposes of the Act. (Catalog of Federal Domestic Assistance 13.263). Past and current training project grants have provided support for primarily, single discipline and single level occupational safety and health training programs, e.g., in occupational medicine, occupational health nursing, industrial hygiene, safety engineering, etc., at either the graduate, undergraduate or technical and paraprofessional level. The multidisciplinary scope of occupational health and safety has been recognized by many to be diverse and complex. It has also been realized that special problems arise at the workplace from which new concepts develop that do not fall within any single, traditional discipline. Yet, within this framework, increased numbers of people must be educated to achieve effective prevention of the many occupational health and safety hazards that occur at the workplace.

The objective of this competition is to provide a mechanism for combining and expanding existing activities and arranging for coordinated multi-discipline and multi-level training and continuing education in occupational safety and health under a single grant servicing a geographic region. The program is intended to afford opportunity for full- and part-time academic career training, for cross training of occupational safety and health practitioners, for mid-career training in the field of Occupational Health and Safety, and access to many different and relevant courses for students pursuing various degrees. Further, the combination of these should result in cross-fertilization among the various disciplines and levels of occupational safety and health practice.

It is anticipated that Centers will form from bases of ongoing educational, research and training activities in occupational safety and health. It is not intended to generate these activities de novo as this would not net the objectives of this program.

*Eligibility Requirements*

An eligible applicant is any public or private nonprofit educational or training agency or institution located in a State: provided that no agency or institution is eligible for assistance for a separate training project grant in any project period in which it receives an educational resource center grant. However, this will not preclude an existing training grant from being incorporated into an educational resource center grant award.

A Center may be comprised within one educational institution or agency or within an association of two or more institutions or agencies. Educational and administrative justification for any joint arrangement must, however, be fully documented in the application. If such proposals are made, each institution, proposing to participate in a joint arrangement must also participate in the application by delineating the educational and training activities that in totality constitute the Educational Resource Center and which, through interaction and proximity, will improve the probability of the success of the total program, as indicated in the guidelines below. Current Public Health Service policy covering consortia and collaborative arrangements must be complied with. A proposal for a Center which is in effect a collation of unrelated training activities will not be considered responsive.

*Characteristics of an Educational Resource Center*

An Occupational Safety and Health Educational Resource Center should be an identifiable organizational unit within the sponsoring organization and shall have the following characteristics:

—Cooperative arrangements between a medical school (with anestablished program in preventive or occupational medicine); school of nursing and school of public health or its equivalent, and school of engineering or its equivalent. Other schools or departments with relevant disciplines and resources may be expected to be represented and contribute as appropriate to the conduct of the total program, e.g., toxicology, biostatistics, environmental health, law, business administration, education, etc.

—A Director who possesses a demonstrated capacity for sustained productivity and leadership in occupational health and safety training, He shall oversee the general operation of the Center Program and shall, to the extent possible, directly participate in training activities.

—A full-time professional staff representing various disciplines and qualifications relevant to occupational safety and health to be capable of planning, establishing, and carrying out or administering training projects undertaken by the Center.

—Training and research expertise, appropriate facilities and ongoing training and research activities in occupational safety and health areas.

—A program for conducting education and training of occupational physicians, occupational health nurses, industrial hygienists/engineers and safety personnel. There shall be full-time students in each of these core disciplines, with a goal of a minimum of 30 full-time students. Training may also be conducted in other occupational safety and health career categories, e.g., industrial toxicology, biostatistics and epidemiology, ergonomics, etc. Training programs shall include appropriate field experience including experience with public health and safety agencies and labor-management health and safety activities.

—Impact on the curriculum taught by relevant medical specialties, including radiology, orthopedics, dermatology, internal medicine, neurology, perinatal medicine, pathology, etc.

—A program to assist other institutions or agencies located within their region including schools of medicine, nursing and engineering, among others, by providing curriculum materials and consultation for curriculum/course development in occupational safety and health, and by providing training opportunities for faculty members.

—A specific plan for preparing, distributing and conducting courses, seminars and workshops to provide short-term and continuing education training courses for physicians, nurses, industrial hygienists, safety engineers and other occupational safety and health professionals, paraprofessionals and technicians, including personnel of labor-management health and safety committees, in the geographical region in which the Center is located. The goal shall be that the training be made available each year to a minimum of 200–250 trainees representing all of the above categories of personnel, on an approximate proportional basis with emphasis given to providing Occupational Safety and Health training to physicians in family practice, as well as industrial practice, and industrial nurses. Where appropriate, it shall be professionally acceptable in that Continuing Education Units (as approved, for example, by the American Med-

ical Association, American Nursing Association, etc.) may be awarded, These courses should be structured so that either educational institutions, public health and safety agencies, professional societies or other appropriate agencies can utilize them to provide training at the local level to occupational health and safety personnel working in the workplace. Further, the Center shall have a specific plan and demonstrated capability for implementing such training directly and through other institutions or agencies in the region, including cooperative efforts with labor unions and industry trade associations where appropriate, thus serving as a regional resource for addressing the problems of occupational safety and health that are faced by State and local governments, labor and management.

—Specific mechanisms to implement the cooperative arrangements, e.g., between departments, schools/colleges, universities, etc., necessary to insure that the comprehensive, multi- or core-disciplinary training and education that is intended shall be engendered.

—A Board of Advisors or Consultants, with representation of the user and affected population, including representation of employers and employees, of the Center outreach and continuing education and training programs should be established by the grantee institution to assist the Director of the Center in periodic evaluation of the Center activities.

An application for a Center grant must address each of the above points. The nature and organization of the appropriate administrative teaching and support staffs and necessary supplies, equipment, facilities, etc., should be clearly detailed in the proposal and clearly related to the budget requested. This program cannot provide funds for new construction or major alterations or renovations, thus facilities must be available for the primary needs of the proposed Center activities.

*Criteria for Review*

The applications for Occupational Safety and Health Educational Resource Centers solicited in this announcement will be evaluated in national competition. The review is expected to involve a site visit. The reviewing applications criteria utilized include:

—The overall potential contribution of the project toward meeting the needs for qualified personnel to carry out the purposes of the Occupational Safety and Health Act of 1970, the expressed purpose of which is to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources—by providing for training programs to increase the number and competence of personnel engaged in the field of occupational safety and health."

—The need for training in the areas outlined by the application, including projected enrollment, recruitment, regional needs both in quality and quantity, similar programs, if any, within the geographic area.

—The extent to which arrangements for day-to-day management, allocation of funds and cooperative arrangements are designed to effectively achieve Characteristics of an Educational Resource Center, above.

—The extent to which curriculum content and design includes formalized training objectives, minimal course content to achieve certificate or degree, course descriptions, course sequence, related courses open to students, time devoted to lecture, laboratory and field experience, the nature of the latter (primarily applicable to academic training).

—Previous record of training in this or related areas, including placement of graduates.

—Methods proposed to evaluate effectiveness of training.

—The competence, experience and training of the Center Director and of other professional staff in relation to the type and scope of training and education involved.

—Institutional commitment to Center goals.

— Academic and physical environment in which the training will be conducted, including access to appropriate occupational settings.

— Appropriateness of the budget required to support each component of the program.

*Operational Aspects*

Although the mechanism for support for the Center will be a training grant, it will differ from other grants in its emphasis on priority of occupational safety and health training in the medical and nursing disciplines and in conducting an outreach program in curriculum development and continuing education projects designed to increase admissions to and enrollment in occupational safety and health

training of persons who, by virtue of their background and interest or position, are likely to engage or participate in the delivery of occupational health and safety services.

While it is expected that each Center will plan, develop, direct and execute its own program, it must also be responsive to the identified needs of the National Institute for Occupational Safety and Health, both in content and direction. The award of a Center grant will establish a special collaborative relationship between the National Institute for Occupational Safety and Health and the grantee institution. NIOSH staff, with consultation and assistance from representatives of the kinds of user groups of the Center program (e.g., academic labor, management and public health and safety agencies) will provide initial and continuing review and evaluation of the Center programs.

From 2005 to 2010, the number of trained occupational safety and health (OSH) professionals has steadily increased. There were 1,191 graduates during the past 5 academic years (from 2005–06 to 2009–10). Of these 1,191 ERC graduates 978 (82 percent) entered careers in OSH or entered more advanced degree programs in OSH. This is due to the increase in awareness of OSH and the comprehensive curriculum which provides a variety of continuing education opportunities for OSH professionals. Of the 287 ERC graduates in 2009–2010, 234 (82 percent) entered careers in OSH or entered more advanced degree programs in OSH.

Within the context of a budget that requires tough choices, we put forth a proposal to discontinue Federal funding for the ERCs. We recognize the vital role of occupational safety and health professional training. This proposal is one of many difficult reductions we proposed as part of the fiscal year 2012 budget.

FUNDING FOR THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH'S AGRICULTURE, FISHING AND FORESTRY PROGRAM

*Question.* The Administration's fiscal year 2012 budget request also zeroed out all funding for the National Institute for Occupational Safety and Health's (NIOSH) Agriculture, Fishing and Forestry Program.

How does the rate of occupational injury and illness and fatalities in agriculture, fishing and forestry (AgFF) compare with injury rates in general industry.

Did the 2007 National Academy (NA) review of NIOSH's Agriculture, Forestry and Fishing research program recommend elimination of the AgFF program?

Did the NA review recommend relocating AgFF research activities to the Department of Labor or USDA?

Answer. The fatality rate in the Agriculture, Forestry, and Fishing industry is more than seven times higher than that of general industry. Although the data from 2009 are still provisional, based on the Bureau of Labor Statistics (BLS), Census of Fatal Occupational Injuries, workers in the Agriculture, Forestry, and Fishing industry had an average fatality rate of 28.1 per 100,000 full-time equivalent workers from 2006–2009 while general industry had an average rate of 3.8 per 100,000 full-time equivalent workers during the same time period. The rate of nonfatal occupational injuries and illnesses in the Agriculture, Forestry, and Fishing industry is slightly higher at a rate of 5.6 per 100,000 full-time equivalent workers than that of general private industry at a rate of 4.1 per 100,000 full-time equivalent workers from 2005–2009.

While the 2007 National Academy (NA) review of NIOSH's Agricultural, Forestry and Fishing research program raised some questions about the impact of this research on workplace injury and illness, it did not recommend elimination of the AgFF program.

The NA review did not recommend relocating AgFF research activities to the Department of Labor or USDA. Instead, NA recommended that the AgFF program continue to partner with appropriate Federal and State agencies and establish additional interagency partnerships to increase the capacity for carrying out research and transfer activities.

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## QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

CHILD WELFARE FINANCE REFORM

*Question.* Could you explain the Administration's vision for foster care reform, and why the need for reform is so urgent?

Answer. The President's budget proposes $2.5 billion over 10 years to align financial incentives with improved outcomes for children in foster care and those who are receiving in-home services or post-permanency services from the child welfare system, in order to prevent entry or re-entry into foster care. We envision States that

receive performance-based funding to be able to support activities that can improve outcomes for children who have been abused or neglected or at risk of maltreatment. We believe our proposal will keep the focus on moving child welfare in the right direction, particularly during these difficult budget times in States. The proposal incentivizes all States to improve outcomes by allowing them to earn additional funds that can be invested in activities that can drive further progress for the children and families served.

We look forward to working with Congress on developing specific details, guided by the principles outlined in our fiscal year 2012 budget:

—Creating financial incentives to improve child outcomes in key areas, by reducing the length of stay in foster care, increasing permanency through reunification, adoption, and guardianship, decreasing rates of maltreatment recurrence and any maltreatment while in foster care, and reducing rates of re-entry into foster care;

—Improving the well-being of children and youth in the foster care system, transitioning to permanent homes, or transitioning to adulthood;

—Reducing costly and unnecessary administrative requirements, while retaining the focus on children in need;

—Using the best research currently available on child welfare policies and interventions to help the States achieve further declines in the numbers of children who need to enter or remain in foster care, to better reach families with more complex needs, and to improve outcomes for children who are abused, neglected, or at risk of abuse or neglect; and

—Expanding our knowledge base by allowing States to test innovative strategies that improve outcomes for children and reward States for efficient use of Federal and State resources.

CHAFEE FOSTER CARE INDEPENDENCE PROGRAM

*Question.* Can you explain why, in light of the rising number of foster youth who "age out" of care, the Administration has not proposed to increase funding for Chafee?

Answer. In an environment of limited resources, we have chosen to provide additional funds to align financial incentives with improved outcomes for children in foster care and those who are receiving in-home services or post-permanency services from child welfare system, in order to prevent entry or re-entry into foster care. States may use these funds to provide services to youth who are in foster care before they age out as well as provide post-permanency services to those who age-out of the foster care system. We believe our proposal will keep the focus on moving child welfare in the right direction, particularly during these difficult budget times in States.

*Question.* If Congress does not meet the President's budget request of $3.3 billion for the Health Centers Program, what will be the impact on rural and urban underserved populations? Can you also describe the economic impacts of not adequately funding the Health Centers Program?

Answer. It will reduce to some extent the expansion of the Health Center Program (and its associated economic impact) into new underserved rural and urban communities.

*Question.* Recognizing the vital role School Based Health Centers play in serving as a safety net provider for our children and adolescents, why wasn't funding for the operations of School Based Health Centers included in the fiscal year 2012 budget request? For fiscal year 2013, do you see putting School Based Health Centers in the President's budget as an approach that could be utilized to grant greater access to care for our youth?

Answer. School-Based Health Centers may apply for operational support under the Community Health Center program. For example, interested school-based health centers could have applied for the Affordable Care Act New Access Point opportunity announced last August to support new healthcare service delivery sites, if Health Center Program eligibility criteria were met. Previous operational funding for health center sites serving school-aged populations and/or located in schools has been awarded under the Community Health Center Program.

*Question.* HHS, as well as other Federal agencies, has found great success with telehealth programs in the treatment of high-cost patients. As these programs advance, where do you see the best opportunities not only to maximize cost savings but to provide patients with better care and improve clinical outcomes?

Answer. The Telehealth Network Grant Program (TNGP), grants have offered underserved populations the opportunity to access a diverse variety of clinical services to underserved people in rural areas which include: allergy, asthma control, cardi-

ology, diabetes care and management, pain management, remote patient monitoring, and a variety of other services.

For the relatively more mature Telehealth Networks (TNGP–TH) provisions, one clinical health outcome measure, diabetes case management, is being collected, as well as several outcome measures related to improving access and program efficiency. One of the responsibilities of OAT's Regional Telehealth Resource Centers (TRCs) is to track evidence-based telehealth practices in their regions, and share that information through the technical assistance that they provide to HRSA grantees, rural and other underserved communities. The TRCs share information about cost savings, improved quality and increased access through telehealth applications via their websites, webinars, conference calls, presentations at conferences, and one-on-one consultations.

*Question.* What are the other areas within the Department of Health and Human Services where Federal support for telehealth technology can be initiated or expanded?

Answer. HRSA's formal telehealth authority is through ORHP's OAT, as mentioned in the previous question. HRSA's ORHP is not aware of other areas within the Department of Health and Human Services where Federal support for telehealth technology can be initiated or expanded.

*Question.* What areas within HHS, including the Centers for Medicare and Medicaid Services and the Center for Medicaid and Medicare Innovation could be used to increase Federal support for telehealth?

Answer. CMS continually looks for ways to expand the use of telemedicine in our programs to provide high quality healthcare services in the most efficient manner possible. To that end, CMS annually considers requests from the public to add to the list of telehealth services covered by Medicare Part B, and adds new telehealth services as appropriate as part of the Medicare Physician Fee Schedule rulemaking process. CMS also recently finalized new rules for telemedicine services to ensure that patients in rural or remote areas will continue to receive access to high quality, cutting-edge medical care through the use of telemedicine from many of their local hospitals. The new finalized rules streamline the process that hospitals and critical access hospitals (CAH) use for credentialing and granting privileges to physicians and practitioners who deliver care through telemedicine. The new rule will also permit hospitals to more easily partner with non-hospital telemedicine entities, such as teleradiology facilities, to deliver specialty care via telemedicine.

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## QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

### THE EFFECT OF REDUCING NIH FUNDING TO 5 PERCENT BELOW FISCAL YEAR 2010

*Question.* In February the House passed an appropriations bill for fiscal year 2011 that proposed cutting the National Institutes of Health's (NIH's) budget by $1.6 billion or 5 percent compared to NIH's fiscal year 2010 budget.

Please provide the NIH's perspective on how such a cut would impact the NIH and our Nation's economic recovery?

Answer. A $1.6 billion decline from NIH's fiscal year 2010 budget levels could have adverse consequences for the research community and could delay current research efforts. It could result in lost opportunities to develop more cost effective diagnostics and treatments in areas such as developmental disorders, addiction, mental illness, infectious disease, cancer, heart disease, and neuro-degeneration.

Specifically, in the area of translational research, more than 100 clinical trials and studies for more precise tests and more effective treatments of common and rare diseases affecting millions of Americans could be halted or curtailed. Medical practices that could have been shown obsolete or needlessly expensive would not be fully evaluated.

In the area of basic research, in just the last 2 years, advances in whole genome sequencing, methods to grow stem cells not derived from human embryos, automated equipment that can perform thousands of experiments at the same time, and previously untried drug design techniques have all become available for the first time, providing unprecedented opportunities for research advances at relatively low cost, many of which could be delayed by these budget cuts. Reductions in funding the pipeline of basic research could slow the discovery of fundamental knowledge about how we grow, age and become ill. Valuable research supporting the prevention of a host of costly, debilitating chronic conditions could suffer setbacks. Some projects could be difficult to pursue at reduced levels and could be cancelled; others could require scope modifications that would dramatically alter the potential research outcomes.

Budget cuts could effect universities and the private-sector. Grantee personnel budgets may be reduced. Training grants could be materially impacted and the population of qualified research trainees and advanced science instructors could diminish. Some universities, especially those with research programs in earlier stages of development, may need to prioritize between training new physicians and scientists and closing laboratories. In the private sector, high-tech and low-tech small-business suppliers could face order cancellations. New equipment prototypes and laboratory methods important to private-sector pharmaceutical and device research could delay development, leaving fewer product options available for U.S. companies to offer as exports in response to the expected rapid rise in health spending in China and the developing world. Supplies of highly-trained technology workers in America could further diminish.

*Question.* Approximately how many NIH-funded jobs could be lost as a result of a 5 percent cut to the agency's budget?

Answer. NIH estimates that 10,500 full-time-equivalent (FTE) positions could potentially be lost as a result of a $1.6 billion cut to the agency's budget. This estimate is based on the average number of FTE per million dollars of funding reported by recipients of research funds under the Recovery Act.

*Question.* Congenital Heart Disease (CHD) is one of the most prevalent birth defects in the United States and a leading cause of birth defect-associated infant mortality. Due to medical advancements more individuals with congenital heart defects are living into adulthood, unfortunately our Nation has lacked a population-surveillance system for adults with CHD. The healthcare reform law included a provision, which I authored, that authorizes the CDC to track the epidemiology of congenital heart disease, with an emphasis on adults with CHD and expanding surveillance. If adequately funded, what could be the public health impact of this surveillance system and how could it advance our understanding of the prevalence or CHD across subgroups (including age and race/ethnicity).

Answer. Development of population-based surveillance for congenital heart disease across the lifespan would be a critical first step in generating information on prevalence across different age groups, race/ethnicity and socioeconomic groups in the population, as well as possible determinants of health disparities in neurocognitive outcomes, disabilities, survival, and quality of life. This population-based approach to identifying and following affected persons over time would have a significant public health impact by:

—*Estimating the true prevalence of CHD in the United States*.—It is estimated that about 1 million adults are living with CHD in the United States, and given the improvements in treatment and decreasing mortality, this number continues to grow. However, this estimate is imprecise without population-based surveillance systems to track adolescents and adults with CHD. Accurately determining national prevalence estimates of CHD requires high-quality population-based surveillance of a representative sample of affected individuals using standardized surveillance methods.

—*Estimating the healthcare costs associated with CHD*.—All adults with CHD have significantly higher rates of healthcare utilization than their peers. Furthermore, if adults with CHD develop other chronic conditions, such as diabetes, the interactive effect of the congenital anomaly with the other diseases remains unknown. Currently, estimates of direct costs for adults are often specific to inpatient admissions, and do not include hospitalizations in which CHD was not the primary reason for admission nor costs associated with outpatient visits, prescription medications, or other indirect costs for the affected individuals, their families, and society. Therefore, information from a population-based surveillance system would improve planning for the future utilization of healthcare resources and enhance our understanding of the economic costs of CHD among adults.

—*Identifying factors associated with adverse outcomes across the lifespan*.—Persons with CHD are at risk for adverse health outcomes such as neurodevelopmental and cognitive outcomes and premature death, yet little is known about risk factors for these outcomes and how they differ among subpopulations. Identifying and following affected persons over time to track adverse outcomes could help us understand factors such as health disparities that might predispose to or ameliorate adverse outcomes, and characterize the health services needs of this population.

—*Providing reliable, evidence-based information to guide diagnosis, management, and secondary prevention efforts*.—Currently, many adults with CHD in the United States receive inadequate care because of the lack of information to guide the clinical management of a child with a congenital heart defect as he or she ages into adulthood. Adults and their healthcare providers have become

increasingly aware of the need for reliable, evidence-based information to guide diagnosis, management, and secondary prevention efforts.

Collecting and analyzing data on outcomes over time could improve understanding of the long-term course of CHD, the factors that might influence such course, and the health services needs across the lifespan. These data could also help inform efforts to develop effective primary and secondary prevention strategies directed at reducing the public health impact of CHD. The data could also be used to develop and evaluate the effectiveness of interventions such as guidelines for routine preventable care for children, adolescents, and adults with CHD designed to reduce poor outcomes and high cost of treating individuals who otherwise do not seek or receive adequate care until in a medical crisis.

*Question.* Currently, when a person enrolls in Medicare, their Social Security Number (SSN) is used the basis of their Medicare identification number. The Social Security Inspector General has indicated that this creates a risk of identity theft and fraud and has suggested that the SSN be removed from the Medicare card. How do you think this risk to Medicare beneficiaries and the Federal program could be reduced?

Answer. CMS is currently investigating the viability and costs of a range of options for removing the SSN from Medicare beneficiary cards. There are considerable costs associated with changing the Medicare beneficiary identifier, not only for CMS but also for our public and private sector partners. The SSN identifier in the health insurance claim number (HICN) is the basis of eligibility for Medicare, and is integrated in more than 50 CMS systems, as well as communications with our partners in the Social Security Administration, State Medicaid departments, private Medicare health and drug plans, and over 2 million healthcare providers and suppliers. The risks of disruptions in beneficiaries' access to care are considerable.

I want to emphasize, however, that CMS shares your concerns about the importance of safeguarding and protecting Medicare beneficiaries from identity theft. We have taken many important steps to minimize the display of SSNs or HICNs on Medicare cards. We removed the SSN from various notices and publications sent to beneficiaries, and from beneficiary reimbursement checks. We prohibited Part C and D Plans from using the SSN or HICN as a beneficiary identifier. We have also taken action to educate beneficiaries about steps they should take to prevent identity theft and fraud, including posting information on the CMS website, and adding information to the "Medicare & You" Handbook.

*Question.* On December 20, 2010 you sent a response letter entitled "Concern on Hepatitis" to Members of Congress, which directed Assistant Secretary Dr. Howard Koh to convene an interagency working group tasked with developing an HHS Action Plan on Viral Hepatitis. Can a specific date be provided for when the Action Plan will be released? Once the Action Plan is released how will HHS prioritize resources and give direction to the various Departmental operating divisions to ensure steps are taken to curtail the escalating costs associated with viral hepatitis and the costly outcomes such as liver cancer and end-stage liver disease?

Answer. We anticipate that the HHS Action Plan for the Prevention and Treatment of Viral Hepatitis will be released on May 12, 2011. The Action Plan will help HHS improve its current efforts to prevent viral hepatitis by leveraging opportunities to improve coordination of viral hepatitis activities across HHS operating divisions and by providing a framework for HHS to engage other governmental agencies and nongovernmental organizations in viral hepatitis prevention and care. For example, the Action Plan calls for the alignment of HHS guidelines for the diagnosis of Hepatitis B and Hepatitis C infection. Such alignment will improve provider understanding, thus supporting screening efforts and promoting earlier diagnosis of viral hepatitis. Identifying and disseminating best practices regarding prompt linkage of persons testing positive for viral hepatitis into needed care and treatment and developing effective medical management models for use in priority populations, like injection drug users, will improve care outcomes and reduce the negative health outcomes of chronic hepatitis. Finally, on the basis of available funding, the NIH will expand existing clinical trial networks to expand studies of viral hepatitis treatment. Improving treatment for hepatitis C and other causes of viral hepatitis will eventually decrease the number of persons with chronic hepatitis, thus decreasing the costly sequelae of end stage liver disease.

## QUESTIONS SUBMITTED BY SENATOR JACK REED

### CDC STATE CANCER REGISTRIES (PEDIATRIC CANCER SURVEILLANCE)

*Question.* The fiscal year 2012 budget for the Centers for Disease Control and Prevention (CDC) proposes to consolidate a variety of programs that address chronic disease into a Coordinated Chronic Disease Prevention and Health Promotion Grant Program. This program will mix core funding with competitive grants to States and other entities. CDC's cancer-related efforts are included in this new program.

As the author of the Conquer Childhood Cancer Act, which authorized investment in childhood cancer surveillance efforts—among other provisions—I am particularly concerned that the consolidation will take attention away from sub-populations. For example, more timely and accurate data collection of pediatric cancer cases and treatments can help researchers determine appropriate treatments and interventions. I helped secure $3 million for this effort last year and it was welcome news to the entire pediatric cancer community.

It appears that with the new approach, States will allocate funds to improving outcomes among large populations where very small changes can make a big difference. While this will help them secure additional, competitive grant funding, there are smaller populations that will likely receive less attention.

How will you ensure that States continue to apply the funds they receive to continue to build their pediatric cancer surveillance efforts?

Answer. The President's fiscal year 2012 budget proposes to consolidate eight separate disease-specific budget lines—Heart Disease and Stroke, Diabetes, Cancer, Arthritis and other Conditions, Nutrition, Health Promotion, Prevention Centers, and non-HIV/AIDS adolescent and school health activities including Coordinated School Health—into a single comprehensive grant program, the Coordinated Chronic Disease Prevention and Health Promotion Grant Program. This consolidation is intended to provide integrated services to State and local health departments by maximizing the reach and impact of every dollar invested by CDC to prevent chronic diseases and promote health in a variety of environments, including schools, and to a variety of sub-populations, including children.

The National Program of Cancer Registries (NPCR) is essential to CDC's efforts to prevent and control cancer. Representing 96 percent of the population, data from NPCR are vital to understanding the Nation's cancer burden and are fundamental to cancer prevention and control efforts at the national, State, and local level. Information about cancer cases and cancer deaths is necessary for health agencies to report on cancer trends, identify populations with the highest cancer burden in order to target interventions, assess the impact of cancer prevention and control efforts, participate in research, especially on small and disparate populations, such as American Indians/Native Alaskans, and respond to reports of suspected increases in cancer occurrence. NPCR is the main source of data on rare cancers—including some pediatric cancers—which can be difficult to study in regional registries. CDC remains committed to conducting public health surveillance, monitoring, and tracking trends in chronic disease risk factors, incidence, and mortality while enhancing access and utilization of population-based surveillance data at the State and local level.

Pediatric cancer is an important public health issue, and has far reaching social, emotional, and physical impacts on children and their families. CDC has implemented a range of key activities related to the Caroline Pryce Walker Conquer Childhood Cancer Act. To date, CDC has:

—Hosted an expert panel to identify gaps in pediatric cancer research and surveillance. This panel helped inform CDC's decision to build cancer registry infrastructure in ways that facilitate pediatric cancer research, enhance registry capacity and reporting speeds, and create new data linkages for research use.

—Secured contractor support to simplify and streamline the process for seeking multiple State institutional review board (IRB) approval for conducting pediatric cancer research. Work is being done to assess State level barriers to research across multiple States requiring linkage to registries or patient contact, and to identify optimal State policies for research.

—Developed a Funding Opportunity Announcement (FOA) to supplement 12 central cancer registries through NPCR to support pediatric cancer surveillance, including early case capture. Funded cancer registries will identify, recruit, and train all potential sources for reporting pediatric and young adult cancer cases, and develop procedures and mechanism to implement early case capture. This FOA will be released in summer 2011.

CDC ENVIRONMENTAL HEALTH (HEALTHY HOMES/LEAD POISONING PREVENTION)

*Question.* The President's budget proposes to consolidate and reduce by 50 percent the funding for CDC's Healthy Homes/Lead Poisoning Prevention. I am particularly concerned that the budget proposes reducing funding for a program—designed to ensure safe housing—that is extremely cost effective particularly for New England.

In Rhode Island, 70 percent of the State's housing stock was build prior to 1978, when the use of lead paint was prevalent and 10 percent are still in need of desperate repair. Over the past 10 years, Rhode Island has received $40 million for lead poisoning prevention initiatives and, as a result, just 2.3 percent of children are found to have elevated lead blood levels in 2007, which is down from 8.8 percent in 1997.

Cuts to this program will fall squarely on the backs of low-income families and communities of color since they are disproportionately impacted by environmental health hazards. It will result in a decrease in blood lead screening rates and efforts to eliminate lead hazards that still exist today. What are the long-term impacts that reducing this funding will have on States, healthcare costs, lost school days for students, and loss of productivity for parents?

Answer. The goal of the new CDC Healthy Environments consolidated program is to maintain a multi-faceted approach through surveillance, partnerships, implementation and evaluation of science-based interventions to address the health impact of environmental exposures in the home and to reduce the burden of asthma through comprehensive control efforts. As the Healthy Environments program is implemented, the number of funded recipients will decrease from 40 to 34 to implement Healthy Homes programs and only State health departments will be eligible to apply for funding; this will help save significant overhead costs as fewer resources will need to be devoted to grantee management when there are fewer individual grantees. A healthy homes approach works to mitigate health hazards in homes such as lead poisoning hazards, secondhand smoke, asthma triggers, radon, mold, safe drinking water, and the absence of smoke and carbon monoxide detectors. Findings indicate that multi-component, multi-trigger home-based environmental interventions are effective at improving overall quality of life, reducing healthcare costs and improving productivity. By integrating the National Asthma Control Program (NACP) and the Healthy Homes/Childhood Lead Poisoning Prevention Program, CDC's aim is to establish and maintain a more coordinated approach to this multifaceted public health challenge.

*Question.* Can you please explain the impact on Rhode Island, and the country, if discretionary funding were to be reduced from its current 2010 level, in terms of patients served, patient health status, and the economy as a whole?

Answer. Reductions in the annual health center appropriation level will impact the ability of the Health Center Program to meet projected patient targets nationally and in Rhode Island. Depending on the size of the reduction, it may limit or eliminate the Program's ability to expand the program and/or sustain current program investments and achievements.

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QUESTIONS SUBMITTED BY SENATOR MARK PRYOR

*Question.* I understand that the Health Resources and Services Administration funding is proposed to be reduced in the Administration's fiscal year 2012 budget proposal. Further, the Administration is proposing to eliminate the Public Health Improvements account based on the fact that this account is entirely earmarked.

What Federal funding streams are available for hospitals to apply for facilities and equipment grants?

Answer. The Health Resources and Services Administration's (HRSA) Office of Rural Health Policy (ORHP) published a manual last year, targeted to critical access hospitals, outlining the various steps involved in planning, financing and carrying out construction projects.HRSA also facilitates the funding of equipment for rural hospitals to provide or receive clinical services at a distance through the Telehealth Network Grant Program (TNGP) administered by HRSA/ORHP's Office for the Advancement of Telehealth (OAT). The TNGP supports not-for-profit organizations and offers up to $250,000 per year in funding to demonstrate how telehealth programs and networks can improve access to quality healthcare services in underserved rural and urban communities. By statute, the TNGP limits equipment expenditures to 40 percent of each grant award. We anticipate that a TNGP funding opportunity announcement will be released in fiscal year 2012, subject to appropriations. Although the TNGP funds equipment, its focus is the funding of telehealth networks that provide clinical services to underserved populations and the evaluation of telehealth technology's effectiveness.

*Question*. Are any of these funding sources targeted at rural hospitals?

Answer. Rural Hospitals are eligible to apply for the USDA funding and TNGP funding. The Telehealth Network Grant Program (TNGP), administered by the Health Resources and Services Administration (HRSA)/Office of Rural Health Policy's (ORHP) Office for the Advancement of Telehealth (OAT) is a primary conduit for demonstrating how telehealth programs and networks can improve access to quality healthcare services in underserved rural and urban communities. TNGP grants demonstrate how telehealth networks improve healthcare services to: (a) expand access to, coordinate, and improve the quality of healthcare services; (b) improve and expand the training of healthcare providers; and/or (c) expand and improve the quality of health information available to healthcare providers, patients, and their families.

*Question.* The fiscal year 2012 budget request for LIHEAP totals $2.569 billion. This is down from an fiscal year 2011 request of $5.3 billion and an fiscal year 2010 enacted level of $5.1 billion.

While I understand the budget constraints that we are facing right now, I am concerned about families losing this assistance. What resources are out there to assist families with energy costs in lieu of LIHEAP assistance?

I know there are several formulas used to calculate how funding is distributed. In Arkansas, we are put at a disadvantage in the summer months because most of the funding is spent on heating during the winter and little is left over for cooling during the summer. Residents in southern States rely on LIHEAP for cooling as well as heating. How can the LIHEAP funding be adjusted so that southern States can better help their citizens during the hot summer weather?

Answer. Several other ACF programs, including TANF and the Social Services and Community Services Block Grants, provide assistance to low income people which may be used for home energy costs. Outside of HHS, assistance for home weatherization is provided by the Department of Energy. The fiscal year 2012 President's budget requested $320 million for this purpose, an increase of 52 percent above fiscal year 2010. States also provide substantial home energy assistance, $2.6 billion in fiscal year 2009, primarily from rate assistance from publically regulated utilities and State/local home energy assistance funds.

LIHEAP block funds are distributed to States by statutory formula. States determine how to distribute their allocation between heating and cooling assistance. Prior to 1984, funds were allocated to States based largely on their numbers of low income people and the National Weather Service's standard measure for the need for heat. In 1984, Congress enacted the new formula to adjust State allocations to reflect total home energy costs (heating and cooling) by low income households. This formula takes effect when the appropriation for the formula grant exceeds $1.975 billion. Since fiscal year 2009, LIHEAP appropriation language has capped the amount of funding distributed by the new formula at $840 million.

*Question.* Frequently, I hear concerns about the availability of healthcare providers in rural areas. Many of the rural areas in Arkansas have an aging community of healthcare providers, and the citizens of those communities are worried about preserving access to care. Can you discuss priorities you are working on to ensure we have enough healthcare providers to deliver quality healthcare in rural areas?

Answer. The President's budget included funding to support rural healthcare that focus on improving recruitment and retention of healthcare providers in rural areas. The Health Resources and Services Administration's (HRSA) National Health Service Corps (NHSC) serves as a key resource in this area as 60 percent of the placements for NHSC practice in rural areas. In addition, HRSA's Office of Rural Health Policy is funding the Rural Training Track (RTT) Technical Assistance Center grant to support the existing rural training tracks around the country and to assist communities in developing new RTT programs. HRSA also supports the work of the National Rural Recruitment and Retention Network, a 50 State consortium of clinician recruiters who work to match doctors, nurses and dentists with an interest in rural practice with rural communities in need of a practitioner. Last year, the Rural Recruitment and Retention Network supported the placement of more than 1,030 clinicians in rural areas.

*Question.* State-based health insurance exchanges will be created to make affordable, quality insurance options available to every American. Debates have been taking place in some States about whether or not States should move forward in setting up exchanges that will be run by State governments before the Supreme Court rules on the constitutionality of the individual mandate. Can you briefly describe the opportunities States have to establish exchanges and what the role could be for either State governments or the Federal Government depending on what decisions States make?

Answer. To receive a multi-year Establishment grant, States must commit to establishing an Exchange. Recognizing that not all States are far enough along to make this determination, grants for up to 1 year of funding will not require a State to commit to operating its own Exchange. By statute, Territories must commit to establishing, and ultimately establish, an Exchange to receive any Exchange grant funding.

Through both the Planning and Establishment grants, States are held to achieving milestones for important Exchange implementation activities such as insurance market research, stakeholder consultation, and assessment of current State eligibility and enrollment systems. If a State ultimately chooses not to implement its own Exchange, or HHS determines a State is not ready to operate an Exchange by 2014, HHS may benefit from this work when it establishes a federally operated Exchange in that State.

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## QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

### CLASS ACT

*Question.* The CLASS Act attempts to address an important public policy concern—the need for non-institutional long-term care—but it is viewed by many experts as financially unsound. The President's fiscal commission recommended reform or repeal of the CLASS Act. You stated to health advocacy groups that, "it would be irresponsible to ignore the concerns about the CLASS program's long-term sustainability in its current form." The President's budget proposal includes a request of $120 million for the CLASS Act, which would be the first discretionary appropriation for the program. If you are unable to certify that it will be sustainable absent a massive taxpayer infusion of funds, why would Congress want to appropriate the requested $120 million in taxpayer funds for a program that experts project will fail?

Answer. We share your view that the CLASS Act addresses an important public policy concern. About 14 million people spend more than $230 billion a year on long-term services and supports to assist them with daily living. Four times that many rely solely on unpaid care provided by family and friends. Despite public misperception that Medicare and Medicaid will cover their long-term care costs, Medicare is only available for time-limited coverage of very specific types of skilled nursing facility services and while Medicaid is the largest public payer of these services, it is only available for people with few financial resources, such as those who were forced to spend their retirement on long-term care and have no place left to turn. The CLASS program represents a significant new opportunity for all Americans who work to prepare themselves financially to remain as independent as possible under a variety of future health circumstances.

The Affordable Care Act requires HHS to develop an actuarially sound benefit plan that is fiscally sustainable. The discretionary request will finance the start up costs associated with establishing the CLASS program. All programs have start up costs, and this one is no different. This funding will be used to establish a solid benefit plan, develop an IT system to help consumers enroll, and implement an information and education plan to ensure participation and fiscal sustainability. This bridge will enable the program to begin enrolling individuals and collecting premiums, which will then be used for benefits once participants are vested and have an eligible claim.

I appreciate your consideration of this request, recognizing that HHS is still in the process of developing the actuarially sound benefit plan. We will not implement a program unless it is solvent and sustainable, as required by the statute. Prior to collecting any premiums, HHS will publish a notice of proposed rulemaking and present three actuarially sound benefit plans, as required by statute, to the CLASS Independence Advisory Council. These transparent processes will help HHS ensure the CLASS program starts with every expectation of sustainability; thus, the $120 million request will help the program with its critical startup activities, such as ensuring a significant education and outreach effort for broad enrollment.

*Question.* What will prevent from the Department from subsidizing this alleged self-sustaining program with taxpayer funds once it is implemented and then fails?

Answer. The law clearly states that the program must be able to pay for benefits with the premiums it takes in and that no taxpayer dollars may be used to pay for CLASS benefits. Section 3208(b) of the CLASS Act prevents HHS from using taxpayer funds to pay benefits. Specifically, the Act states "No Taxpayer Funds Used To Pay Benefits—No taxpayer funds shall be used for payment of benefits under the CLASS Independent Benefit Plan. For purposes of this subsection, the term 'tax-

payer funds' means any Federal funds from a source other than premiums deposited by CLASS program participants in the CLASS Independence Fund and any associated interest earnings."

*Question.* The budget proposal for the CLASS Act includes $93.5 million in new Federal spending for "information and education" to ensure that an adequate number of individuals will enroll in the program. While I do not agree with Congress appropriating $120 million for an insolvent program, it makes even less sense to spend $93.5 million of that funding to promote a program that we know as currently structured will fail. How do you justify spending such a large sum of money on promotion efforts given you will be a promoting a program that is not yet defined?

Answer. This $93.5 million will be used to educate Americans about the immense costs of long-term care and their ability to financially prepare for these costs. While a direct objective of this effort will be to expand the risk pool of individuals voluntarily enrolling in the CLASS program, we expect it to also help Americans begin other private preparations for these costs and ultimately reduce demands on State and Federal budgets. By October 1, 2012, HHS is required by statute to designate an actuarially solvent benefit plan that is solvent throughout a 75-year period. These funds will be used to promote this benefit plan, which will have been made available for comment before final designation.

*Question.* Given the significant actuarial concerns raised about the solvency of the CLASS program, will you agree that all education and outreach materials about the CLASS program will be vetted by independent actuaries who can attest to their completeness and accuracy? I am concerned because it is my understanding that the Medicare actuary did not sign off on the 2010 Medicare mailer that stated, "keep Medicare strong and solvent." Clearly, that statement was not entirely accurate and CMS spent $18 million to distribute these false claims.

Answer. HHS is required to designate an actuarially sound benefit plan that is solvent throughout a 75-year period. By law, the methods and assumptions used to determine the actuarial status of the CLASS Independence Fund will be reviewed and certified by the Chief Actuary of the Centers for Medicare & Medicaid Services and the financial solvency of the program will be documented in an annual report to Congress. The education and outreach materials will be consistent with these reviews.

*Question.* Modeling suggests that if you have a 2–3 percent participation rate the program is not sustainable. Absent massive media campaigns, how do you know that there will be greater participation? How do you know the market will receive this concept?

Answer. Broad participation is necessary to mitigate adverse selection and ensure the solvency and sustainability of the CLASS program. The proposed $93.5 million information and education effort will help inform eligible Americans about enrolling in the program. In addition, HHS will focus on recruiting employers to participate in the program, further improving enrollment. We also intend to conduct research to determine the best ways to communicate with consumers about the program and their options, and we will discuss the findings from this research with the CLASS Independence Advisory Council to help inform our estimates of participation in the program.

*Question.* On March 22, the Wall Street Journal highlighted the problems with the Social Security Disability Insurance system, including the inconsistent standards used by State offices that adjudicate claims. As an example, the article pointed to one administrative law judge in Puerto Rico that approved 98 percent of the Social Security disability claims he heard during fiscal year 2010. I am concerned that the inconsistent standards across States in the Social Security Disability Insurance system could apply to the CLASS Act. Secretary Sebelius, will the CLASS Act require a new State-based system to process claims and if so, how will you ensure standards remain consistent across States?

Answer. Section 3205 of the statute precludes use by the CLASS program of the State determination system for Social Security disability claims. At this time, we are considering how to implement the eligibility assessment process through which participants will claim benefits. Considering the voluntary, self-funded nature of this national program, we believe the eligibility assessment system should be consistent across the Nation. Thus, one possible approach that we are considering is contracting with a neutral third-party administrator, like the type servicing private long-term care insurance carriers, to ensure standardization of assessments consistent with the CLASS Act and its regulations.

PREVENTION AND PUBLIC HEALTH FUND

*Question.* If the Prevention and Public Health Fund is repealed, how will agencies fund the programs you have moved?

Answer. The Administration strongly opposes legislation that attempts to erode the important provisions of the Affordable Health Care that are making healthcare more accessible and affordable for all Americans. The Prevention and Public Health Fund is central to reducing the burden of chronic disease and reducing the healthcare costs associated with treating these diseases. Repeal of the Prevention and Public Health Fund would affect current year plans and have a direct programmatic impact. The Prevention Fund is central to reducing the burden of chronic disease and reducing the healthcare costs associated with treating these diseases. HHS has not replaced the entire base of program funding with Prevention and Public Health resources. Rather, the fiscal year 2011 allocation primarily builds on the prevention activities underway at HHS.

*Question.* The Affordable Care Act gives the Committee on Appropriations transfer authority for the mandatory funding provided through the Prevention and Public Health Fund. In fiscal year 2010, the Prevention Fund transferred $500 million toward prevention efforts, and in fiscal year 2011 $750 million should be transferred. Each fiscal year 2011 continuing resolution that has passed has included the transfer of these funds. Clearly it is the intent of the Committees on Appropriations to direct the transfer of this funding. Yet, you announced a spending plan for these funds on February 9, 2011, without the enactment of a full year appropriations bill. This means those dollars will be obligated without any congressional input or oversight. Is it the Department's intention to obligate these funds without Congressional transfer authority?

Answer. The Affordable Care Act in section 4002 gives the Committee on Appropriations transfer authority for the mandatory funding provided through the Prevention and Public Health Fund. If Congress had directed the transfer of fiscal year 2011 Prevention and Public Health Fund resources, the Department would have followed the transfer provided in law. The full-year appropriations bill for fiscal year 2011, however, did not direct the transfer of these funds, and section 4002 of the Affordable Care Act gives the Secretary authority to transfer resources from the appropriated amount within HHS.

*Question.* OMB claims that the "Education Research Centers overlap activities offered by the Department of Labor's Occupational Safety and Health Bureau." However, the mandate of the two agencies is different. The National Institute for Occupational Safety and Health is mandated to conduct research and provide professional training in occupational safety and health, while OSHA is mandated to regulate occupational safety and health conditions in the workplace and provide worker training. Therefore, Madam Secretary, where is the overlap?

Answer. OSHA's Outreach Training Program (OTP), OSHA Training Institute (OTI) Education Center, and Resource Center Loan Program all focus on employee training. OTP provides employee training in basic occupational safety and health courses in construction or general industry safety and health hazard recognition and prevention while the Resource Center Loan Program offers a collection of training videos to help increase employee knowledge of workplace safety. The OSHA Training Institute (OTI) Education Center program was initiated as an extension of the OSHA Training Institute, which is the primary training provider of the Occupational Safety and Health Administration. OTI targets Federal and State compliance officers and State consultants, other Federal agency personnel, and the private sector. While these programs focus on employee training, the ERCs support professional training and provide academic programs and research training in the core areas of industrial hygiene, occupational health nursing, occupational medicine, and occupational safety.

*Question.* The OMB justification for elimination of Education Research Center's is that the original programmatic plan was to provide funding for institutions to develop and expand existing occupational health and safety training programs and that this goal has been met. However, the statutory goal of the Education Research Centers is "to provide an adequate supply" of qualified occupational safety and health professionals. Has this goal been met? Before you answer, Madam Secretary, I would like to point out that according to the Bureau of Labor Statistics, employment of occupational health and safety specialist and technicians is expected to increase 11 percent during the timeframe of 2008–2018.

Answer. No. The establishment of a set of high quality training programs was the necessary first phase of the original long-range plan. The subsequent and critical steps for providing an adequate supply of qualified safety and health practitioners and researchers require ongoing resources to provide trainee support (for example,

stipends, tuition and fee reimbursement, and research supplies), and to maintain the training program infrastructure, which includes a high-quality faculty and training environment. Within the context of a budget that requires tough choices, we put forth a proposal to discontinue Federal funding for the ERCs. We recognize the vital role of occupational safety and health professional training. This proposal is one of many difficult reductions we proposed as part of the fiscal year 2012 budget.

*Question.* In the fiscal year 2012 budget request, the President eliminates funding for the Children's Hospitals Graduate Medical Education program. In explaining the elimination, the Administration said it "prefers to focus on targeted investments to increase the primary care workforce." Although they represent 1 percent of all hospitals, children's hospitals train more than 40 percent of general pediatricians. Since the inception of the program, children's hospitals have increased their training by 35 percent, helped address workforce shortages, and improved access to care. When there is a need for an expanded physician workforce nationwide, why are you supporting the elimination of a program that trains the primary care workforce for children?

Answer. Within the context of a budget that requires tough choices, we put forth a proposal to discontinue these general subsidies. This proposal is one of many difficult reductions we would not have put forth under different fiscal circumstances. We recognize the vital role that children's hospitals and pediatric providers play in providing quality healthcare to our Nation's children.

Children's hospitals would continue to be able to compete for funding through the competitive grant programs for which they are eligible. For example, six children's hospitals received over $16 million in fiscal year 2010 from the Primary Care Residency Expansion program funded by the Affordable Care Act. Pediatric residencies can also be supported through the new Teaching Health Center Graduate Medical Education Program created by the Affordable Care Act, which supports primary care medical residents in community-based ambulatory care settings.

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## QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

*Question.* The President's fiscal year 2012 budget for the Department of Health and Human Services proposes the elimination of the Delta Health Alliance at the Health Resources and Services Administration and also proposes the elimination of the Delta Chronic Disease Assessment and the Centers for Disease Control and Prevention. Mississippi has the highest obesity rate in the nation. What are your plans to address the health problems in the Mississippi Delta region?

Answer. The Health Resources and Services Administration (HRSA) currently supports 21 Health Centers in Mississippi and they focus on providing access to quality healthcare for underserved populations. In addition, HRSA's Office of Rural Health Policy (ORHP) has several grant programs which are available to address health disparities in the Mississippi Delta Region.

### MISSISSIPPI STATE DEPARTMENT OF HEALTH FUNDING

*Question.* The President's budget proposes the elimination of the Preventive Health and Health Services Block Grant and proposes a new consolidated chronic disease grant program at the Centers for Disease Control and Prevention. The budget justification says this new grant program will not be a formula grant structure, but rather it will be competitive. Rural areas and States without capacity will be disproportionately affected by competitions. I am concerned that the new chronic disease grant program will create a scenario where the rich get richer and the poor get poorer. What are your plans to ensure that State health departments have the capacity to compete for funds at the Centers for Disease Control?

Answer. Chronic diseases—such as heart disease, stroke, cancer, diabetes, and arthritis—are among the most common, costly, and preventable of all health problems in the United States. Historically, CDC has funded categorical programs in State health departments to address these diseases as well as their common risk factors of obesity, poor nutrition and/or inadequate physical activity. Under the current structure, not all States are funded for these programs.

Because of the inter-relatedness of many common chronic diseases and their risk factors, the Coordinated Chronic Disease Prevention and Health Promotion Grant Program will support essential public health functions at the State level including epidemiology, evaluation, policy, communications and program management. Such an approach will strengthen State based coordination and therefore improve program efficiencies, provide leadership and support for cross-cutting activities and enhance the effectiveness of chronic disease prevention and risk factor reduction efforts across the included categorical programs.

State health departments are eligible to receive funding through the Coordinated Chronic Disease Prevention Program. State health departments are required to deliver programming that reaches across the State and reduces specific disparities within the State, including rural areas. In addition, recognizing the importance of supporting all States, including rural areas, $115 million of the $528 million available is intended to support all State health departments, territories, and some Tribes to establish or strengthen leadership, expertise, coordination of chronic disease prevention programming, surveillance and evaluation. In addition, health departments will be eligible to apply for competitive awards to strengthen coordination of chronic disease prevention programs and implement evidence-based prevention strategies. These competitive grants to State health departments, territories, some tribes and other entities will support activities addressing:

—Policy and environmental approaches to improve nutrition and physical activity in schools, worksites and communities;

—Interventions to improve delivery and use of selected clinical preventive services; and

—Community programs to support chronic disease self management to improve quality of life for people with chronic disease and to prevent diabetes, heart disease and cancer among those at high risk.

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QUESTIONS SUBMITTED BY SENATOR LAMAR ALEXANDER

*Question.* As a former Governor, I am deeply concerned with the Medicaid expansion in the new health law. Tennessee's previous Governor Bredesen, a Democrat, has called it "the mother of all unfunded mandates" and estimated that it will cost Tennessee and additional $1.1 billion for 2014–2019, and that is even with the Federal Government is paying 100 percent of the expansion population from 2014–2016. CBO recently estimated that it will cost States $60 billion through 2021.

The new law also mandates that Medicaid primary care physicians be reimbursed at 100 percent of Medicare rates in 2013–2014, for which the Federal Government will pay for those 2 years. But this creates a funding cliff for 2015. To keep doctors in their programs, States will either be forced to continue to pay Medicaid primary care physicians 100 percent of Medicare rates, or these physicians will effectively see a 40–50 percent cut for in 2015. According to the TennCare Director, the requirement to increase provider reimbursement to 100 percent of Medicare would cost Tennessee roughly an additional $324 million per year.

How are States going to shoulder these additional burdens in the current budget crises most of them are experiencing? Is the administration considering any kind of flexibility options to offer to States in order to avoid being crushed by all the mandates and maintenance of effort requirements?

Answer. We recognize that the economic downturn has forced States to make hard choices to control State spending, and that there are no easy answers. Recognizing the challenges facing States, I sent a letter to Governors in early February outlining existing flexibility and reaffirming the Department of Health and Human Services'—and the Center for Medicare & Medicaid Services'—commitment to working with States to improve care and manage costs in the Medicaid program. As part of that effort, CMS has undertaken an unprecedented level of outreach to States to help them strategize on ways to improve the efficiency of their Medicaid programs in light of current State budget challenges. To accomplish this task, CMS has created Medicaid State Technical Assistance Teams (MSTATs) that are ready to provide intensive and tailored assistance to States on day-to-day operations as well as on new initiatives. As of mid April, CMS has been contacted by 22 States for technical assistance. We are ready to continue working with States to explore new ways to manage their programs that will increase efficiency, reduce spending, and improve health for Medicaid beneficiaries.

*Question.* One of the problems with the Medicaid expansion is that there is an access problem for patients in the program being unable to see a doctor willing to treat them. There are varying reports on providers not willing to see Medicaid patients, like the 2006 report from the Center for Studying Health System Change Only stating that only about one-half of U.S. physicians accept new Medicaid patients.

Even the CMS chief actuary stated in an analysis done in April, ". . . it is reasonable to expect that a significant portion of the increased demand for Medicaid would be difficult to meet, particularly over the first few years."

By adding 16–18 million more people into the program, what is your administration doing to address access issues for all these new beneficiaries?

Answer. I am committed to ensuring access for Medicaid beneficiaries. The Affordable Care Act provision which helps States boost their payment rates to Medicare levels for 2 years is a good first step, as are all of the provisions that reform our healthcare delivery system to align payments with higher quality care. Federal funding will be available to cover 100 percent of the initial cost of the mandated increases in provider payment for primary care services.

The newly formed Medicaid and CHIP Payment and Access Commission (MACPAC) will play an important role by providing research and analysis on provider payment rates and access in the Medicaid program. In the initial MACPAC report, issued in March 2011, there was extensive discussion about the difficulties in analyzing access issues, and the need to develop additional data sources and new analytic approaches. On May 6, 2011, we published a proposed rule that integrated the MACPAC approach into a strategy to develop a transparent process for States to collect and analyze access issues. We anticipate working closely with MACPAC to learn about best practices and approaches in sustaining access in 2014 and beyond.

*Question.* Has HHS done an analysis of how many providers are not seeing new or any Medicaid patients? If not, can CMS look into this?

Answer. Access to providers by Medicaid recipients is of paramount importance. As a requirement for States' participation in the Medicaid program, they must ensure that "payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to the general population in the geographic area." As noted above, CMS is currently undertaking rulemaking to provide guidance to States on compliance with this requirement, which includes a framework for State and Federal review. Through the rulemaking process, we are welcoming public notice and comment on our proposed approach, which provides for States to review access through a three-part framework, focusing on beneficiary needs, provider enrollment, and service utilization.

Because States have primary responsibility for managing data on eligible beneficiaries and for enrolling and reimbursing Medicaid providers, States have the most accurate and up to date information on the number of providers participating in each State's Medicaid program, the percent of those accepting new Medicaid patients, and whether those numbers are comparable to the availability of providers for the general population in the area. Our proposed strategy is to require States to perform the initial analysis of available data and issue access reports for both Federal and public scrutiny.

*Question.* In your January testimony to the HELP Committee, you mentioned tax credits as a way that the law will keep down premiums. I realize that people who receive the tax credits or subsidies will pay less out of their own pocket for premiums, but are you saying that these tax credits/subsidies will bring down the underlying premiums and or the underlying cost of healthcare?

Answer. Many provisions of the Affordable Care Act make healthcare more affordable for American families and businesses, including tax credits and premium assistance, new oversight of private insurance premiums growth, delivery systems reforms that will bend the healthcare cost curve, and larger purchasing pools through Exchanges.

Insurers often raise premiums to protect themselves against unpredictable market conditions. Premium tax-credits offered through Exchanges make health insurance coverage attainable for individuals who have not previously been able to afford the costs of health insurance and will enable wider participation in the health insurance market. Keeping more people in the insurance market at all times, and not just when they get sick, will lead to greater predictability and stability in the individual market.

*Question.* According to estimates from Senate Finance minority tax staff last year, only 7 percent of Americans would qualify for subsidies and would see these cost savings. What about everyone else? Even CBO has said premiums for families buying coverage on the individual market would see premiums increase by $2,100 a year.

Answer. Even after full implementation of health reform, most Americans will continue to receive insurance through their employers, as has traditionally been the case. CBO estimates that nearly 20 million Americans without access to affordable or adequate coverage through their employers or other sources will receive premium tax credits or cost-sharing subsidies through the Exchanges.

*Question.* You also stated in your HELP testimony that the new law "is bringing down premiums for consumers by limiting the amount of premiums insurers may spend on administrative costs and by giving States resources to beef up their review process."

How do you square this statement with recent news articles that some insurers are raising premiums as a result of the new law?

Answer. According to our analysis and those of some industry and academic experts, any potential premium impact from the new consumer protections and increased quality provisions under the Affordable Care Act will be minimal. We estimate that the effect will be no more than 1 to 2 percent. This is consistent with estimates from the Urban Institute (1 to 2 percent) and Mercer consultants (2.3 percent). Insurers themselves have also reached a similar conclusion. Pennsylvania's Highmark, for example, estimates the effect of the legislation on premiums from 1.14 to 2 percent.

Any premium increases will be moderated by out-of-pocket savings resulting from the law. These savings include a reduction in the "hidden tax" on insured Americans that subsidizes care for the uninsured. By making sure that high-risk individuals have insurance and emphasizing healthcare that prevents illnesses from becoming serious, long-term health problems, the law will begin to reduce costs resulting from the treatment of patients at the acute stage of illness. The law prioritizes prevention, making many services available without cost-sharing, invests in prevention in communities across the country, and contains a series of provisions designed to improve the way we pay for care.

In addition to the coverage and delivery system changes that will begin to bend the cost curve, the law provides valuable new tools to ensure that consumers are getting value for their premium dollar. Already, we have provided 44 States and the District of Columbia with resources to strengthen the review and transparency of proposed premiums. CMS is making up to $250 million available for States to improve their rate review infrastructure and to fight unreasonable rates. Rate review allows States to examine and in some cases reject or modify the insurance rate before implementation. At the end of the year, the new medical loss ratio standard requires carriers to rebate premiums back to consumers if they fail to meet the standard. Rate review and medical loss ratios work together to help consumers. We will also keep track of insurers with a record of unjustified rate increases; those plans may be excluded from health insurance Exchanges in 2014.

*Question.* There has been a lot of news coverage lately about the more than 1,100 annual limit waivers granted by your administration. Additionally, several States have applied for waivers from the medical loss ratio (MLR) requirement.

Would it not make more sense for HHS to consider a blanket waiver of annual benefit limits and MLR standards until 2014?

Answer. The Center for Consumer Information and Insurance Oversight (CCIIO)'s waiver policy represents a transition to 2014, when annual limits will be eliminated and limited medical benefit plans will be a thing of the past. Until 2014, the transition ensures that insurance plans that can remove annual limits do so. Those that cannot remove annual limits without significantly raising premiums or reducing access to benefits can receive waivers. This transition assures that Americans can keep this limited coverage until more comprehensive coverage options are available to all in 2014. CCIIO is approving 1 year waivers and collecting data on limited benefits plans that will inform our approach for future years.

The medical loss ratio provision allows CCIIO to adjust the percentage if the potential exists to destabilize the individual market in a State. To date, one State, Maine, has received a reduced loss ratio. Each State market is different and CCIIO has established a process by which a State may apply, if they believe the potential exists for disruption. CCIIO will evaluate each application against the criteria set forth in regulation and guidance.

*Question.* Does the HHS have contingency plans for larger than expected expenditures for subsidies if more employers drop coverage than expected?

Answer. The reforms in the Affordable Care Act are intended to complement and strengthen the existing employer-based insurance system, not to replace it. We believe that the MLR requirements, review of annual rate increases, and delivery system reforms will help slow the growth of insurance costs to businesses so they can continue to provide the insurance their employees and families need and depend on.

The Congressional Budget Office has found that any decrease in employer-sponsored coverage because of the Affordable Care Act would be minimal. On the contrary, the Affordable Care Act provides tremendous benefits for employers that will encourage them to continue to offer health insurance coverage to their employees. In the coming years, the Congressional Budget Office estimates that health insurance premiums could decrease by up to 3 percent for employers. The new law also provides $40 billion in tax credits to help small businesses purchase coverage for their employees. In 2014, small businesses will be able to purchase private insurance through the Exchanges, which will provide them with the same purchasing power as large businesses.

*Question.* In the last Congress, HHS received enormous appropriations of tax dollars with very little Congressional direction on the use of those funds going forward. HHS received $1 billion as part of the Federal stimulus program and approximately $2 billion more per year in the future as part of the new healthcare law, all for the Mobilizing for Action through Planning and Partnerships (MAPP) intervention grants. HHS was given these enormous streams of taxpayer dollars without clear direction on the specifics of how those funds should be used.

CDC appears to be using these taxpayer dollars to fund advocacy organizations at the State and local level who engage in legislative advocacy for higher taxes and restrictions focused on consumer goods, which raises a number of serious concerns. Using Federal tax dollars for legislative advocacy is against the law, as the appropriation itself is subject to a restriction clearly prohibiting that the agency from using Federal funds to engage in direct or grassroots lobbying for changes in State or local laws. There also is a Federal criminal statute—the Anti-Lobbying Act—making it a criminal offense to "influence in any manner . . . an official of any government, to favor, adopt, or oppose, by vote or otherwise, any legislation, law, ratification, policy or appropriation."

As a former Governor, I think it is totally inappropriate for the executive branch to unilaterally decide what is or isn't a good State or local law worthy of financial support. If the Administration has a legislative agenda, it should work with the Congress to enact it through the legislative process.

In response to questions about the use of these funds during congressional hearings last year, CDC Associate Director Pechachek, stated that, "The prohibition against lobbying does not mean that communities are prohibited from interacting with policy makers such as legislators in order to promote the goals of the Communities Putting Prevention to Work Program."

How can a program have as a main, underlying objective to seek changes in State and local laws when the Federal Government specifically prohibits the use of Federal grant moneys to engage in direct or grassroots lobbying? Do you agree with this concern?

How much of the billions of dollars in spending under the stimulus and new healthcare law has been used to support efforts to change local and State laws? Would you provide this Committee with the details of that information?

Answer. As part of the American Recovery and Reinvestment Act (ARRA), Congress provided $650 million in funding for CDC to implement the Communities Putting Prevention to Work (CPPW) program. In addition, approximately $44 million from the Prevention and Public Health Fund supported quality but unfunded CPPW grantees, as well as media and evaluation, in fiscal year 2010. CPPW grantees are tackling important health problems, focusing on tobacco, nutrition and physical activity. Addressing these health challenges requires action at the community level, often to make changes that give individuals greater opportunities to make healthy choices.

CDC strictly adheres to all Federal laws prohibiting the use of Federal funds to lobby, and even goes beyond statutory requirements to restrict the activities of grantees at the local level when Federal funds are involved. CDC regularly educates all grantees on Federal laws related to funding awards, including anti-lobbying provisions. CDC references Additional Requirement (AR)-12 "Lobbying Restrictions" in all of its Funding Opportunity Announcements (FOAs), and all prospective recipients must agree to these restrictions prior to receiving funds. The AR states, in part, "Any activity designed to influence action in regard to a particular piece of pending legislation would be considered 'lobbying.' That is, lobbying for or against pending legislation, as well as indirect or 'grass roots' lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies."

CDC is careful to monitor the use of Federal funding, and to ensure that grantees comply with Federal law and the specific guidance of the Funding Opportunity Announcement and conditions outlined in the AR–12. However, anti-lobbying provisions do not prohibit communities from interacting with policymakers through proper official channels, in order to educate them about the burden of chronic diseases and their associated risk factors, as well as evidence-based strategies to promote health. There are many activities that are allowable under Federal law which community leaders may decide to pursue; moreover, policy change does not have to include formal legislative action. For example, health departments may choose to work with local transportation and planning departments to ensure that urban design policies include opportunities for people to be active. Local businesses may voluntarily decide to change their food procurement policies and to provide a greater

selection of healthy food options for employees in vending machines and cafeterias. Transit systems may determine on their own to make their trains and buses smoke-free. Each of these is an example of a type of policy change that impacts people in their daily lives, without requiring legislative action at the local, State, or Federal levels.

CDC supports community efforts to foster these types of linkages between health departments and key stakeholders from multiple sectors across a community, while strictly adhering to all Federal laws prohibiting the use of Federal funds to lobby. CDC carefully monitors the activities of grantees and the use of Federal funds to ensure compliance with Federal law, the specific guidance of the Funding Opportunity Announcement, and conditions outlined in AR–12.

*Question.* One of the major concerns I have heard from constituents about the new health law is that it will lead to government control and rationing. Treatment choices should be made between doctors and patients, rather than by folks in Washington, DC.

While the FDA has announced its decision to withdraw its approval for Avastin for breast cancer treatment, the European equivalent (the EMEA) has confirmed the use of Avastin for breast cancer. Shouldn't American women on Medicare have access to this drug as well?

Answer. I recognize the critical importance of the physician-patient relationship, especially in deciding an appropriate drug therapy treatment. The Medicare statute authorizes coverage of items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury in the Medicare population.

At this time, CMS is not making any changes to its coverage or reimbursement policies for Avastin and is waiting until the resolution of the FDA process before deciding whether to make any changes. While we do periodically consider new evidence about Medicare-covered drugs or treatments to evaluate whether changes in coverage decisions are warranted, it would be premature to speculate on possible changes in Medicare coverage of Avastin, if any, that may be made in response to future FDA actions.

*Question.* Avastin is an expensive treatment option. Can you affirm that the FDA was looking purely at science rather than the cost of the drug when making its decision?

Answer. The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring that drugs and biologics are safe and effective. In determining whether a product should be labeled for a particular indication, FDA takes seriously our obligation to carefully weigh the risks and benefits for the patient. Specifically, FDA considers whether the benefits of the drug, including the magnitude of those benefits, outweigh the product's potential toxicities for the indicated use. The Food and Drug Administration does not factor costs into its drug approvals or safety related decisions. FDA's Center for Drug Evaluation and Research has proposed to remove Avastin's indication for metastatic breast cancer based on the Center's evaluation of efficacy and safety data available from clinical trials, without considering the cost of the drug. FDA has not yet reached a final decision on this proposal, and this matter will be the subject of a hearing in June 2011.

*Question.* More than 40 States have laws in place to ensure those on private insurance have access to cancer drugs even if they are "off-label." Shouldn't women on Medicare have the same guarantee?

Answer. At this time, CMS is not making any changes to its coverage or reimbursement policies for Avastin and is waiting until the resolution of the FDA process before deciding whether to make any changes. While we do periodically consider new evidence about Medicare-covered drugs or treatments to evaluate whether changes in coverage decisions are warranted, it would be premature to speculate on possible changes in Medicare coverage of Avastin, if any, that may be made in response to future FDA actions. I would note, however, that, generally, Medicaid coverage of a drug is contingent upon that drug having FDA approval. I cannot speak to the process behind the coverage decisions of other insurance providers.

*Question.* If many of the roughly 18,000 women using Avastin for metastatic breast cancer find it effective, and scientific experts at the National Comprehensive Cancer Network, the leading cancer compendia, support its use, can you assure me that Medicare will not restrict coverage of this product?

Answer. I recognize the critical importance of the physician-patient relationship, especially in deciding an appropriate drug therapy treatment. The Medicare statute authorizes coverage of items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury in the Medicare population.

At this time, CMS is not making any changes to its coverage or reimbursement policies for Avastin and is waiting until the resolution of the FDA process before deciding whether to make any changes. While we do periodically consider new evi-

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QUESTIONS SUBMITTED BY SENATOR LINDSEY GRAHAM

*Question.* Can you explain FDA's process for approving drugs for new indications?

Answer. Secretary Sebelius: In order for a new indication for a drug or biologic product to be marketed in the United States, it must be shown to be safe and effective for its intended new use.

In 1998, FDA published guidance for manufacturers planning to file applications for new indications of approved drugs or biologic products. In this guidance, FDA articulated its thinking on the quantity of evidence needed in particular circumstances to establish substantial evidence of effectiveness. The guidance discussed the standards and data requirements for approval of new indications so that duplication of data previously submitted in the original application could be avoided. In particular, FDA addressed situations in which a single adequate and well-controlled trial of a specific new use could be supported by information from other adequate and well-controlled trials, such as trials in other stages of a disease, or in closely related diseases.

The new drug or biologics licensing application that is submitted by the manufacturer in support of a new indication must include the requisite clinical trial information demonstrating safety and effectiveness, and supportive clinical pharmacology, preclinical and product quality information, as needed. FDA scientists review the submitted information and determine whether or not the product may be approved for the new use if the benefits of treatment are found to outweigh the risks for the intended population.

*Question.* Am I correct in my understanding that FDA does not consider the cost of a drug during its approval process? If cost is considered, how does that cost factor into FDA's decision to approve drugs for certain indications?

Answer. Yes, you are correct. In deciding whether to approve a drug, FDA cannot and does not take price into account.

*Question.* I am aware that Avastin is a very expensive drug, and I have been made aware of concerns that cost could have been a factor in FDA's decision to remove the breast cancer indication from Avastin's label. Did Avastin's cost play any role in FDA's decision regarding the drug?

Answer. The Food and Drug Administration is responsible for protecting the public health by ensuring that drugs and biologics are safe and effective. In determining whether a product should be labeled for a particular indication, FDA takes seriously its obligation to carefully weigh the risks and benefits for the patient. Specifically, FDA considers whether the benefits of the drug, including the magnitude of those benefits, outweigh the product's potential toxicities for the indicated use. The Food and Drug Administration does not factor costs into its drug approvals or safety related decisions. FDA's Center for Drug Evaluation and Research has proposed to remove Avastin's indication for metastatic breast cancer based on the Center's evaluation of efficacy and safety data available from clinical trials, without considering the cost of the drug. FDA has not yet reached a final decision on this proposal, and this matter will be the subject of a hearing in June, 2011.

*Question.* What is HHS's policy for awarding grants to organizations that advocate for specific policy positions?

I have heard concerns that Federal stimulus dollars targeted to public health were awarded to advocacy organizations who lobby State and local governments for specific policy changes regarding food and beverages. Can you provide details regarding the grant-making process for public health programs including the information required for proposal when submitted and how often HHS audits grant recipients to be sure they are complying with the aims of the HHS' grant programs?

Answer. Applicants for (and recipients of) Federal grants, cooperative agreements, contracts, and loans are prohibited by 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," from using appropriated Federal funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a member of Congress, an officer or employee of Congress, or an employee of a Member of Congress with respect to the award, extension, continuation, renewal, amendment, or modification of any of these instruments. These requirements are implemented for HHS in 45 CFR part 93, which also describes types of activities, such as legislative liaison activities and professional and technical services that are not subject to this prohibition. Appli-

cants for HHS grants with total costs expected to exceed $100,000 are required to certify that they: have not made, and will not make, such a prohibited payment; will be responsible for reporting the use of non-appropriated funds for such purposes; and will include these requirements in consortium agreements, other subawards, and contracts under grants that will exceed $100,000 and will obtain necessary certifications from those consortium participants and contractors.

Disclosure reporting is required after award as indicated and must be certified annually either through providing submitting disclosure statements by doing so on the SF–LLL, Disclosure of Lobbying Activities. Where there are no disclosures to report the grantee certifies this fact by signing the face page of the application without the need to submit the forms. The grantee certifies that there are no lobbying activities to report when they sign the face page of the application.

Consistent with Federal law, in its grant programs, CDC references Additional Requirement (AR)-12 "Lobbying Restrictions" in all of its Funding Opportunity Announcements (FOAs), and all prospective recipients must agree to these restrictions prior to receiving funds. The AR states, in part, "Any activity designed to influence action in regard to a particular piece of pending legislation would be considered 'lobbying.' That is, lobbying for or against pending legislation, as well as indirect or 'grass roots' lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies."

CDC is careful to monitor the use of Federal funding, and to ensure that grantees comply with Federal law, the specific guidance of the FOAs, and conditions outlined in AR–12. Grants or cooperative agreements funded by the American Recovery and Reinvestment Act are also subject to this policy. We note, however, that many organizations engage in advocacy using funding from other sources, and that this does not bar them from applying for and receiving funding from CDC. Recipients are permitted to use their own funds to lobby, so long as it can be demonstrated or shown that the funds that were used for lobbying were entirely separate from any appropriated funds they received from the Federal Government. Recipients are required to disclose all lobbying activities along with their application. CDC only provides funds to undertake activities outlined in the FOA.

CDC's Procurement and Grants Office (PGO) provides specific budgetary oversight to ensure the appropriate use of Federal funds. CDC grants management specialists and program staff are significantly involved in the planning and monitoring of recipient activities, review and approval of spending details, and tracking of grantee drawdown of funds. PGO staff participate in annual site visits to all funded communities. One example is the Communities Putting Prevention to Work (CPPW) program, which has a robust plan for performance monitoring in order to ensure that Federal funds are used effectively and appropriately. The plan positions CDC staff to identify early warning signs that a program is using Federal funds for unauthorized and inappropriate activities. Furthermore, an electronic performance monitoring system provides a central repository for collecting information from a number of program monitoring sources. CDC also complies with other mandatory directives, such as OMB Circular A–133, which requires every organization receiving $500,000 in aggregate Federal grants to submit to annual financial audit. The results of these audits are used in periodic grantee reviews to identify grantees that may present a risk to the control or integrity of fund use.

*Question.* I have heard concerns that Federal stimulus dollars targeted to public health were awarded to advocacy organizations who lobby State and local governments for specific policy changes regarding food and beverages. Can you provide details regarding the grant-making process for public health programs including the information required for proposal when submitted and how often HHS audits grant recipients to be sure they are complying with the aims of the HHS' grant programs?

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be responsible for reporting the use of non-appropriated funds for such purposes; and will include these requirements in consortium agreements, other subawards, and contracts under grants that will exceed $100,000 and will obtain necessary certifications from those consortium participants and contractors.

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SUBCOMMITTEE RECESS

Senator HARKIN. And with that, again, Madam Secretary, thank you and the subcommittee will stand recessed.

[Whereupon, at 11:37 a.m., Wednesday, March 30, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2012

**WEDNESDAY, MAY 4, 2011**

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 10 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Brown, Shelby, and Cochran.

## DEPARTMENT OF LABOR

### OFFICE OF THE SECRETARY

**STATEMENT OF HON. HILDA L. SOLIS, SECRETARY**

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee of Labor, Health and Human Services, and Education, and Related Agencies will now come to order.

First of all, welcome back to the subcommittee, Madam Secretary. Your appearance today comes at a critical point for your Department and for our Nation's workforce.

After a long and difficult recession, our economy is slowly recovering, but too many workers are unemployed or underemployed, and more needs to be done to ensure that all Americans benefit from economic growth, not just the few at the top. At the same time, Congress and the administration must work together to reduce our budget deficits and restore fiscal discipline.

FISCAL YEAR 2011 APPROPRIATIONS BILL

A first step was taken last month when we completed action on the fiscal year 2011 appropriations bill. This bill made significant cuts to the Department of Labor, more than $800 million, or 6 percent below the fiscal year 2010 level. And yet, we maintained important investments in employment and training programs, worker protections, and the fight against the worst forms of child labor. The cuts could have been more damaging. The House alternative, H.R. 1, targeted programs that serve the most vulnerable Americans, including drastically cutting job training for people who have lost their jobs as a result of layoffs. It's hard to see the wisdom of

a cut like that when the real unemployment rate really is close to 16 percent in this country. Thankfully, the fiscal year 2011 bill rejected that approach.

FISCAL YEAR 2012

Now we turn to fiscal year 2012. Regrettably, we already know that programs that benefit American workers are once again being targeted for draconian cuts. The budget passed by the House last month takes the approach that the deficit should be addressed by enacting yet another tax cut bonanza for those at the top while ripping the social safety net for seniors, people with disabilities, and low income, and slashing funding for education and training. In fact, the House budget would cut education and training programs by 15 percent in fiscal year 2012.

I believe there's a better way, and history offers a guide. When President Clinton took office in 1993, he faced a similar situation in terms of the budget. He proposed a balanced approach that included spending cuts and necessary revenue increases while continuing to make crucial investments in education, infrastructure, and research, areas that are absolutely essential if we're going to create jobs and stay competitive in the global economy. The plan worked, and worked brilliantly. It created large budget surpluses, 22 million new jobs, and 116 consecutive months of economic expansion, the longest in American history. I believe we need that same balanced approach today.

Madam Secretary, there is no question that the fiscal year 2012 budget for the Department of Labor will remain tight. But, the President rightly puts a high priority on programs that are critical to our long-term fiscal health, especially in the areas of employment and training, as well as a new workforce innovation fund that Congress created in the fiscal year 2011 bill.

I'm also pleased to see that the budget request continues the Disability Employment Initiative that Congress started in fiscal year 2010. With almost 80 percent of Americans with disabilities not currently in the labor force, we need to do much better, and I believe this initiative will help.

Your budget also proposes important investments that will help address mine safety and health, worker misclassification, and workplace safety and health activities. I was particularly pleased to see a proposed increase for Bureau of International Labor Affairs (ILAB), which leads our fight against the worst forms of child labor around the world. And I thank you for that, Madam Secretary.

On a related note, I'd like to thank you for your efforts on the framework of action to support the implementation of the Harkin-Engle Protocol targeted at child labor in the cocoa sectors of Ghana and the Ivory Coast.

Madam Secretary, I know you are well aware of the many important priorities competing for resources in our Labor-HHS appropriations bill. Your testimony in this hearing will help inform us as we do that work.

And before we hear from you, Madam Secretary, I would yield to Senator Shelby for his opening statement.

STATEMENT OF SENATOR RICHARD C. SHELBY

Senator SHELBY. Thank you, Mr. Chairman.

Madam Secretary, I look forward to hearing your testimony today on the 2012 budget request. As the chairman has said, we're in difficult economic times. The unemployment rate is 8.8 percent. When you consider the underemployed and those who have stopped looking for work, which the Department of Labor does not incorporate in the unemployment statistics, the real unemployment rate is actually much higher, at 16.2 percent.

The Federal deficit is $1.65 trillion. In fiscal year 2012, I believe we need to make cuts to our discretionary budget. I don't think we have any choice. The Department of Labor's fiscal year 2012 budget request reduces Federal spending by 5 percent, compared to fiscal year 2010 levels. And while the Department of Labor should be recognized for cutting spending, a feat not accomplished by every Department in the year 2012, I do not believe, myself, a 5-percent reduction within the Department of Labor goes far enough. In this difficult economic environment we need to cut spending today.

DUPLICATION IN DEPARTMENT OF LABOR TRAINING PROGRAMS

To get Federal spending under control in the long term, we must reduce spending in the short term. The first place to begin to reduce expenditure is by eliminating duplication among Department of Labor training programs. On March 1, the Government Accountability Office, GAO, released a report on duplication within Federal programs. I'm concerned that 44 of the 47 Federal employment and training programs that the GAO identified overlap with at least one other program. I would think we could all agree that providing the same services to the same population but through separate administrative structures does not make sense. Many Federal workforce programs meet important skill needs. But, the workforce system could be better aligned across agencies and streamlined to ease access for both workers and employers. And while I understand the implementation could be challenging, collocating services and consolidating administrative structures would increase efficiencies, and it would certainly reduce costs.

GOVERNMENT ACCOUNTABILITY OFFICE REPORT

To the greatest extent possible, we should not have duplication within the Federal Government, and certainly not within one Department. The GAO report makes a number of recommendations that would move the system in that direction. And I think our subcommittee needs to seriously consider them.

Second, as the GAO report pointed out, we do not know the effectiveness of most of the Department of Labor programs. In last year's testimony before this subcommittee, Madam Secretary, you stated that you understand the importance of evaluating the Department of Labor workforce programs, and you have, quoting you, "a new commitment to program evaluation." Those were your words. A year later, I see few results. Job Corps has not had a rigorous evaluation since 2003—8 years ago. The program's funding, under the Workforce Investment Act was supposed to be evaluated in 2005, and now we will not have results until 2013. How can this

subcommittee make funding decisions without having thorough reviews of programs? I believe we should have clear metrics and a results-driven evaluation process to ensure that we fund only the most successful programs.

Finally, over the past 10 years, the Federal Government's regulatory reach has greatly expanded. The administration continues to want to extend that reach, even though costly new regulations, I believe, are oppressing economic growth in the business community. According to the Center for the Study of American Business at Washington University, $1.3 trillion is lost each year in total U.S. economic activity due to Federal regulations throughout our Government. We need to work together to reduce excessive burdens on businesses and job creation while still maintaining workplace health, safety, and basic employment protections.

I'm particularly concerned regarding draft rule proposals on welfare benefit plan disclosures and on the definition of a fiduciary. I will have questions for the record on both of these topics.

Mr. Chairman, I thank you for holding this hearing. I look forward to continuing to work with you as we move toward the 2012 appropriation process.

Senator HARKIN. Thank you very much, Senator Shelby.

Senator COCHRAN. Mr. Chairman, may I ask unanimous consent to join you and Senator Shelby in welcoming the witness——

Senator HARKIN. Absolutely.

Senator COCHRAN [continuing]. And having my statement be included at this point in the hearing record?

Senator HARKIN. Absolutely. Absolutely——

Senator COCHRAN. Thank——

Senator HARKIN. [continuing]. Senator Cochran.

Senator COCHRAN. Thank you. Welcome.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, thank you for calling this hearing to discuss funding for the Department of Labor for fiscal year 2012. I appreciate Secretary Solis attending today and look forward to her testimony.

Madame Secretary, I want to thank you for your continued support of Job Corps and the YouthBuild program within the fiscal year 2012 budget. Workforce development programs targeted at youth are critical to developing occupational skills as they work toward their chosen career field. Mississippi has three Job Corps centers that serve over 1,400 students each year and six YouthBuild programs throughout the State. These programs have given numerous out-of-school, out-of-work Mississippi youth the opportunity to obtain their General Equivalency Diploma (GED) or high school diploma and gain critical vocational training. I look forward to continuing to work with you on these important programs.

Thank you, Mr. Chairman.

Senator HARKIN. And any other Senators who are not here, or may come later, their written statements will be made a part of the record.

Secretary Solis was confirmed as the 25th Secretary of Labor on February 24, 2009. First elected to public office in 1985, as a member of the Rio Hondo Community College board of trustees, Secretary Solis also served in the California State Assembly from 1992 to 1994; in 1994, made history by becoming the first Latina elected to the California State Senate. As the chairwoman of the California Senate Industrial Relations Committee, she led the battle to in-

crease the State's minimum wage. She also authored a record 17 State laws aimed at combating domestic violence. Secretary Solis also was a management analyst with the Office of Management and Budget (OMB) in the Civil Rights Division and, as we know, also served as a U.S. Representative from the 32d congressional district in California from 2001 to 2009. Secretary Solis graduated from the California State Polytechnic University, in Pomona, and earned her master's degree at the University of Southern California.

So, Madam Secretary, you have a sterling background, and a background that fits in very well with your job and your leadership at the Department of Labor. And let me, again, just thank you for that great leadership that you've provided over the last couple of years. We have seen, I think, dramatic improvement in the morale. And we've see a lot of good things happening out there, especially in areas of worker safety and worker health protections. And I just want to compliment you for that and welcome you back to the subcommittee.

Your statement will be made a part of the record in its entirety. And you can please proceed as you so desire.

Thank you.

SUMMARY STATEMENT OF HON. HILDA L. SOLIS

Secretary SOLIS. Thank you so much, Chairman Harkin and Vice Chairman Shelby and, obviously, Senator Cochran, for being here. It's a pleasure to come back here before you, to the subcommittee, and provide my testimony to you.

Since I came before you last year, there have been a lot of changes in our economy, as you well know, and throughout our country. But, what has not changed is the desire of the American public, and that is for us to work together to address the challenges facing working-class people and especially those people that are underemployed or unemployed. While there is broad agreement that the Government has to start living within its means, I hope we can also agree that we have to make those investments that will allow our future to prosper by out-innovating out-competing, out-educating, and making sure that everyone here has a fighting chance to be successful. For the Department of Labor, that means preparing Americans for jobs of tomorrow as well as ensuring that those jobs are both safe and that they are fair.

The President's 2012 budget reflects difficult choices but retains the critical investments needed to get America back to work and in safe jobs. It also does so in a way that shows our commitment to innovation. I want to thank you, Mr. Chairman, for supporting the Workforce Innovation Fund within this recent budget agreement. I look forward to working together with you to build on the initial investment in a way that will make the public workforce investment system more efficient, more streamlined, more targeted to best serve our Nation's workers. This is an example of where we did make a tough choice in the budget. Instead of adding funds on top of existing programs, we redirected funding from a slower spending statewide set-aside to create a competitive grant program. Some of the concerns that Senator Shelby has raised I believe will be addressed in this Innovation Fund.

WORKFORCE INVESTMENT ACT

There was a similar choice that we had to make that you had to make, as well: recent cuts that were made in the Workforce Investment Act, overall. In crafting the future of WIA, the Workforce Investment, I hope that we can find a way to strike a good balance between local service dollars, statewide activities, and competitive grants that don't replicate or duplicate programs. I'm looking for ideas to provide new areas and innovative pursuits, as also—and looking, also, for a system that will help provide those reforms that we're talking about here today.

I know that you've also faced tough choices in eliminating, in fiscal year 2011, funding for green job training programs. As the economy recovers, however, I strongly believe that green jobs still will remain a growing segment of this economy and will take us further, in the 21st century, to cut our dependence on foreign oil and as well as relying on those countries that may not be supportive of our goals, overall.

Preparing workers for these jobs will be a vital component of winning the future, and restoring the investment will allow us to continue to work with industry to ensure that American workers have the opportunity to gain the skills and credentials to move into better and high-paying jobs. And hopefully those jobs will stay here on our shores.

I also want to emphasize that our budget maintains our commitment to helping the most vulnerable populations, those that are veterans, women, and other people that serve us well, here in our country. We focus our resources and our Nation's—on our Nation's veterans, including additional funds to help veterans in transition to civilian employment, and for homeless veterans, as well.

One of my priorities in that program is targeting women veterans, many who are coming home have served us abroad and are finding it very, very difficult to find employment, but also, to help their families. We maintain the funding, in both ETA and ODEP, for the Disability Employment Initiative that you, Mr. Chairman, have championed. We recognize, also, that young people need skills to qualify for the jobs of the future, and request additional funds for the YouthBuild Program and the Job Corps operations.

WORKER PROTECTION

At the Department of Labor, we take very seriously our obligation to both protect workers and to protect those businesses that play by the rules and provide their workers a safe and fair workplace. No worker should have to worry about whether they are going to come home safely at the end of a shift or get paid for the work that they do. And no employer should have to compete against companies that cut corners on safety or evade the law.

The fiscal year 2012 budget builds on recent gains from our worker protection agencies. As an example, the Occupational Safety and Health Administration, OSHA, must ensure that all employers live up to their obligation to provide a safe workplace. Fiscal year 2012 budget provides the enforcement and regulatory staff and resources we believe are necessary to meet that challenge. It also maintains and expands on our commitment on compliance as-

sistance programs, including the Voluntary Protection Program and the free Onsite Consultation Program that focuses on small businesses.

Also within OSHA, we include additional funds to respond to the challenge of implementing a greatly expanded Whistleblower Protection Program that the Congress enacted.

The Upper Big Branch mine disaster, as you recall, 1 year ago, resulted in the needless loss of 29 miners, and the worst mining disaster since the creation of the Mine Safety and Health Administration. In light of this tragedy, the budget request includes additional resources so necessary to ensure that the Department has the right tools needed to best protect our miners. The request includes funding to continue to reduce the backlog of contested citations at the Federal Mine Safety and Health Review Commission. And I thank you for your attention that you have paid to this problem in the recent budget agreement. We must also continue our efforts in this area to ensure that we're holding accountable mine operators who fail to meet their legal and moral obligation and responsibility to provide safe mines.

I also wanted to highlight a few other priority areas at DOL. The budget request contains an increase for EBSA, the Employment Benefit Security Administration, that protects employee benefits for more than 149 million people by safeguarding the integrity of 718,000 pension plans and 2.6 million health plans. Our recent request also includes resources in the Wage and Hour Division and other agency partners to prevent misclassification which is often misused by employers by classifying workers as independent contractors in order to avoid their legal obligation to pay taxes or follow employment laws.

One of my goals as Secretary has been to build upon a balanced pattern of global trade. Unless workers' rights, wages, and working conditions are respected in countries abroad that we trade with, workers will be at a disadvantage in the global economy, particularly U.S. workers. The budget includes an increase of this work by our Bureau of International Labor Affairs while maintaining resources in ILAB's effort to combat child labor. Again, I want to thank the chairman for his tireless effort on our behalf and those many millions of children.

Before closing, I want to emphasize our commitment to improving how we deliver services. We're constantly scrutinizing ourselves and looking for opportunities to improve and to do things much smarter. I'm particularly proud of our adoption of a rigorous self-evaluation program. We have a new chief evaluation officer who is helping us measure our impact of our programs to find out what works and what does not work. And I welcome the opportunity for her to have a discussion with each of you.

And I also want to note that the budget includes a proposal to strengthen the integrity of unemployment insurance. And we look forward to working with Congress on that matter.

Again, I want to thank you for the opportunity to present our budget. I look forward to working with all of you. And I hope that we'll continue to make headway in the coming year.

Thank you for the opportunity to be here.

[The statement follows:]

PREPARED STATEMENT OF HILDA L. SOLIS

Chairman Harkin, Ranking Member Shelby, and members of the Subcommittee, thank you for the invitation to testify today. I appreciate the opportunity to discuss the fiscal year 2012 budget request for the Department of Labor.

There is broad agreement that the Federal Government has to start living within its means. Now that our economic recovery is gaining strength, we must come together, reduce our deficit, and get back on a path that will allow us to pay down our debt. But we must do it in a way that protects the recovery, protects the investments we need to grow, create jobs, and helps us win the future. Building on the 2012 budget and borrowing from the recommendations of the bipartisan Fiscal Commission, the President recently proposed a balanced approach to achieve $4 trillion in deficit reduction over 12 years. Part of this plan is to keep annual domestic spending low by building on the savings reflected in our 2011 budget agreement. That step alone will save us about $750 billion over 12 years. The administration is committed to making the tough cuts necessary to achieve these savings—including to programs we care about—but will not sacrifice the core investments we need to grow and create jobs.

The 2012 budget request for the Department of Labor includes a number of these difficult cuts, but it also includes key investments that would allow us to win the future by out-innovating, out-educating, and out-building our global competitors. Getting America back to work is a top administration priority as we seek to spur growth in the U.S. economy. It is important to promote the creation of "good jobs," and the Department of Labor plays a vital role in this goal by helping workers find and prepare for new jobs, helping employers find skilled workers, and enforcing statutory obligations that keep workers safe and help them keep what they earn.

INVESTING IN THE FUTURE

The Department of Labor fiscal year 2012 budget invests in the future by working toward my vision, Good Jobs for Everyone. The Department's budget focuses on this vision in a fiscally responsible manner by:

—Getting America Back to Work;

—Keeping Workers Safe; and

—Helping Workers Provide for Their Families and Keep What They Earn.

GETTING AMERICA BACK TO WORK

To get America back to work and win the future, the Department will prepare workers with the tools they need to succeed in the 21st century economy, help workers and firms find each other, and support innovative strategies to promote economic recovery. The budget documents have been provided to the Committee and are available on our website, but for now, I want to share the key investments with you:

—*Workforce Innovation Fund*.—The public workforce investment system is more important now than ever, but we need to make it more efficient, streamlined, and targeted to serve our growing customer base. To ensure that our investments in employment and training are focused on reform, the Departments of Labor and Education will invest in a Workforce Innovation Fund that will drive innovation and reinvigorate America's workforce development system. The Fund represents a small but crucial investment in innovative, evidence-based, and cost-saving workforce investment strategies that will significantly impact formula-funded activities well into the future. We were pleased that the final 2011 budget agreement included funding for the Fund. Our commitment to innovation is also reflected in requests for green jobs innovation activities and, of course, for evaluation so that we can improve our knowledge of what works.

—*YouthBuild*.—Developing the skills of our Nation's youth is critical to ensuring that our workforce is ready to succeed in the future. The 2012 budget requests additional funds for the YouthBuild program, which provides disadvantaged youth, including youth with disabilities, with a pathway to employment or post-secondary education. In fiscal year 2012, we will continue to implement the YouthBuild random assignment evaluation—the first rigorous impact evaluation ever conducted of the program—to measure the program's impacts on participants' post-program employment and earnings and to build knowledge of what works.

—*Unemployment Insurance Solvency and Integrity*.—This administration is committed to protecting the financial integrity of the UI system and helping unemployed workers return to work as swiftly as possible. Two major legislative proposals would strengthen the unemployment insurance safety net. One would

help States improve the solvency of their unemployment accounts in the Unemployment Trust Fund (UTF), while providing temporary tax relief for employers. The other would create incentives for States to adopt Short-Time Compensation programs and expand their use nationally through implementation grants and a temporary Federal program in order to help avert layoffs. Another legislative proposal would focus on reducing UI improper payments by giving the States new tools and resources that will strengthen the fiscal integrity of the UI system

—*Job Corps*.—Our Job Corps program has a long history of preparing disadvantaged youth for a successful transition into the workforce. The 2012 budget would request additional funds for the program, and continues an ambitious agenda to improve the program's performance.

—*Veterans' Employment and Training Service*.—We know returning veterans can contribute greatly to our economy. The request for the Department's Veterans' Employment and Training Service includes additional funds for the Homeless Veterans Reintegration Program to provide employment and training assistance to almost 27,000 homeless veterans, including continuing our outreach to homeless women veterans. In addition, the budget request funds the Transition Assistance Program for service members and their spouses, including expansion of services to retiring Reserve and National Guard members. Transition Assistance Program workshops play a key role in helping service members transition swiftly and successfully to civilian employment.

—*Disability Employment Initiative*.—It is also important to continue our efforts to ensure that our workforce system effectively serves persons with disabilities. To accomplish this, the Department's budget includes funding for the Employment and Training Administration and the Office of Disability Employment Policy to continue the Disability Employment Initiative begun in fiscal year 2010. This initiative works to build the capacity of the WIA One-Stop Career Center system to serve job seekers with disabilities by improving coordination across programs, leveraging resources, and prioritizing the provision of service to job seekers with disabilities (adults and youth) through the Social Security Administration's Ticket to Work program.

KEEPING WORKERS SAFE

Winning the future requires a successful competitive market where all firms are playing by the rules to keep workers safe. Workers should be safe in their jobs and we need to ensure that our worker protection efforts keep up with the changing economy. The fiscal year 2012 budget builds on recent gains for our Worker Protection agencies. Some of the highlights of our worker protection request include:

—*Occupational Safety and Health Administration*.—The Occupational Safety and Health Administration (OSHA) must ensure that all employers are able to provide safe workplaces to their employees. The request would expand OSHA's commitment to preventing injuries, illnesses and fatalities by deterring employers in the most hazardous workplaces who exhibit a profound disregard for worker safety and health. The fiscal year 2012 budget also includes funds to support OSHA's work with the 21 whistleblower programs it administers in order to reduce the backlog in whistleblower claims, expedite the handling of received complaints, and prepare for a high volume of complex cases resulting from recently passed laws.

—*Mine Safety*.—The Upper Big Branch mine disaster just over 1 year ago resulted in the needless loss of 29 miners' lives and was the worst mining disaster in the last 40 years. To prevent future such tragedies, the budget request includes additional resources for the Mine Safety and Health Administration (MSHA) to ensure that the Department has the tools we need to best protect miners. The Budget also requests funding for the Office of the Solicitor (SOL) to reduce the enforcement backlog of contested citations at the Federal Mine Safety and Health Review Commission (FMSHRC). Funds would also support Administrative Law Judges processing Mine Safety and Health citation cases at FMSHRC. We must continue our efforts in this area to ensure that we are holding accountable mine operators who fail to meet their legal and moral responsibility to operate safe mines.

HELPING WORKERS PROVIDE FOR THEIR FAMILIES AND KEEP WHAT THEY EARN

*Employee Benefits Security Administration*.—The Department's Employee Benefits Security Administration (EBSA) protects the employee benefits for more than 149 million people by safeguarding the integrity of 718,000 pension plans, including 401(k) plans, 2.6 million health plans, and a similar number of other employee ben-

efit plans. The additional requested resources will support the significant increase in congressional action aimed at strengthening benefit security for working Americans and their families. The Department's efforts will make plans more secure and help ensure that workers and their families receive the benefits to which they are entitled from their plan and under the law.

*Pension Benefit Guaranty Corporation*.—The Budget proposes to strengthen the defined benefit pension system for the millions of Americans who rely on it by giving the PBGC Board the authority to adjust premiums and directing PBGC to take into account the risks that different sponsors pose to their retirees and to the pension insurance program. In order to ensure that these reforms are undertaken responsibly, the budget would require 2 years of study and public comment before any implementation and the gradual phasing-in of any increases.

*Employee Misclassification Prevention and Detection Initiative*.—The budget reproposes a multi-agency Misclassification Initiative that would coordinate Federal and State efforts to remedy violations that may result from the misclassification of employees as "independent contractors" and mitigate future violations.

Other priorities from the budget submitted by the President in February include additional funds for the Bureau of International Labor Affairs. The fiscal year 2012 budget includes funds to allow ILAB to collect additional information for its responsibilities for reporting on labor rights in countries that have free trade agreements and trade preference programs with the United States. The budget will also continue the Bureau's longstanding commitment to combating child labor internationally and to building international relationships that improve global working conditions and strengthen labor standards around the world.

CONCLUSION

To summarize, the 2012 budget provides targeted investments to help workers and firms better find each other, prepare Americans with the skills needed for the jobs of today and the jobs of the future, and ensure that we have a fair and equitable labor market for firms and workers. Our efforts will help to get America back to work, foster safe workplaces that respect workers' rights, provide a level-playing field for all businesses, and help American workers provide for their families and keep the pay and benefits they earn. I am committed to achieving the goal of Good Jobs for Everyone while the administration focuses on our shared long-term goal of reducing the Federal deficit. I believe it is possible to do both and stand ready to work with you in the weeks and months ahead on a responsible way forward.

Mr. Chairman, thank you for inviting me today. I am happy to respond to any questions that you may have.

Senator HARKIN. Thank you very much, Madam Secretary.

We'll start a round of 5-minute questions.

EMPLOYMENT OF PEOPLE WITH DISABILITIES

Madam Secretary, I know you share my deep concern about what happened in a situation in Iowa a couple of years ago. It was uncovered in April 2009. Again, for your benefit, and others, here's what happened. We found people with disabilities, 21 men, were working in a turkey processing plant. They had been employed by Henry's Turkey Service, out of Goldthwaite, Texas—shipped up to Iowa—and had been working in this turkey processing plant, some for as long as almost 20 years. They were living in an old bunkhouse, an old schoolhouse—106-year-old schoolhouse—where the boilers didn't work. It was cold. Cockroaches were everywhere. And these men were bused from there to the workplace and back again. They were making 41 cents an hour—subminimum wage—41 cents an hour. And they were working right next to people making $12 an hour, doing the same job. I mean, it's not that they were picking up after them, they were doing the exact same work. And so, this was uncovered. It became quite a scandal.

I have since visited—now, those men have been taken out of there. I've since visited with some of those employees in Waterloo, but some went back to Texas. Some are still in Iowa, and they're

working. And they're working not at subminimum wage jobs, but at regular integrated employment. In fact, one even started his own business, which is a lawn care business in Waterloo.

WAGE HOUR DIVISION

Now, why do I raise this issue? I raise it because, from 2000 to 2008, the Wage and Hour Division lost 20 percent of its staff. John McKeon, Deputy Administrator of the Department of Labor's Wage and Hour Division, told me, before I held the hearing that we held on this subject in the HELP Committee, that there are many employers in the United States who pay less than the minimum wage and, "have never seen a Wage and Hour investigator." And that's sort of what happened in Iowa.

As I understand it, they were visited, years ago, and then, every year, all they have to do is just send in a piece of paper. They just send in a piece of paper saying that, "We're complying," and that's the end of it. The turkey place was called Atalissa—Atalissa. And so, we refer to it as the *Atalissa* case, which raises, in my mind, if that happens in Iowa, how many more Atalissas are there out there? And as you know, I am taking the opportunity in the HELP Committee and with the Workforce Investment Act, to take a look at this area of subminimum wage, and how people with disabilities are funneled into subminimum wage jobs. They're never given any training, never any upgrading of skills, never tested to see, can they do something else? Obviously, if these men were doing the same job as nondisabled people, they should have been paid the same rates. There should have been integrated employment.

So, I guess I just wanted to bring that to your mind and to your attention and just ask you, again, what actions your Department's taking to prevent this sort of situation from happening again, and to find out how many other places like this exist in our country?

Secretary SOLIS. Mr. Chairman, I also am appalled by this particular case. And I know the last time that I came before this subcommittee, I think you brought it up at that time, as well. Since that time, I'm happy to report that our Wage and Hour Division, because of the support that we received, we're able to bring back the enforcement capability that we lost in the last 10 years.

And what we have done, in this particular case, is to look at those individuals that are working with the 14(c) program, particularly identifying this population, and looking through a survey, a compliance survey, to see where we have gaps, where we have found problems. And I can tell you that I will make sure that you get the results of our survey that will be due to us in about 4 to 6 weeks.

And with that, I would say that we have made sure—and this one particular case that you're talking about—at the time, they were not certified under the 14(c) program, but we did have our Wage and Hour personnel take action, as well as our solicitor. That particular situation is being litigated in courts right now. And we're finding that there were some major, major violations of the Fair Labor Standards Act. And these individuals, I believe——

Senator HARKIN. Yeah.

Secretary SOLIS [continuing]. Will find justice.

And I would tell that we're going to continue to look at these kinds of abuses, because we know that if it happened there, it could very well be happening somewhere else. And we want to get to the bottom of that.

Senator HARKIN. I thank you for that. And I also—I just might say, they got initial summary judgment for $1.76 million. But, then again, that doesn't—that helps, but that doesn't take care of the losses they've had in Social Security, for example, payments that they're going to need when they get older. And some are on the verge of retirement right now. So, thank you.

Secretary SOLIS. I'd be happy to work with you on that——

Senator HARKIN. I appreciate it.

Secretary SOLIS [continuing]. On strengthening——

Senator HARKIN. I appreciate it.

Secretary SOLIS [continuing]. This program.

Senator HARKIN. This case just shocks the conscience. Just shocks the conscience. Thank you very much, Madam Secretary.

Senator Shelby.

RECOVERY EFFORTS IN ALABAMA

Senator SHELBY. Thank you, Mr. Chairman.

Madam Secretary, last week, tornados devastated my home State of Alabama. It was the worst that we've experienced in my lifetime, and probably in most people's lifetime in the whole South. I toured the damage, last Friday, with the President. And we've had a number of Cabinet Secretaries who were down there Saturday and Sunday. I'm going back down there next week with the HUD Secretary, who's already been there.

Could you tell me what the Department of Labor is doing to assist the people of Alabama in their recovery efforts? I know you're doing some things. But, you know, we're facing dire circumstances.

Secretary SOLIS. Right. Senator, also I want to convey my condolences to the families there, as well as to the other States that are affected, and tell you that this is a constant reminder of my role at the Department of Labor, because we have a special funding that is made available. Fortunately, we have some funds for them. In fact, this morning, before I came to this hearing, I signed off on what we call the National Emergency Grant, the NEG, that will be going to Alabama, to those, I believe, 67 counties that are eligible, under FEMA——

Senator SHELBY. That's fine.

Secretary SOLIS [continuing]. To receive funding. The amount is for about $10 million to help provide temporary jobs for those individuals, whether they work for private or public sector, if they've lost their homes. They'll be hired. They can help provide with cleanup. They'll also be able to help provide with any repair, renovation, reconstruction for low-income housing, as well as provide assistance for weatherization. And particularly, people that are eligible for other types of Federal aid, they will be able to help those individual households repair.

I know this is a small amount, given the catastrophe there. And I would imagine that the Governor and yourself will be working with my staff, my Assistant Secretary——

Senator SHELBY. Sure.

Secretary SOLIS [continuing]. Jane Oates, who was contacted very early on, and had our staff out in the field. In this tornado, unfortunately, we lost some State staff from——

Senator SHELBY. We did.

Secretary SOLIS [continuing]. Various WIA programs, that lost their homes and lost their lives, as well.

So, we know this is tragic. And I am also prepared, once we have more notification from the other States that have not yet completed their applications, to make a visit out there myself, as I did a year ago, when we heard about the BP oilspill. We have a necessity to be on top of safety and protection for workers, as well.

Thank you.

## NATIONAL LABOR RELATIONS BOARD

Senator SHELBY. Well, thank you very much. And I know there are other States, including the State of Mississippi that Senator Cochran represents, that were affected here.

I want to turn to another area. On April 20 of this year, the acting General Counsel of the National Labor Relations Board issued a complaint against the Boeing Company, alleging that it violated Federal law by deciding to transfer a second airplane production line from a union facility in the State of Washington to a nonunion facility in the State of South Carolina. The complaint said this was discrimination. It's interesting that the National Labor Relations Board used the word "transfer," as its production line does not, and never did, exist in Washington State. I make this point because, if the production line never existed in Washington and was not planned or committed there, there were no jobs lost there.

Madam Secretary, I understand that the National Labor Relations Board is an independent agency. But, I'd like to hear your thoughts on the underlying issue here, that private U.S. business cannot freely open new facilities in right-to-work States without fear of retaliation by the U.S. Government and this administration. Is that the policy of this administration?

Secretary SOLIS. Senator, I would just say to you—and you just emphasized that—that this in an independent agency, the NLRB. And while they are currently going through their decision or—I can't really comment on what they are—on what the counsel there is——

Senator SHELBY. I know it's not directly under you. You have an opinion on it, or you'd just rather not——

Secretary SOLIS. No. No, I don't have, other than to tell you that this administration strongly supports the efforts of those that want to associate with unions and collectively bargain.

Senator SHELBY. And what if they don't want to associate with them?

Secretary SOLIS. They have those rights, as well.

Senator SHELBY. Do they support that, too?

Secretary SOLIS. I believe so.

Senator SHELBY. I hope so.

Secretary SOLIS. I believe so. Yes.

JOB CORPS PROGRAM

Senator SHELBY. I want to get into the Job Corps, if I could, in my limited time. Job Corps is the Nation's largest vocationally focused education and training program for disadvantaged youths. For the year 2012, the administration included $1.7 billion for Job Corps. I'm concerned about the lack of clear metrics within the Department for evaluating Job Corps. It's my understanding the Job Corps Program has not had a rigorous evaluation since the Mathematica administrative data study concluded in 2003, 8 years ago. And that study concluded that the program's cost exceed its benefits.

Further, according to a study published in the American Economic Review in 2008 entitled, "Does Job Corps Work?", Job Corps participants were less likely to earn high school diplomas, according to this study, and earned an average of only 22 cents more an hour than nonparticipants. The study even showed that the program had no effect on college attendance or completion.

These are disturbing statistics, given that the Federal Government spends an average of $27,000 per Job Corps participant over a 9-month period. As we all know, for $27,000, a person could earn their associate's degree or attend several years at a university somewhere in America.

Madam Secretary, what are your thoughts on the justification for spending $1.7 billion on a workforce training program that has few, that I see, published results, and clear problems with management of taxpayer funds? What's your defense of that?

Secretary SOLIS. Senator, first of all, I'd like to tell you that I am a strong believer of the Job Corps Program. And since I have been in charge of the program in the last 2 years, we have made, I think, some tremendous strides in trying to make sure that we do provide the metrics and evaluation. And I would tell you that, yes, that last review that you talk about that was done in 2001, it's unfortunate that, in the past 10 years, or so, that there wasn't a closer look at what the metrics are.

But, I would tell you that what we are doing now is instituting more evaluation from within our own program. And I would tell you that, in program year 2009 through June 2010, 20,000 students attained high school diplomas in—and their general equivalency diploma (GED), 30,000 students completed career and technical training in 11 high-growth areas.

Senator SHELBY. What's the percentage of that? That's good, but——

Secretary SOLIS. Seventy-six percent of—in 2009, were—graduates were placed in employment, or some chose to go in the military.

Senator SHELBY. Okay.

Secretary SOLIS. So, we are doing a better job. But, I realize that one of the goals that we have to look at here is, What career are these folks going into?—not just a job, not just a part time, or not just a minimum wage job, but also a career. So, we've instituted, I think, a whole platform to have them look at renewable energy—green jobs. We can transition from construction into a new hybrid technological area.

And it's hard, because these students are the ones that—our society, or maybe their families, have failed them. And I would tell you that, in many instances—and I know Senator Cochran might agree—that these students—young people—not all of them are young, some of them are 21, 24 years old—have stepped up, in many ways, when there's disasters. When Katrina happened, I know some of them were out there helping to rebuild homes——

Senator SHELBY. Yeah.

Secretary SOLIS [continuing]. For even people who were less fortunate than themselves. And I look to these students as our future leaders, many who have transformed their lives, many who have served—even in my own office, have come and have shared their talent and skills with us. And I think that, in many cases, it's a well-kept secret. Yes, we could make improvement with Job Corps. But, we should not somehow push aside the enormous resource that we have with these young people. We only have 124 centers. And, at best, there hasn't been sufficient funding to help make them more effective and more, how could I say, directed toward those good careers that we all know that they can be a part of.

Senator SHELBY. Well, I want to—I'm not proposing we abolish Job Corps. I'm thinking, in trying to work with you and Senator Cochran and others, to improve it. Because, I know it does do some good. And I know, for a lot of people, it's their last hope. But, we can always improve it.

Secretary SOLIS. Absolutely.

Senator SHELBY. I hope you're committed to that.

Secretary SOLIS. I am. I am, sir. And I would love to be able to visit with you——

Senator SHELBY. Absolutely.

Secretary SOLIS [continuing]. And one of our Jobs Corps centers——

Senator SHELBY. Thank you.

Secretary SOLIS [continuing]. So that we can look at those things together.

Senator SHELBY. Thank you, Mr. Chairman.

Secretary SOLIS. Thank you.

Senator HARKIN. Thanks, Senator Shelby.

Senator Cochran.

Senator COCHRAN. Mr. Chairman, thank you.

Madam Secretary, welcome to our subcommittee. We appreciate your being here to discuss the budget request for the programs under the jurisdiction of your Department.

JOB CORPS CENTER, GULFPORT, MISSISSIPPI

Mentioning the Job Corps center reminds me that, in Hurricane Katrina, we had a devastating hurricane, as you recall, and everybody does, that struck the gulf coast area of the country. And our Job Corps center in Gulfport, Mississippi, was totally destroyed. And so, we had a lot of displaced people who had been working there and living there. Progress has been made, but I wonder whether or not you can give us some idea about when the construction, or reconstruction, of that center might be completed. We had heard 2012. Now we're hearing it might be delayed well over into

2013 or 2014. What is the latest information you can provide the subcommittee with on that subject?

Secretary SOLIS. Yes, thank you, Senator Cochran. I would just say that, at the Gulfport center, students, as you know, have already been enrolled. So, we have about one-half the number of students that we could handle there. That's about, I believe, 145 that are currently there and enrolled. We know that we have to continue to build out the rest of the facility, which is going to take us some time. We believe that we're making progress on the permanent construction. That's what you're talking about. And I can see—possibly by mid-August of this year, we should be able to see that permanent dormitory established there that I know you're concerned about. The rest of the center, the design will probably be complete in another 2 years—2 to 3 years, unfortunately. But, it remains a focus of what our efforts are there. And believe me, I will keep you up to date, and my staff will. And I'm just excited that we're able to serve with those 145 students that are currently on campus.

Senator COCHRAN. We appreciate your personal attention to that and the leadership that the Department is providing to get that back into operation as soon as possible. Thank you.

YOUTHBUILD PROGRAM

There's another program, that I was curious about your assessment of it, called "YouthBuild." And it's targeted to younger workers. It's a training program but a workforce development program all at the same time. It gives high-risk youth opportunities to develop occupational skills with vocational training as they work. Could you tell us what the program is achieving, if it's working? Do we continue to support it under your budget request?

Secretary SOLIS. Thank you, Senator Cochran. I am delighted that, through the YouthBuild Program, and especially the funding that we received in the last two cycles, have been able to help us focus better on providing better certificates and measurements for student success. And one of the highlights, I think, of our effort has been to really infuse technology. So, whether it's healthcare, IT, or whether it's renewable energy, changing the focus, in some ways, from construction to renewable energies. And I've actually been able to see this on the ground, where young men and women—and I'm delighted to say "women"—are getting enrolled in these programs and really learning the crafts, the crafts that will help provide them with better training, better skills, and giving them a job. And most students that enroll in the program are tied in, typically with either an apprenticeship program, in some cases, and in some cases, with a business developer in construction, that will hire those individuals up as rapidly as they're trained.

So, I would say to you that the program—actually, I would love to see it expanded, because I think it is well worth our investment there. And I know that many people, again, that come into that program sometimes are the hardest ones to serve, because they may not have completed their high school education. Some may not be as motivated as others. And once they find collegiality amongst their other peers, they then become competitive with themselves. And I've seen them develop leadership skills and actually work in

new industries that are actually going to help to bring back our economy, especially when it comes to conservation and restructuring and retrofitting of some of our aged housing and commercial buildings. I see a lot of them that are very enthusiastic about the program.

Senator COCHRAN. Thank you. I'm also advised there's other good news from my State. One program, in particular, the on-the-job training provided under the Workforce Investment Act, has been particularly successful in Mississippi. And I wanted to pass that assessment from my staff on to you, and thank you for the leadership on that.

OFFICE OF DISABILITY EMPLOYMENT POLICY

And Disability Employment Service is another area where I think the Department is making important contributions. That's a well coordinated effort, I'm told, providing those with disabilities rehabilitation services, encouraging them, monitoring their progress. Some of the highest rates of rehabilitation in the country, at over 70 percent, are being observed under that program. It's the Disability Employment Initiative.

Secretary SOLIS. Yes.

Senator COCHRAN. And I thank you for your leadership in that area, as well. Are you familiar with those reports?

Secretary SOLIS. Yes, I am. Yes, I am. And I want to thank the chairman and this subcommittee for supporting the funding for that program. And it continues, I think, to be something that really is refreshing, because it helps to shine a light on the fact that the disabled community has been underrated. In fact, what we're finding, from our own assessments, is that they tend to perform better in the workplace. And we are losing out, as a country, if we don't utilize the skills and talents that they have.

So, we know that good models exist in Iowa and other States, and we want to continue to build that out. Under the leadership of my Director for ODEP, Kathy Martinez, she has been tremendous. You know, she is—I call her one my Charlie's Angels, who's been out there, really helping to fight, and really parlay the importance of providing the disabled community with the tools that they need. They're not asking for a handout. They're asking for a hand up, an ability to be able to work in different employment situations. And when we find employers that are willing to do that, they are going to make those businesses shine. And we've seen it already evidence. And I'm very delighted that, through the leadership of this chairman, that we're looking at expanding this effort, also, to include our one stops. So, there are one-stop centers. We have 3,000 of them. We'll also start looking at how we can better serve that population and address their issues, up front.

Senator COCHRAN. Thank you.

Thanks, Mr. Chairman.

Senator HARKIN. Thanks.

Senator Brown.

Senator BROWN. Yeah. Thanks, Mr. Chairman.

Welcome, Madam Secretary.

AFRICAN-AMERICAN UNEMPLOYMENT

Talk to me about African-American unemployment. African-American unemployment is 16 percent—official unemployment. We know it's higher than that, almost twice the white unemployment rate of 8.7 percent. What is DOL doing specifically to address the endemic, long-term very serious problem of black unemployment?

Secretary SOLIS. It's a very serious problem, Senator. And I know it's one that we care a lot about.

I recently visited Ohio and several States there, and met with several faith-based leaders to talk about how we can begin, in a better way, to target our funding and our proposals. One thing I will tell you is that we, under the ARRA Program, were able to target about $150 million in career pathways out of poverty, targeting communities that have unemployment rates above, say, 50 percent. Those went into particular communities of color. We continue to also provide reintegration programs for ex-offenders. It's something very important. And with our YouthBuild Program and our Job Corps Program, I think it's safe to say that about 40 percent to 60 percent are African-American.

We need to do more, obviously. And we do need to have assistance, in terms of providing them with the job training opportunities that will put them into good careers that won't just lead to a paycheck, but a career. And I think that's what we're trying to do in some of our new rollout of programs.

We just announced, for example, in the H1B Program, through fees that we received, $240 million in grants that will go out to help dislocated workers, but also working with industry to help provide new technical training to their current incumbent workers, hopefully open up that slot to allow for a dislocated worker. Hopefully, it will be those in those communities most distressed. So, that is going to be our focus for that particular program.

But, we continue to work with our community colleges, our workforce investment boards, and with the faith-based community to see how we can better improve the status of African-Americans.

But, again, one of the things I have to tell you—and you know this better than I—is that one of the things we have to do is aspire for higher education. That's why the President has talked a lot about providing opportunities for Pell grants, for assistance, for financial aid, so that individuals can receive a community college degree and hopefully get better training, because it is a more competitive workforce.

2012 BUDGET RESOLUTION PASSED BY HOUSE

Senator BROWN. Thank you. You mentioned Federal job training programs, WIA, and other things. The—I'm concerned, with the 2012 budget resolution that passed the House, the consolidation of multiple programs serving a range of populations—minorities, veterans, individuals with disabilities, dislocated workers, at-risk youth—into a single, one-size-fits-all voucher program, and squeezing those programs to the point of tens of billions of dollars, over the next 10 years. Does the administration share the view approved by the House, that now is the time to significantly reduce investments in workforce training? Is that something that you op-

pose? Would you talk to us about, you know, sort of a critique of that, and what direction you think we should go in, if you disagree?

Secretary SOLIS. Well, Senator, as you know, the President and the debate right now is about working within our means. And that obviously is something that we do take serious. And we did take that step in this budget.

And I would say to you that we have attempted to keep the integrity of our programs in place. As the President said, we don't want to hurt the innovation, the ability to not be able to compete, and the fact that we have to keep our vulnerable communities front and center.

So, I would say to you that my personal commitment is to try to keep the integrity of these programs in place. I realize, as a former member, like yourself, that we don't have the luxury of being able to cut back on these very vital programs that help provide people the ability to get back to work. There are so many people that are, how could I say, feeling let down, that they don't have an opportunity to get a job right away. And those are the very folks that we have to keep in place. Those are the very folks that we have to make sure that they receive training, that they go to our one-stop centers and they keep engaged. Because, the farther they are away from that ability, an employer, chances are, will not want to hire them up. And we've seen that evidenced already in the workplace, where actually employers are saying, if someone's been out of work more than 6 months or 1 year, they may not be the first person that they're going to look at, in terms of their résumé. So, I'm very concerned about this.

Senator BROWN. My last—thank you—my last question, Mr. Chair.

EXPANSION OF TRADE ADJUSTMENT ASSISTANCE

Madam Secretary, the administration did something very important, many things very important, in the Recovery Act. Specifically what I want to talk about, just for a moment, is the expansion of trade adjustment assistance to expand it, not just to the service industry, but to—I mean, not just to manufacturing, but service and those job layoffs and retraining in—where not only—not exclusively with countries with whom we had a free trade agreement. That—you know, we were able—it was in effect til the end of December of this past year; we were able to get a 6-week extension with—you know, the—late in December, as you know. And you helped us with that. But, this—the expanded TAA eligibility lapse for service workers and workers who lost their jobs in—as a result of——

Secretary SOLIS. Right.

Senator BROWN [continuing]. Of job loss in countries with whom we didn't have a free trade agreement, that—so, what's the Department doing? Is the Department, now that that's lapsed—I—number one, I'd like the administration to take a stronger position on TAA. You know, some people have called TAA "funeral expenses" for these trade agreements, frankly. But, at least TAA is something. And now we don't even have TAA for these workers that have lost their jobs because of trade agreements that were wrong-headed. I remember your work in the House against some of them—CAFTA and some others. What—is the administration going to speak more

forcibly—forcefully on the extending of TAA and extending of the health credit—the HCTC, health care tax credit? And what are you doing, in terms of processing these applications, when the program—the expansion of the program is expired on TAA?

Secretary SOLIS. Well, Senator, we are very concerned that there was not a decision to extend the TAA Program. And it is of great concern. And it is affecting many dislocated workers at this time. And I do believe that the program is worthy of being reinstituted, because I know it does make a difference, especially for people from the Midwest, in your case, your State, and other places where we've seen industries leave our country and go to other places, where it has made a difference to help provide as a safety net for people to transition into new jobs. I saw it happening, time and time again, these last 2 years, especially in the automobile industry. We saw a lot of dislocated workers that received this assistance and were able to make the transition quickly to get higher skills or healthcare coverage and be able to make that transition.

And as you know, that story, I think, is a good story, especially with the automobile recovery, where we've seen that now GM, Chrysler, and those folks have been able to put back some lines of assembly and also put people back, and they've paid back their loans.

But, TAA is very important. That discussion has to go on. I understand there are individuals that still have questions about it and are trying to tie that in with other trade agreements. I would hope that the—that this body would do the right thing and extend it on its own, if possible. But again, that is not something that I can determine.

Senator BROWN. Well, but we——

Secretary SOLIS. But, I wholeheartedly support it.

Senator BROWN. Thank you. But, we need the administration to speak much more forcefully than they have on the importance of TAA. You weren't absent, as an administration—and I know your personal feelings on this—you weren't absent, last December, on this, but you weren't nearly as vocal as an administration that stands for workers and stands for retraining and stands for an industrial moving forward that we have not done so well, in the last few years, on. So, that's a plea to you.

Thank you, Madam Secretary.

Senator HARKIN. Thank you very much, Senator Brown.

Senator Shelby.

Senator SHELBY. Mr. Chairman, I have a couple of questions, and then I have a number for the record. If I can ask the rest of them, after I ask these two, for the record, I'd appreciate it very much.

GAO REPORT

Madam Secretary, I want to go back into some of the GAO reports. In January, the GAO released a report on multiple employment and training programs, and the report stated, and I'll quote, "Little is known about the effectiveness of the employment and training programs we identified because only five reported demonstrating whether outcomes can be attributed to the program through an impact study, and about one-half of all the programs

have not had a performance review since 2004." That was the GAO.

Despite unemployment being at 8.8 percent, officially, the Department of Labor, it's my understanding, has not taken action to address its ineffective programs. In fact, based on the GAO survey of Department of Labor officials, only 5 of 47 programs have studies that assess whether the program is improving employment outcomes.

Madam Secretary, how do you respond to these troubling issues identified in the GAO report? And, if you want to, you can answer that for the record.

Secretary SOLIS. Thank you, Senator. I would just say to you, as I mentioned earlier, that the report that was—that you're citing was done in the previous administration, was supposed to be completed, I believe, at that time. That's why I signed a contract so that we could continue to do our own evaluation and have that done, which began in 2009.

[The information follows:]

DEPARTMENT OF LABOR'S PERFORMANCE MEASURES

Nearly all of the Department of Labor's two dozen employment and training programs include strong accountability features and performance metrics on employment, retention and earnings measures. We are strengthening our accountability further, as demonstrated by the Departmental 2011–2016 strategic plan, which places an increased focus on performance-based management. Performance measures are being reassessed for consistency across programs throughout the workforce system to promote better outcomes for individuals of all skill and need levels, particularly those who are not yet ready and able to move quickly into a good job. We believe that workers and employers should have ease of access to information about past participants' outcomes, to make informed decisions about which programs are most likely to meet their needs.

In addition to the annual employment and training performance reviews conducted at the Federal, State, local and training provider levels, the Department has been working diligently over the past 2 years to restore the rigor of our evaluation studies. Specifically, I established the Chief Evaluation Office (CEO), which was staffed in May 2010. The purpose of this office is to coordinate the Department's research and evaluation agenda in order to increase its capacity to conduct high quality, rigorous evaluations.

Further, the GAO has noted in a recent March 2011 report the marked improvement in the dissemination of research reports by the Employment and Training Administration under my leadership at the Department of Labor. The GAO noted that, "The 34 research reports published by ETA in 2008 took, on average, 804 days from the time the report was submitted to ETA until the time it was posted to ETA's research database. By contrast, from 2009 through the first quarter of 2010, the average time between submission and public release was 76 days, which represents a more than 90 percent improvement in dissemination time compared with 2008." [1]

Also, since 2009, approximately half the evaluations the Employment and Training Administration (ETA) has funded have been rigorous, random assignment impact evaluations. These include the Workforce Investment Act (WIA) Gold Standard Evaluation of the Adult and Dislocated Worker Programs (WGSE), the YouthBuild Impact Evaluation, the Reintegrating of Ex-Offenders Random Assignment Evaluation, the Impact Evaluation of Green Jobs, Health Care and High Growth Training Grants and the Transitional Jobs Impact Evaluation, all of which will examine net impacts on employment, retention and earnings, and include benefit-cost analyses. ETA was able to fund these evaluations through an increase in fiscal year 2010 appropriations and the large one-time infusion of funds made available to the Department through the American Recovery and Reinvestment Act of 2009.

While rigorous random assignment impact studies, such as the WGSE, provide the most credible information on program effectiveness, these are also highly re-

[1] U.S. Government Accountability Office, "Employment and Training Administration: More Actions Needed to Improve Transparency and Accountability of Its Research Program," March 2011, p. 26.

source intensive and take a range of 3 to 7 years to implement and complete. Mindful of the statutory responsibility for evaluation, and to address the knowledge gap until the WGSE results are available, in 2009 the ETA released the results of a quasi-experimental net impact evaluation of the WIA Adult and Dislocated Worker programs.[2] This study uses the next-best methodology when random assignment is not available. This evaluation found positive long-term earnings impact for both programs, though the impacts were more substantial for the Adult program than for Dislocated Workers. ETA plans to publish interim findings of the WGSE in 2013, and the final report will be available in 2016, although this schedule is dependent upon continued appropriations for the evaluation of WIA programs.

Secretary SOLIS. The results of that study——

Senator SHELBY. Is this ongoing?

Secretary SOLIS. Yes. And that will become available in 2013. It does take time, because——

Senator SHELBY. It does.

Secretary SOLIS [continuing]. You're looking at different factors. But, nevertheless, since I've been here, we have begun this evaluation.

Senator SHELBY. Have you seen some of the preliminary work?

Secretary SOLIS. Not necessarily——

Senator SHELBY. Not yet?

Secretary SOLIS. No. But, as I said earlier, that some of the results that we have seen from our own evaluation, our in-house, shows that during the program year June 2009 to June 2010, 76 percent of our workers exiting the WIA dislocated program, and 69 percent of the workers exiting the adult worker training, found a job within 3 months. And after that—and that—and I think those are good statistics——

Senator SHELBY. That's good.

Secretary SOLIS [continuing]. Considering a bad economy, when you're finding four——

Senator SHELBY. It's tough.

Secretary SOLIS [continuing]. To five people are competing for one——

Senator SHELBY. It's tough out there with skills, right now.

Secretary SOLIS. Yes.

Senator SHELBY. We understand that. But, my interest is probably—coincides with yours, that we want these programs to work. And we have to measure them. And if they don't work, we figure out something that will work. Because, the end game is to get people back to in the employment. Is that right?

Secretary SOLIS. Yes. And, Senator, I would say that one of the things that we need to focus on is reauthorizing WIA, because that's really going to help us. What I've heard, time and time again, is that this is an old system that has to be restructured. It has to look at new segments, regional issues, and really look from the bottom up, not from the top down.

Senator SHELBY. I think we know somebody that deals with authorization close to us today.

TRANSITION ASSISTANCE PROGRAM

If I could, I'd like to get into another program, the Transition Assistance Program. The unemployment rate for veterans of the wars

[2] The Workforce Investment Act Non-Experimental Net Impact Evaluation: Final Report may be found at ETA's Research Publication Database Web site.

in Iraq and Afghanistan rose to 15.2 percent in January 2011 which is well above the official national rate of 8.8 percent. This is the highest rate recorded since the Bureau of Labor Statistics began tracking this data in 2006. And these are our veterans, recent veterans.

Madam Secretary, are we doing all we can to assist our veterans, particularly as they attend the Transition Assistance Program classes prior to discharge from the military service? It's my understanding that the Transition Assistance Program, which the Labor Department administers for the Department of Defense, was recently revised; its first substantive revision since the first gulf war. Is there data or any information yet on whether the revised program is actually helping veterans find jobs, particularly 21st century jobs that will sustain them—in information technology, health-related professions, and the energy industry—jobs that are meaningful?

I believe we owe our veterans a lot. And I'm sure you'd share this.

Secretary SOLIS. I couldn't agree with you more, Senator. And, as a former House member, this was one area—while I didn't sit on that committee—I was very concerned with the training and the TAP program. That's why I asked my Assistant Secretary, Ray Jefferson, who runs that division, to take a keen look at what was going on there. And what we found was that, yes, there hadn't been evaluations. There weren't any metrics to really identify the people that went through the process, if they really found employment.

We're doing a better job. We're investing money. We have a whole evaluation and a request for proposal to look at how we can improve the program. We have new partners. And I'm happy to report that we even have engaged outside entities like the U.S. Chamber of Commerce, who has agreed to help us identify opportunities for employment, something that should have happened 10 years ago. This program was neglected for the last 8 years. I admit that. I wasn't here——

Senator SHELBY. I know you weren't.

Secretary SOLIS [continuing]. For all that time. But, I can tell you that one of the concerns that this administration has is making sure that we don't just help that soldier, male or female, but we also help the family. Because, the family can also help provide assistance——

Senator SHELBY. Absolutely.

Secretary SOLIS [continuing]. If they're given the right tools and information. Training, especially for wounded warriors—very important. I've seen some tremendous programs that have come out of efforts, that identify good careers. For example, helmets to hardhats, where actually an individual can go in through a training and apprenticeship program, and then, after they leave and are discharged, can actually continue in that program in their State, and then be hired up almost immediately, making a six-figure salary. And that, to me, is something that we ought to be expanding and looking more at.

I'm looking forward to working with the Department of Defense (DOD)—and we have, with the Veterans Administration (VA)—to

improve upon these services. This couldn't be one of the most, if not one of the most important areas that I often look at.

WOMEN VETS

And I'm particularly concerned about returning women vets. We've had a number of women, young women who've gone in, who are also faced with a lot of challenges, one that isn't easily identified when they come back home. Many have been through different posttraumatic stress and also need our help. Many are not apt to identify, in many cases, that they are veterans, as well. Because, when you find them, in some cases, homeless or in a shelter, they won't say that they were a vet, because they feel ashamed. And we have to remedy that. And we have to let everyone know that——

Senator SHELBY. They should be proud.

Secretary SOLIS [continuing]. They're needed, that they're needed.

Senator SHELBY. They should be proud of what they've done. And you're absolutely right that if we can get them back in the workforce, it will help them readjust to civilian life, because they've gone through a heck of a lot.

Secretary SOLIS. Absolutely.

Senator SHELBY. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Shelby.

JOB CORPS EVALUATION

Madam Secretary, I don't have any other questions, just, again, a follow up on what Senator Cochran talked about earlier. You had an exchange with him on the Job Corps, I believe. And I think Senator Shelby asked a question about the efficiency and effectiveness of Job Corps. Yes, it does cost $27,000 per person. But, let me give you one example of a young woman that I know that was in our Job Corps center in Dennison, Iowa.

Our Job Corps center in Dennison, Iowa, was the first in the Nation, by the way—oh, this has been 20-some years ago—that actually added a facility whereby young single mothers could come and bring one or two children with them, and be housed there in a safe environment. They have a Head Start program right there for these kids, plus the healthcare benefits and things like that, that accrue to them.

You take a young single mother who dropped out of high school when she was about a sophomore, had some unfortunate things happen to her, is now 18, 19 years old, two children and no hope, no family, no structure, and headed toward a life of drugs and crime. She gets sent to the Job Corps center. Her kids have a great place to stay. They're in a Head Start program and she's in a program where she's going to get her GED, and then she's being trained for a career. She sees a future ahead of her now. She has all the hope and all of the kind of internal support mechanisms she needs to go out there and do something.

Does that cost $27,000 a year? You bet it does. But, the cost to society of not doing that, I submit to you, will be 10, 20, 30 times that much—the cost to society—if we don't do that.

RETURN ON INVESTMENT

So, I know Job Corps. You look at it and you wonder about the rate of return on investment, as they say, and things like that. But, I don't mind an indepth look. I think we should have it evaluated. I agree with you on that. If there's places that can be tightened up, it should be done. But, in certain cases, this is just going to be—it's not a quick fix. Some of these young people are just not a quick fix. And it takes some time.

But, it's been my experience, with the Job Corps centers over the last 30 years, as a Congressman before this, that sure, there are obviously those that don't make it. There are those that drop out, and don't make it. But, I would say, the success rate that I have been able to see has been tremendous. And what they do in the local community and the local businesses and the synergism, the inner workings with these kids and young people in the Job Corps centers with the local business community, and how they work things out, it's just been for a rural area, it's been quite a thing to see.

So, I just—again, count me as a great supporter of Job Corps. I don't want to turn a blind eye to things that need to be done to make it more effective. And I hope we can work together, and work in a bipartisan——

Senator SHELBY. Absolutely.

Senator HARKIN [continuing]. Fashion to do that.

Senator SHELBY. We want the end result, don't we?

Senator HARKIN. And we want the end result. Exactly right. Exactly right.

So, Madam Chairman, thank—or, Madam Secretary, thank you.

Secretary SOLIS. Thank you both. Thank you. I thank the subcommittee.

And I do want to work with you on evaluation. I think that, yes, we are in hard budget times. We realize that. But, I think, again, if we can preserve the quality of the intent of these services, and help those people that really deserve the help, I think——

Senator HARKIN. Yeah.

Secretary SOLIS [continuing]. We're on the same page.

Senator HARKIN. I'll just add one other thing to my good friend—and he is a great friend of mine—Senator Shelby—is that we are working on WIA. We've been working on it for a long time, even before I was chairman. And hopefully, we're going to have a bill this year.

Secretary SOLIS. Good.

Senator SHELBY. If I could, Mr. Chairman, I just want to reemphasize that we all—Senator Harkin was relating some examples of where Job Corps really works with people and everything—that's what we all want. We want to help these people, because if we don't help them, as he's pointed out, they will be—a lot of them will be in trouble. They will be on welfare for most of their life, if not in prison. I won't say everybody, but so many of them. And this is a chance to help them. We just want to make sure that the programs are working. Let's pump them up. If they're not working, let's find out why they're not working.

Secretary SOLIS. Right.

Senator SHELBY. Because, the need for people—and the help is going to be there—we just want the program to work.

Senator HARKIN. Absolutely.

Secretary SOLIS. Thank you.

Senator SHELBY. Okay.

Senator HARKIN. Amen.

## ADDITIONAL COMMITTEE QUESTIONS

Secretary SOLIS. Thank you both. Thank you. It's a pleasure. Thank you.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

### QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

#### EMPLOYEE BENEFITS SECURITY ADMINISTRATION

*Question.* Since fiscal year 2009, the Employee Benefits Security Administration has created efficiencies in its programs, eliminated lower-priority spending and realized other cost savings. What additional steps will EBSA complete in fiscal year 2011? What is proposed in the fiscal year 2012 budget request?

Answer. Our new paperless participant complaint intake system is scheduled to become fully operational by the end of fiscal year 2011. Currently 92 percent of inquiries and complaints handled by our Benefit Advisors (BAs) are received by phone. We will encourage the use of our new electronic intake process which will be more efficient for the BAs and will be more user friendly for the public. When the paperless system is operational, all participant inquiries/complaints regardless of how they are received will be managed electronically. Currently, participants can submit inquiries electronically; however, the submission does not auto-populate the inquiry database and make assignments to the appropriate office for handling. The new system will more efficiently direct electronic inquires to a Benefit Advisor in the appropriate office and transmit the response for electronic approval and clearance. The system will provide basic contact information for the participant and the subject of the inquiry/complaint that will auto-populate our tracking system. The new paperless system will include standard language paragraphs to be used in correspondence when responding to all types of participant inquiries and will include an e-mail wizard that will allow us to more efficiently contact the participants and plan sponsors to resolve complaints. This will substantially improve the efficiency of the overall Participant Assistance Program.

By the end of fiscal year 2011, EBSA will have implemented a new call management system and web-based reporting tool throughout its regional offices. This system helps EBSA to achieve performance measure targets through more efficient workload management. Also, it allows EBSA to handle more live calls, reduces hold times and dropped calls, and provides managers with real time performance data in order to adjust duty roster schedules. Answering calls live ensures contact with the participant and is more efficient by eliminating call-backs, voice mail messages, and customer service complaints to Congressional offices, DOL managers and other officials.

The EBSA reporting compliance program is continuing to adapt to the new EFAST2, wholly electronic, Form 5500 processing system which became operational in fiscal year 2010. The new EFAST2 makes Form 5500 data available faster—within 24 hours of a filing being made. Consequently, EBSA is able to analyze and review data on a "real time" basis and then apply a customized approach in targeting filings with significant errors.

*Question.* What will the Employee Benefits Security Administration achieve in terms of workload and performance in fiscal year 2011?

Answer. The fiscal year 2011 information and data provided in the fiscal year 2012 congressional budget justification was based on an annualized continuing resolution at fiscal year 2010 enacted appropriations. While the final fiscal year 2011 appropriation approximated these funding levels, the delay in appropriations creates challenges in achieving workload and performance goals. At this point, we expect the performance for the Employee Benefits Security Administration (EBSA) to differ from the fiscal year 2011 information in the fiscal year 2012 congressional budget justification as follows:

| Workload measure | Original fiscal year 2011 workload in fiscal year 2012 CBJ | Fiscal year 2011 revised | Difference |
|---|---|---|---|
| Civil Investigations Processed | 3,282 | 2,900 | −382 |
| Criminal Cases Processed | 247 | 200 | −47 |
| Participant Inquiries (Field) | 246,000 | 233,000 | −13,000 |
| Participant Inquiries (NO) | 10,000 | 12,000 | +2,000 |
| Indictments | 84 | 82 | −2 |
| Compliance Seminars | 10 | 6 | −4 |
| Regulatory Projects | 237 | 250 | +13 |
| Individual Exemptions | 122 | 130 | +8 |
| Section 502(l) Waivers | 15 | 6 | −9 |
| Exemption Processing Time | 301 | 430 | +129 |

All remaining fiscal year 2011 workload estimates remain as presented in the fiscal year 2012 CBJ.

*Question.* The Department has proposed a new regulation defining "fiduciary" under the Employee Retirement Income Security Act of 1974. What benefits would the proposed regulation have for employers—especially small employers—that sponsor retirement plans?

Answer. Investment advisers have assumed an increasingly important role in helping employers, especially small employers, choose an appropriate menu of investments choices for 401(k) plans and in advising employees and IRA holders on how to allocate their individual account balances. Although ERISA specifically provides that investment advisers may be fiduciaries, and employers and employees often rely heavily on their advice, advisers often have no accountability for their recommendations because the Department's current regulation stipulates a five-part test which makes it easy for these advisers to avoid fiduciary status.

The Department's proposal would address this problem by providing that those who purport to give impartial investment advice for a fee will be held to ERISA's fiduciary standards of prudence and loyalty, and preventing them from using compensation arrangements that conflict with these duties. Small business owners, in particular, are often not equipped to make plan investment decisions on their own. In selecting appropriate plan investments and investment options for their employees, small businesses depend on impartial expert advice. The Department's proposed regulation will give these employers recourse against advisers who fail to uphold the standards of a plan fiduciary.

WAGE AND HOUR DIVISION (WHD)

*Question.* The fiscal year 2012 budget identifies savings related to the operation of a toll-free employer compliance assistance call center. Please describe how this proposal will achieve the identified savings with at least the same level of services currently provided.

What steps will WHD complete in fiscal year 2011 that create efficiencies and realize other cost savings?

Answer. In order to improve the ability to provide timely and accurate customer service at each of the more than 200 offices nationwide, the Wage and Hour Division (WHD) is in the process of implementing a telephone system with automated call distribution and integrated voice response technology. Once all new hardware and software are fully deployed in fiscal year 2011, WHD will be better able to route calls for more efficient transfers and referrals, manage staffing needs to be more responsive to callers, record and monitor calls for quality and training purposes, and collect and analyze telephone usage statistics.

With the full implementation of the new computer telephony system, WHD will be able to provide better and timelier service to the public, and at lower cost than it did with the call center.

*Question.* What additional cost savings are proposed in the fiscal year 2012 budget request?

Answer. The fiscal year 2012 budget request indicates program decreases for Employment Compliance Assistance and the Call Center of $2,290,000 and 12 FTE. Over the last 2 years WHD has hired additional in-house technicians who can answer calls more effectively and accurately and as noted above, WHD is already in the process of upgrading its own telephone infrastructure in order to improve the ability to provide timely and accurate customer service at each of the more than 200 offices nationwide.

*Question.* What will the WHD achieve in terms of workload and performance in fiscal year 2011?

Answer. The fiscal year 2011 information and data provided in the fiscal year 2012 congressional budget justification was based on an annualized continuing resolution at fiscal year 2010 enacted appropriations. At this point, we expect the performance for the Wage and Hour Division (WHD) to be consistent with the fiscal year 2011 information in the fiscal year 2012 congressional budget justification.

With the additional investigative resources added to the agency over the past 2 years, the WHD expects an increase in the number of compliance actions that it is able to complete in a fiscal year. For example, WHD estimated a 20 percent increase in the number of concluded compliance actions for fiscal year 2011, or approximately 5,400 additional cases above the 26,500 completed in fiscal year 2010. The newly hired investigators have now completed much of their basic training requirements, and as a result, are contributing to the agency's investigation production numbers.

WHD also expects to see an increase in the number of directed investigations that it completes in fiscal year 2011—particularly in high risk industries, i.e., those industries with high minimum wage and overtime violations and among vulnerable worker populations where complaints are not common. WHD's fiscal year 2011 directed investigations are being concentrated in the agricultural, construction, and hotel/motel industries and in specific program areas. The program areas include the FLSA Section 14(c) program in which employers are certified to employ disabled workers at wages below the Federal minimum wage and the Davis-Bacon and related Acts and Service Contract Act government contract programs. WHD offices are also conducting directed investigations in industries in which young workers are employed and at risk of injury. In fiscal year 2011, WHD will complete a pilot study related to H–2B compliance in the resort segment of the hotel/motel industry. The agency will also examine compliance in the residential construction sector.

Finally, WHD has revised its Davis-Bacon wage survey processes to improve the quality and timeliness of wage determinations published by the agency. WHD, for example, is now utilizing State prevailing wage determinations as the basis for issuing more current highway wage rates. This change, coupled with improvements to the survey process, has positioned the agency to complete during fiscal year 2011 all 26 surveys that were initiated in 2010.

*Question.* According to the preliminary results from the WHD's 2010 review of the authority established under 14(c) of the Fair Labor Standards Act, 23 percent of Section 14(c) certificate holders were found in compliance with only 57 percent of consumers paid in compliance with this section of the law. What specific steps will WHD take in fiscal year 2011 and under the fiscal year 2012 budget request to improve these unacceptably low compliance rates?

Answer. We agree that the 2010 evaluation of employer compliance with Section 14(c) of the Fair Labor Standards Act produced disappointing results. In response to the evaluation findings, WHD conducted investigation-based evaluations of a randomly selected sample of 154 community rehabilitation programs (CRPs) that were certified to employ individuals with disabilities at less than the minimum wage. The agency conducted full investigations of randomly selected CRPs from three employer groups: all certified CRPs, CRPs with prior violations, and CRPs that had conducted a self audit as part of the certification process.

In the baseline evaluation, 65 percent of the cases, which represent approximately 3 percent of the nationwide population of community rehabilitation programs (CRP), were randomly selected for investigation. Twenty-three percent of the investigated CRP's were in compliance with all laws enforced by Wage and Hour for both Section 14(c) workers and other staff workers. Seventy-two percent had monetary violations.

With respect to the evaluation of prior violators, 42 cases representing 49 percent of the nationwide population of CRP's with prior investigations were selected. Nineteen percent of the investigated CRP's were in compliance with all laws enforced by WHD for both Section 14(c) workers and other staff workers, and 69 percent had monetary violations.

For CRPs that conducted a self-audit as part of the certification process, 47 cases, representing 24 percent of the CRP's with prior self-audits, were randomly selected for investigation. Fifteen percent of the investigated CRP's were in compliance with all laws enforced by WHD for both Section 14(c) workers and other staff workers, and 83 percent had monetary violations.

Despite the low compliance rates found in all three evaluations, the data appear to be more nuanced than the rates suggest. The majority of the violations resulted from incorrect or untimely prevailing wage and commensurate wage determinations. Other violations were caused by confusion about the appropriate minimum wage, owing to the fact that between 2007 and 2010, the Federal minimum wage increased three times followed by further minimum wage increases at the State level. Keeping

pace with these minimum wage adjustments produced many of the violations during the survey period.

WHD has identified a number of internal and external strategies to address these types of violations, including changes to the certification process. Given the high turnover among CRP staff who conduct these wage determinations, WHD is considering additional training requirements for CRPs. WHD is also analyzing the certification process as a potential means for routinely and broadly disseminating information on making wage determinations and other compliance issues to certification applicants. Given the geographic distribution of CRPs, along with their staffing and resource constraints, Web-based training could reach a wider audience with less investment for both WHD and CRPs. Exploring the use of technology in training and maintaining the emphasis on improving wage determinations may address many of the violations found.

OFFICE OF FEDERAL CONTRACT COMPLIANCE PROGRAMS

*Question.* OFCCP recently secured a contract to conduct a program level organizational assessment. What were the findings and related costs savings implemented or planned to be implemented? What additional steps will OFCCP complete in fiscal year 2011 that create efficiencies and realize other cost savings? What additional actions are proposed in the fiscal year 2012 budget request?

Answer. To ensure that it is appropriately staffed and resourced to implement its enhanced enforcement, compliance, regulatory and outreach efforts, OFCCP undertook an independent management and organizational assessment. The goal of the organizational assessment was to evaluate the agency's current structure, staff capabilities, resource allocation, and business process efficiency. The assessment was broken into two distinct parts; the former focusing on the National Office and the latter focusing on the regions. In response to the findings of the first part of the assessment, OFCCP reorganized its National Office and created a Governance Board to address systemic issues and break down organizational barriers. OFCCP is still in the process of evaluating the findings of the regional assessment.

The reorganization involved making the following changes to the structure of the National Office, which were aimed at improving organizational effectiveness and efficiency: (1) create a Communications Team within the Office of the Director; (2) make the Division of Statistical Analysis a unit reporting to the Division of Program Operations; (3) create a separate Testing Unit within the Division of Program Operations; (4) create a separate Data Integrity Team within the Division of Program Operations; and divide the Branch of Budget, Finance and Administrative Services into three specialized parts (the Branch of Budget and Finance, the Branch of Human Resources Liaison and Information Management, and the Administrative Services Unit).

The purpose of the OFCCP Governance Board is to transform the way the agency addresses select operational issues. The independent organizational assessment found that too often, identification and development of solutions to operational issues occurs among functional groups on an ad-hoc basis. This approach is not systematic; nor does it provide a consistent mechanism for divisions and regions to work across organizational boundaries. It encourages stove piping and thus limits the agency's ability to achieve desired outcomes. Additionally, it was suggested that many projects would benefit from broader input from the various segments of the OFCCP workforce.

The OFCCP Governance Board will provide a transparent and sustainable means to address appropriate operational issues across organizational boundaries. Once fully implemented, the OFCCP Governance Board will improve vertical and horizontal communication within OFCCP, strengthen the workforce, create a healthier work environment, and provide better ways to identify issues and solve problems, as well as enable the agency to more effectively achieve output targets, outcome goals as described in the Department's Strategic Plan, as well as other organizational goals. In addition, the OFCCP Governance Board will improve employee morale by sending a message to staff that we are committed to including them in the decisionmaking process.

The Governance Board is designed to augment existing approaches. To ensure success, the process will be developed carefully, beginning with a few high priority projects and expanded over time.

In addition to improvements made as a result of the organizational assessment, OFCCP expects to realize significant savings from its new IT system, the Federal Contractor Compliance System (FCCS), a modern cloud-computing based integrated case and content management information technology solution, which is slated to replace the agency's 20 year old case tracking system, the OFCCP Information System

(OFIS), in fiscal year 2012. In fiscal year 2011, OFCCP devoted $3.815 million to the development of system requirements for FCCS. The agency plans to allocate an additional $2 million to the project in fiscal year 2012.

At present, the compliance review process is completely manual. The FCCS will significantly increase the agency's productivity by fully automating this process. Concurrently, FCCS will eliminate inconsistencies across OFCCP's regions by imbedding business rules in the automated environment, thereby preventing deviations from standard operating procedures. Stand alone functionalities such as word processing, spread sheets, statistical software, and e-mail will be integrated into the FCCS, eliminating the need to exit one system to invoke the other. This will create additional efficiencies in completing and tracking cases. For example, compliance officers must enter case related status updates manually into OFIS. This leads to delays and input errors, and is extremely inefficient. By eliminating the need to manually enter status updates and providing the capability to capture, store, search, retrieve and reference case file documentation, the FCCS will save time spent in reconciling information.

The FCCS will also improve information security. Currently, OFCCP case files are in hard copy and lack advanced safeguards to protect the personally identifiable information and commercial data provided to OFCCP by Federal contractors. The FCCS will enable the agency to create, analyze, generate, schedule, and track cases in a secure electronic environment.

We estimate the FCCS will cost about $23 million over a 10 year period, in contrast to a benefit of about $39 million for that same period. The system is designed to allow the agency to add enhancements and improvements over time. Under OFIS, the agency would not be able to add value in the upcoming years. On the contrary, OFIS would become more obsolete every year, and more expensive to maintain over the same time period. In fact, the overall cost to operate the OFIS system for the next 10 years is estimated to be greater than for FCCS, even when the FCCS acquisition and planning cost, front loaded in the first 2½ years, is factored in. For years 3 to 10, we estimate it would cost twice as much for OFIS to operate as it would for FCCS. Thus, implementing the FCCS will enable OFCCP to realize significant savings over time in addition to large gains in productivity.

*Question.* What will the OFCCP achieve in terms of workload and performance in fiscal year 2011?

Answer. In fiscal year 2011, OFCCP is implementing the following strategic goals to achieve the Secretary's vision of good jobs for everyone: (1) prepare workers for good jobs and ensure fair compensation by increasing workers' incomes and narrowing wage and income inequality, and assisting low wage and the unemployed with gaining access into the labor market and the middle income bracket; and (2) assure fair and high quality work-life environments by eliminating barriers to a fair and diverse workforce. OFCCP has also developed new outcome measures that are being baselined in fiscal year 2011. These measures will be used to target OFCCP's performance in fiscal year 2012 and beyond. The measures are: Compliance rate for Federal contractors; discrimination rate for Federal contractors; and impact of an OFCCP evaluation on future contractor compliance.

To measure and assess workload enforcement efforts, OFCCP has several workload measures that are assessed quarterly. These include completion of 3,500 compliance evaluations in fiscal year 2011, which includes a target of 3,225 supply and service reviews and 275 construction reviews. The agency exceeded its compliance review goals by 18 percent through the first and second quarters of fiscal year 2011. OFCCP also has workload measures for its outreach and compliance assistance work, and has also implemented a new quality control measure that will look at the quality of cases worked on by compliance officers.

To further enhance the effectiveness of the compliance review process, OFCCP focuses its investigative efforts on enforcement priorities once desk audits are completed. The objective is to modify how and where case investigation decisions are determined to ensure efficient use of resources. Specifically, the agency identifies cases for priority review based on the potential and type indicators of discrimination and uses a new concept called Triaging of Cases, to identify similar issues and patterns among corporate-wide establishments and within industries. The agency's focus centers on compensation cases, hiring investigations, veterans and disability investigations, and other investigations including promotions, terminations, and good faith efforts. This concept allows the agency to focus enforcement efforts toward complex investigations, which renders more in-depth, detailed and thorough investigations, including additional onsite verifications.

In addition, OFCCP is using performance accountability measures that assist the agency's enforcement efforts, as well as provide the agency with the ability to make proactive adjustments that will ensure the agency reaches its goal. The performance

accountability efforts include: (1) ongoing monitoring and reporting of field enforcement operations by national and regional office activities; (2) quality assurance and quality Investigations of contractors that assist the agency in achieving its goal to conduct more comprehensive audits; (3) improving the identification of adverse impact indicators in the audit process; (4) identifying compensation disparities; and (5) bringing more Federal contractors into compliance. The agency will also enhance the training of its Compliance Officers with an objective to expand and increase the effectiveness of the agency's enforcement. The training will provide staff with introductory, intermediate, and advanced level training in line with national priorities.

*Question.* Secretary Solis, as you know, I am supportive of your efforts to strengthen the affirmative action requirements of 41 CFR part 60–741, the regulations implementing Section 503 of the Rehabilitation Act of 1973, as amended (Section 503). You issued an Advance Notice of Proposed Rulemaking (ANPRM) last July with a September deadline for comments. Can you please provide an update on where things stand with that proposed rule, and when we can expect to see a final rule? I strongly believe that Federal contractors can play a big role in helping to improve employment outcomes for qualified workers with disabilities, and I am eager to see the Section 503 regulations strengthened as part of a broader effort to increase the number of people with disabilities participating in the U.S. labor force.

Answer. I share your belief that strengthening the Section 503 regulations is an important part of the broader effort to increase the number of people with disabilities in the U.S. labor force. The ANPRM we published last year resulted in 127 comments from disability and veteran advocacy organizations, trade and professional associations, employers, and other interested groups and individuals. All comments we received were considered as we drafted a Notice of Proposed Rulemaking (NPRM), which was submitted to OMB for interagency review under Executive Orders 12866 and 13563 on May 24.

OFFICE OF LABOR-MANAGEMENT STANDARDS (OLMS)

*Question.* In fiscal year 2011, OLMS will eliminate a unit dedicated to audits of international unions. OLMS has determined that these expenses will be better used in core mission work. Please provide supporting data for this conclusion, including how OLMS will enforce relevant laws with respect to international unions.

What additional steps will OLMS complete in fiscal year 2011 that create efficiencies and realize other cost savings?

Answer. In fiscal year 2011, OLMS plans to eliminate the International Compliance Audit Program (I–CAP), which on average, resulted in seven or eight audits per year. Savings will be applied to maintaining FTE levels in OLMS' core mission, compliance assistance and enforcement of employer/consultant reporting. It is important to note that OLMS is continuing to conduct criminal investigations involving international unions based on information of financial improprieties. Criminal investigations are part of OLMS' core mission work and OLMS projects to have sufficient resources to conduct approximately 300 criminal investigations in fiscal year 2011. OLMS is also continuing to conduct union officer election investigations (over 130 cases projected) including investigations of international union officer elections. OLMS will also continue to conduct audits of intermediate body and local unions under the compliance audit program (CAP). OLMS will create efficiencies in the CAP program by improving its audit targeting methods to more effectively identify fraud and embezzlement while conducting fewer audits. Despite fewer audits, OLMS' enforcement program will remain viable and effective. OLMS will also realize efficiencies and cost savings in the election program by working to reduce the number of days it takes to resolve union officer election complaints and, in the reports and disclosure program, by increasing the number of LMRDA reports filed electronically.

*Question.* What additional actions are proposed in the fiscal year 2012 budget request?

Answer. OLMS proposed the following initiatives in the fiscal year 2012 budget request:

—Increase effectiveness of audits by focusing resources on labor unions most likely to be in violation of the law.
—Improve timeliness in resolving union member election complaints.
—Improve the Internet public disclosure service and public access to information reported by unions, union officers, union employees, employers, labor consultants and surety companies under the Act.
—Increase provision of compliance assistance to national and international labor organizations to increase their affiliates' LMRDA compliance by developing, implementing, and extending the number of voluntary compliance agreements

(VCA) to establish goals, baselines, and measures for improving recordkeeping, reporting, and internal controls.
—Improve compliance with minimum bonding requirements of local and intermediate union affiliates by working closely with their parent national and international unions, including those who are not party to a VCA.
—Increase the number of national and international unions whose affiliates conduct audits of their own financial records in accordance with a partnership that develops, delivers, and evaluates a customized local union audit training curriculum for each parent union.
—Increase the number of reports filed by employer-consultant persuaders.
—Reduce delinquency rate of filers of Labor Organization Annual Financial Reports.
—Reduce delinquency rate of chronically delinquent filers of Labor Organization Annual Financial Reports.

*Question.* What will the OLMS achieve in terms of workload and performance in fiscal year 2011?

Answer. The fiscal year 2011 workload and performance data provided in the fiscal year 2012 congressional budget justification was based on an annualized continuing resolution at the fiscal year 2010 enacted level. At this point, however, we expect the performance for the Office of Labor-Management Standards to differ from the fiscal year 2011 information in the fiscal year 2012 congressional budget justification as follows:

OLMS expects that the number of election cases will exceed the projected total of 130. Election cases are predicated on member complaints and during fiscal year 2011, OLMS has received an inordinate number of these cases.

OLMS projects fewer supervised elections (projected 35). The number of supervised elections is a demand-driven measure in that OLMS cannot predict changes in annual numbers, and historically the number of supervised elections has fluctuated greatly (based upon the number of election investigations, ability to reach voluntary agreements, etc.)

OLMS expects to exceed the predicted number of 200 compliance audits and complete at least 350 during fiscal year 2011.

As noted above (SSEC10), OLMS expects to continue to seek increased program efficiencies for the remainder of fiscal year 2011 and into fiscal year 2012.

OFFICE OF WORKERS' COMPENSATION PROGRAMS (OWCP)

*Question.* Since fiscal year 2009, the OWCP has created efficiencies in its programs, eliminated lower-priority spending and realized other cost savings. What additional steps will OWCP complete in fiscal year 2011?

Answer. OWCP continues to modernize its technology systems to automate claims processing and provide greater accessibility and services to customers. Expanded use of teleconferencing has reduced travel costs to conduct informal hearings and conferences and training costs. Technology tools also enable centralization of functions and increases flexibility in workforce assignments and workload organization and management. In fiscal year 2011, OWCP will:

Consolidate Division of Federal Employees' Compensation (DFEC) claims intake and case creation activities from 12 District Office locations to two central sites. Consolidation will improve consistency in the quality of case creation as well as provide operational efficiencies such as reduced contract staff and equipment requirements.

Deploy the Employees' Compensation Operations and Management Portal (ECOMP) to allow electronic filing of Federal Employees' Compensation Act (FECA) claim forms, submission of other documents, and the uploading of documents directly through a secure web-based application.

Deploy DFEC's new interactive voice response (IVR) system that will offer self-help features to callers, greatly improve call routing, and provide greater access to information and assistance services.

DEEOIC continues to actively look for ways to improve customer service and speed benefit delivery. In response to a customer service satisfaction survey conducted last year, new pamphlets and brochures are being developed to be posted online and given out at the Resource Centers. These informational pamphlets will provide clear guidance to the claimant population concerning key benefit and program issues.

Continue, on a monthly basis, the Black Lung program assessment of each district office's workload and the rebalancing of caseloads so as to prioritize the adjudication of new claims filed under the Patient Protection and Affordable Care Act (PPACA).

*Question.* What is proposed in the fiscal year 2012 budget request?

Answer. Requests for additional resources in fiscal year 2012, through which OWCP will continue to create efficiencies in its programs, eliminate lower-priority spending, and realize other cost savings include:

—$1,200,000 in Special Benefits (FECA) to provide for policy review and conversion of the iFECS Case Management System to the new HIPPA International Classification of Diseases standard, ICD–10 mandated by the Department of Health and Human Services. The ICD coding scheme is used by OWCP to identify medical conditions accepted in workers' compensation claims and by the healthcare industry for delivery of services to our claimants.

—$3,200,000 and 9 FTE in Longshore Salaries & Expenses for resources to address the numbers and complexity of Defense Base Act (DBA) claims and reduce processing timeframes. DBA injury and death cases in connection with the wars in Iraq and Afghanistan have increased dramatically, rising from 347 cases in fiscal year 2002 to nearly 15,000 cases in fiscal year 2010, while Longshore resources have remained static.

In addition, OWCP continues to pursue legislative reform of the Federal Employees' Compensation Act (FECA). We estimate that our reform proposal will save the Government (conservatively) between $400 and $500 million in its first 10 years. In addition, the proposal contains several provisions that will improve administration of FECA operations. These include creating a lower benefit level, or "conversion" benefit, once an injured employee reaches Social Security Retirement age or after 1 year of FECA compensation (whichever is later); establishing a uniform compensation rate of 70 percent for all claimants, including schedule awards, and removing benefit augmentation for dependents; moving the 3-day waiting period for benefits from after the 45-day continuation of pay period to the first 3 days following the filing of a traumatic claim; and authority to match Social Security records with FECA claims records without prior claimant approval to ensure continued FECA benefit eligibility.

Fiscal year 2012 funding will enable OWCP to introduce additional customer service improvements and business process and organizational design enhancements, as well as workload management innovations such as Telework and Flexiplace expansion.

*Question.* The congressional budget justification indicates that the Division of Federal Employees' Compensation will take a series of steps related to the recruitment, placement, and accommodations of workers with disabilities. Please provide more specifics on current and proposed actions under existing law.

Answer. Subsequent to last year's kick-off of the new Federal workplace safety and return-to-work (RTW) initiative—"Protecting Our Workers and Ensuring Reemployment" (POWER)—DFEC met with the 14 larger agencies to discuss their current performance levels and actions they will take to meet their POWER targets. The meetings also included discussions about those agencies' organizational and other RTW challenges, opportunities for DFEC to provide assistance, and the agencies' potential for improvement.

Extending those latter topics, DFEC and DOL's Office of Disability Employment Policy (ODEP) are developing a research project to be completed by the end of fiscal year 2012 to document the obstacles that exist in Federal agencies relating to return to work, job accommodations, and placement and the best practices used by agencies to reduce or eliminate these obstacles and increase opportunities for success. This research project also supports the objectives of Executive Order 13548, Increasing Federal Employment of Individuals with Disabilities, which specifically directs the Secretary of Labor to take steps that will foster improved return-to-work outcomes. DFEC and ODEP will utilize the results to offer tailored technical assistance to Federal agencies regarding the adoption and implementation of successful return-to-work practices and related disability employment practices.

To provide an incentive to Federal employers to reemploy injured Federal workers with permanent disabilities, DFEC has begun a program to identify and certify FECA claimants for job placement using Office of Personnel Management (OPM) Schedule A hiring authority. Qualification for Schedule A authority, found at 5 CFR § 213.3102(u), provides an avenue to enhance and expedite hiring of individuals with disabilities (as well as other categories of individuals) for Federal service by removing barriers and increasing employment opportunities. Participation in the program is voluntary on the part of the claimant; however, if they volunteer they must self-identify the nature of their disability. With Schedule A, qualified candidates who meet the OPM guidelines can be hired non-competitively: without the typical recruitment headaches; without posting and publicizing the position; and without going through the certificate process.

*Question.* What will the OWCP achieve in terms of workload and performance in fiscal year 2011?

Answer. Following enactment of the fiscal year 2011 appropriation, OWCP reprioritized workload and activities to support the targets and goals addressed in the fiscal year 2011 congressional budget justification. It is expected that the Federal Employees' Compensation Division, the Coal Mine Workers' Compensation Division, and the Energy Employees Occupational Illness Compensation Division achievements will be close to the established targets. The possible exception is the Longshore and Harbor Workers' Compensation Division which is currently not achieving the GPRA goal of 58 percent of First Payment of Compensation Issued Within 30 days for Defense Base Act cases. The performance for the DBA First Payment measure through the second quarter is 54 percent. The performance targets were based on requested additional funding for nine additional FTE and information technology investments that was not enacted. Longshore's resources have been severely taxed by both the numbers and the complexity of Defense Base Act claims arising from increased activity by civilian contractors supporting the military overseas.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

*Question.* What steps will OSHA complete in fiscal year 2011 and does it propose in fiscal year 2012 to create efficiencies and realize other cost savings in pursuing the agency's mission?

Answer. OSHA has been carefully controlling its Full-Time Equivalent (FTE) ceiling and hiring in fiscal year 2011 to ensure that priority, mission-critical positions are filled. The agency has also been granted Voluntary Early Retirement Authority (VERA) by the Office of Personnel Management for the remainder of fiscal year 2011, which extends to agency operations outside of Washington, DC for the first time in well over a decade. In addition, the agency has reduced funding for discretionary purchases, including travel, contracts and printing. As an example, the agency is starting to utilize video conferencing technology for training, meetings and screening of egregious cases to reduce travel expenses. OSHA is also pursuing technology efficiencies, including the elimination of outdated and redundant equipment, to realize cost savings.

*Question.* How will the modest increase available to OSHA be targeted to carrying out the highest priority activities in fiscal year 2011 and achieving the core mission of the agency?

Answer. OSHA did not receive an increase to its budget in fiscal year 2011. The continuing resolution provided the Department with the authority to move funds from the Departmental Management appropriation to other accounts for the purposes of program evaluation, initiatives related to the identification and prevention of worker misclassification, and other worker protection activities. With this authority, funding was restored to OSHA in the amount of the 0.2 percent rescission for standards development, State program enforcement efforts, and training on identifying worker misclassification.

*Question.* What will the OSHA achieve in terms of workload and performance in fiscal year 2011?

Answer. The fiscal year 2011 information and data provided in the fiscal year 2012 congressional budget justification was based on an annualized continuing resolution at fiscal year 2010 enacted appropriations. At this point, we expect the performance for OSHA to not differ significantly from the information in the fiscal year 2012 congressional budget justification.

MINE SAFETY AND HEALTH ADMINISTRATION (MSHA)

*Question.* What steps will MSHA complete in fiscal year 2011 to create efficiencies and realize other cost savings in pursuing the agency's mission?

The fiscal year 2012 budget identifies savings related to the elimination of the small mines office and the SAVE proposal related to the use of postcards reminders for certain information requests.

Answer. With respect to the Small Mines Office, MSHA is not going to close or eliminate it, but will transfer and integrate the function into the Metal and Nonmetal program. MSHA intended to replace the narrative in the justification during the drafting phase to reflect this, but unfortunately that did not occur.

MSHA will begin mailing the first post card reminders in lieu of the multi-part 7000–2 forms for the CY 2011 second quarter reporting period (April–June). This transition will reflect the beginning of the savings outlined in the SAVE proposal.

*Question.* Please describe how this proposal will achieve the identified savings with at least the same level of services currently provided.

Answer. Implementing the SAVE proposals to move to the mailing of post cards will significantly reduce MSHA's printing and postage costs. MSHA will continue to

mail the multi-part form when requested; however, MSHA is encouraging stakeholders to take advantage of the on-line filing capability.

MSHA believes the transfer of the Small Mines Office function will increase the effectiveness of the program by allowing the managers to focus on areas where their expertise is needed. This will provide more meaningful compliance assistance, leading to lower overall fatality and accident rates at all mines.

*Question.* What additional cost savings are proposed in the fiscal year 2012 budget request?

Answer. The fiscal year 2012 request includes two reductions totaling $3,250,000 reflecting the elimination of a project previously funded through an earmark.

*Question.* How will the modest increase available to MSHA be targeted to carrying out the highest priority activities in fiscal year 2011, including those previously addressed in MSHA reports to the Committee on Appropriations and Office of Accountability reports, and achieving the core mission of the agency?

Answer. In the Department of Defense and Full-Year Continuing Appropriations Act, 2011, Congress appropriated to MSHA an additional $7.27 million (post rescission) above the revised fiscal year 2010 continuing resolution (CR) level. MSHA allocated this funding to address critical projects and needs within its core programs and comply with known congressional interest. Below is a summary of the allocations:

*Federal Mine Safety and Health Review Commission (FMSHRC) Backlog Reduction (SOL): $2,000,000*

Transfer of funds necessary to continue the backlog reduction project for the last 2 months of the fiscal year.

*Federal Mine Safety and Health Review Commission (FMSHRC) Backlog Reduction (MSHA): $750,000*

Funds necessary to continue the backlog reduction project for the last 2 months of the fiscal year.

*Metal and Non/Metal Inspections: $1,300,000*

Funds for overtime and travel to ensure the Metal and Nonmetal enforcement program have the necessary resources to complete its mandated inspections.

*Upper Big Branch Investigation Costs: $550,000*

Funds to offset costs associated with MSHA's investigations into the Upper Big Branch mine disaster above those that were supported through the 2010 supplemental appropriation.

*Coal District 4 Split: $250,000*

In response to concern about the sheer size and responsibility of the District 4 office, whose area of jurisdiction in southwest West Virginia encompassed nearly 400 mines and mine facilities or roughly 20 percent of the Nation's coal mines, MSHA is splitting the District into two more manageable organizations, creating a new District office, D12. This action will better serve MSHA and the mining industry. The creation of two districts to cover southern West Virginia will provide for more effective enforcement oversight and improved management of this significant portion of MSHA's workload. The allocation reflects funding to support the infrastructure of a temporary space while GSA secures a permanent location for the new District 12 office. All items purchased or leased will convey to the permanent location.

*Brookwood-Sago Grants Increase: $500,000*

Increase the Miner Act-established Brookwood-Sago Grants program by $500,000. The program provides funding for the development of educational and training programs and training materials for mine emergency preparedness by providing funding for education and training programs to help identify, avoid, and prevent unsafe working conditions in and around underground mines, and focuses on training materials and training programs for mine rescue and mine emergency preparedness in underground coal mines.

*Enforcement Programs Computer IT support: $1,100,000*

Funding to provide replacement laptop and desktop computer equipment for enforcement staff. Current laptops and desktops are 3–4 years old and only have one-half GB of memory which causes all programs to run very slowly. Some machines are taking as long as 8 minutes to start up. This substantially and negatively impacts productivity by reducing mine site time for the inspectors. These machines will not be able to support Office 2010 if and when DOL/MSHA upgrades to this version. Additionally, Windows 7 would not be able to be supported as the operating

system due to inadequate hardware and memory on current machines. MSHA and DOL have already begun migrating to Windows 7 where the hardware is able to support the move.

*Health Samples Reengineering: $900,000*

Funding to replace MSHA's current obsolete 31-year old COBOL system and provide an application that is fully integrated with MSHA's enterprise database. The new system will significantly reduce maintenance costs and improve processing speed. Reengineering the system will allow for:

—Consistent management of samples data.
—Establish consistent integration of samples monitoring with enforcement activities.
—Provide consistent reporting mechanisms.
—Maintain the ability to perform unique validations based on sample type.
—Provide a consistent mechanism for tracking sample history.
—Provide the capability to create a consistent advisory mechanism for reporting violations to MSHA enforcement personnel.

*Mine Emergency Equipment: $750,000*

Provides funding for the purchase of Mine Emergency Operations (MEO) response equipment. MSHA will purchase:

—Communications vehicle, wireless mesh points and supporting equipment.
—Satellite dish for improved communications.
—Engineering vehicle, trailer and equipment.

*Base Funding Reallocations: −$1,080,000*

MSHA will re-direct lapsed compensation funding to offset increases in the Metal and NonMetal enforcement, which will allow MSHA to ensure that Metal and Nonmetal completes 100 percent of its mandated inspections. Additionally, MSHA is reallocating resources to increase the Brookwood-Sago Mine Safety Grants programs, transfer management of the Mount Hope Lab from Technical Support to the Coal activity, and support MSHA's expanded regulatory program.

*Question.* What will MSHA achieve in terms of workload and performance in fiscal year 2011?

Answer. We expect MSHA to continue its enhanced enforcement efforts, i.e. impact inspections, maintain 100 percent of the mandated inspections, and conduct other inspections/investigations. Although the delay in fiscal year 2011 appropriations created some challenges in achieving workload and performance goals, MSHA expects its workload and performance levels to coincide very closely with the fiscal year 2011 information in the fiscal year 2012 congressional budget justification. The fiscal year 2011 information and data provided in the fiscal year 2012 congressional budget justification was based on an annualized continuing resolution at the fiscal year 2010 enacted appropriation level.

BUREAU OF LABOR STATISTICS (BLS)

*Question.* BLS has taken steps in recent years to reduce travel costs by expanding the use of videoconferencing and web-based services. What additional steps will BLS complete in fiscal year 2011 to create efficiencies and realize other cost savings in pursuing the agency's mission?

Answer. The Bureau of Labor Statistics (BLS) has continued to increase the use of its videoconferencing system, web-based services, and telephone and Internet data collection to mitigate travel costs. The videoconferencing system provides high-quality audio and video for meetings between the BLS national office and its regional locations. In addition, the BLS uses videoconferencing to meet with organizations located outside the United States, where international travel would have been required previously. The BLS has increased its use of WebEx, a web-based service that combines real-time desktop sharing with phone conferencing to conduct some work activities with State and regional staff, rather than traveling to conduct business on site. The BLS has also increased its use of telephone and Internet data collection, thereby reducing the travel costs associated with collecting data. In addition to reducing travel costs, the BLS has been working to identify and, where possible, reallocate unused/unneeded IT equipment (computers, servers, printers, and cellphones) using the Asset Management Application (AMA). The AMA enables the BLS to transfer surplus IT equipment that is still serviceable to offices where it will be used. These strategies have proven to be an effective means to avoid rising costs. The BLS is committed to continuing such practices.

*Question.* In addition to the elongating of the fielding schedules for National Longitudinal Surveys and the elimination of the International Labor Comparisons pro-

gram, what additional cost savings and efficiencies are proposed in the fiscal year 2012 budget request?

Answer. In 2012, the BLS will continue efforts to implement online forms within the Producer Prices and Price Indexes (PPI) program, a survey that currently collects monthly price data by mail and fax. In fiscal year 2011, PPI began work with the centralized Internet Data Collection Facility within the BLS to offer online data collection to select respondents. By the end of fiscal year 2012, the BLS will realize cost savings of approximately $10,000. Offering modern, electronic options to respondents, including use of online data collection, will improve the accuracy, timeliness, and efficiency of data collection for both respondents and the BLS and be more environmentally friendly.

*Question.* BLS also has taken steps to change the relationship with State labor market information agencies, most recently with the centralization of the current employment statistics (CES) program. The Nation requires current, accurate, detailed labor statistics for Federal and non-Federal data users. Please comment on the accuracy of the data being produced through the centralized CES program.

How are DOL agencies and State labor market information agencies interacting with each other and with other Federal and non-Federal entities to address the goals of relevant Federal legislation and the Federal-State cooperative statistics system?

Answer. In March 2011, the BLS assumed responsibility for producing CES State and metropolitan area estimates. The transition went smoothly and, as of early June, the BLS has produced 2 months of estimates under the new protocol. State agencies have cooperated fully with the BLS during the transition. States continue to relay information to the BLS about any local events not captured by the CES sample, and provide analysis and dissemination of the estimates to local data users. Data accuracy remains high as the sample size remains unchanged and is supplemented by local information provided by States. In addition, the centralization will permit the BLS to implement program enhancements in the CES program to improve survey response rates, thereby reducing the statistical error on the estimates. Centralizing operations at the BLS also improves the consistency and transparency of the estimation process, which are important dimensions of quality.

In terms of the overall Federal-State cooperative system for producing Labor Market Information (LMI), the BLS and States continue to work together through the annual cooperative agreement process to produce, analyze, and disseminate data from the CES, Local Area Unemployment Statistics, Occupational Employment Statistics, Mass Layoff Statistics, and Quarterly Census of Employment and Wages programs. Consistent with Section 309 of the Workforce Investment Act of 1998, BLS senior management and 10 State LMI Directors elected by their peers continue to hold regular formal consultations. Representatives of other Federal agencies involved in producing labor market information regularly participate in these consultations as well.

*Question.* Last, the National Research Council held a workshop last year on facilitating innovation in the Federal statistical system. Please comment on DOL agencies' innovation activities and plans.

Answer. To foster innovation at the agency and program level, the BLS has included a number of budget initiatives in the President's budget in recent years. For example, in 2010, the BLS received resources to provide new series on "green" jobs, addressing the need for detailed data on these rapidly evolving industries and occupations. As another example, in 2012, the BLS is requesting resources to modernize its Consumer Expenditure (CE) survey. The CE survey is a critical input for the Consumer Price Index. This initiative will allow for continuous research to incorporate multiple data collection modes to take advantage of new technologies, use new sample and statistical modeling methods to increase cost effectiveness, and assess the feasibility of implementing further improvements.

The BLS also continuously improves its current data products to the extent possible within existing resource levels. For example, in 2010, the BLS released official all-employee hours and earnings data, which provide more comprehensive information for the Bureau of Economic Analysis' National Income Accounts and for analyzing economic trends. Also in 2010, the BLS began publishing, for the first time, national estimates of workplace injuries and illnesses incurred by State and local government workers.

In addition, the National Research Council report highlighted the importance of interagency work in fostering innovation within the Federal statistical system. One current example is the Joint Program in Survey Methodology, which is intended to address the critical and growing need of Federal agencies for highly trained personnel in mathematical statistics and survey methodology.

*Question.* What will the BLS achieve in terms of workload and performance in fiscal year 2011?

Answer. The BLS does not expect the workload and performance goals to differ from the fiscal year 2011 information in the fiscal year 2012 congressional budget justification.

OFFICE OF THE SOLICITOR (SOL)

*Question.* What steps will the Office of the Solicitor (SOL) complete in fiscal year 2011 to create efficiencies and realize other cost savings in pursuing the agency's mission?

Answer. In fiscal year 2011, SOL continues to develop critically needed Legal Technology infrastructure improvements. This initiative began with an evaluation in fiscal year 2009. In fiscal year 2011, we are projected to complete the first of three phases of development. SOL's IT modernization initiative addresses important improvements in SOL's IT/Litigation Support infrastructure, including: replacing SOL's failing case management and time reporting systems (SOLAR/TD), as well as developing capacities in the critical areas of legal document management, document review tools, transcript and evidence management, trial presentation and case analysis. In addition, in fiscal year 2011, SOL continues to build its FTE-related program support capacity, including its professional development and training necessary to ensure that SOL's legal skills are competitive with those of its adversaries and other stakeholders that influence the working conditions and security of America's working women and men.

*Question.* The fiscal year 2012 budget identifies savings related to the elimination of resources for compliance assistance and outreach, longshore litigation, and review of Uniformed Services Employment and Reemployment Rights Act case referrals to the Department of Justice. Please describe how these proposals will achieve the identified savings without compromising SOL's core mission.

Answer. SOL's budget request for fiscal year 2012 was constructed in close coordination with the budget priorities for its DOL client agencies, enabling SOL to forcefully and decisively support the Secretary's vision of "good jobs for everyone." The fiscal year 2012 budget includes three program reductions as follows.

*Eliminate SOL's Compliance Assistance and Public Outreach Activities*.—SOL proposes to cease performing the wide variety of compliance assistance and public outreach activities in which it currently engages, including speeches, presentations, responding to inquiries from and providing training to the public, and supporting the clients' compliance assistance activities.

*Eliminate SOL review of the Veterans Employment and Training Service's (VETS) USERRA case referrals to DOJ*.—The Department of Justice bears the primary authority for litigating cases in this program and engages in a de novo review of the merits of each case. This proposal eliminates SOL's review of the recommendations to DOJ from VETS.

*Eliminate Non-participation memos*.—DOL should discontinue its practice of drafting legal memos to support its decision not to participate in cases under the Longshore and Harbor Workers Compensation Act and Mine Act in the courts of appeals, and should communicate those recommendations orally to OWCP and MSHA.

*Question.* What additional cost savings are proposed in the fiscal year 2012 budget request?

Answer. As described in the response to SSEC24, SOL is in the midst of an IT Modernization initiative that began in fiscal year 2009 and the fiscal year 2012 budget request includes funding to continue this project in fiscal year 2012.

*Question.* What will the SOL achieve in terms of workload and performance in fiscal year 2011?

Answer. The fiscal year 2011 information and data provided in the fiscal year 2012 congressional budget justification (CBJ) were based on an assumed annualized funding level based on the continuing resolution at fiscal year 2010 enacted appropriations. While the final fiscal year 2011 full year continuing resolution approximated these funding levels, the delay in appropriations has created challenges in achieving workload and performance goals. Consistent with the performance and workload information in SOL's fiscal year 2012 CBJ, SOL expects its fiscal year 2011 workload and performance projections to be consistent with fiscal year 2011 information in the fiscal year 2012 CBJ, with the increased production from the temporary and term FTE funded by the fiscal year 2010 supplemental appropriation (and the $2 million transfer from MSHA's fiscal year 2011 appropriations to SOL) to reduce the backlog of mine safety and health cases pending before the Federal Mine Safety and Health Review Commission. At this point, we expect the perform-

ance for SOL to differ from the fiscal year 2011 information in the fiscal year 2012 CBJ as follows:

Historically, including in the fiscal year 2012 CBJ, SOL aggregated its Pre-Litigation Matters and Litigation Matters together as "Litigation Matters" when reporting. Now that SOL has revised its production measures to separate out Pre-Litigation Matters from Litigation Matters, we have revised targets and results for Litigation Matters Opened (formerly referred to as Litigation Matters Received) and Litigation Matters Concluded to exclude Pre-Litigation Matters from the tabulations, and we have included separate figures for Pre-Litigation.

The projected number of Mine Safety and Health litigation backlog matters to be concluded in fiscal year 2011 projection for Litigation Matters Concluded, as reflected in SOL's workload projects, has been revised. The original target was based on a projection from the MSH litigation matters concluded in the first quarter of the backlog project, but based on current trending, that rate is not sustainable as a constant rate over the full project. While we expect this SOL workload measure to trend downward, the MSH litigation backlog project remains on track to exceed our expectations for disposition of cases and citations. It is important to note that the SOL workload projections are not directly comparable to data and projections reported in the Quarterly Reports to Congress for the Targeted Caseload Backlog Reduction Project. This is because SOL's projections are based on SOLAR, which tracks only Litigation Matters Concluded by SOL, and the reports to Congress are based on data provided by the Federal Mine Safety and Health Review Commission, including matters handled by MSHA's CLRs (and not SOL) as well. In addition, these two data sets are based on different time periods.

BUREAU OF INTERNATIONAL AFFAIRS (ILAB)

*Question.* What actions will the Bureau of International Affairs take in fiscal year 2011 to create efficiencies and realize other cost savings in pursuing the agency's mission?

Answer. The President's fiscal year 2011 budget request included additional resources for ILAB to improve its monitoring and enforcement of trade agreements and expand its worker rights technical assistance program. The United States has trade agreements with 13 developing countries and provides trade preferences to approximately 140 other developing countries. These agreements and programs include labor rights obligations. Without the additional requested resources, ILAB has shifted staff from lower priority activities, such as participation in inter-agency processes, to higher priority activities such as labor monitoring and the enforcement. However, we anticipate that monitoring activities will increase as the U.S. negotiates additional trade agreements and ILAB continues to strive for the robust enforcement of trade agreements.

ILAB will continue to coordinate its efforts to address the root causes of child labor and forced labor with those of the International Labor Organization (ILO). ILAB will also continue to search for ways to improve the effectiveness of its programs to advance its goal of improving the livelihoods of exploited laborers and at-risk youth.

ILAB is using research and technology to improve the efficiency of ILAB's operations. Systematic research and analysis on the status of labor rights in trade partner countries allows ILAB to coherently target policy engagement—including trade enforcement actions and technical cooperation activities—to specific countries and issues where the maximum impact may be achieved. ILAB has made substantial progress on developing a system for tracking and sharing information internally and with other agencies. This helps utilize scarce resources as efficiently as possible.

*Question.* What additional steps are proposed in the fiscal year 2012 budget?

Answer. The ILAB budget proposal for fiscal year 2012 included expanded resources (1) for additional staff in the area of monitoring and enforcement of the labor provisions of trade agreements and (2) for expanded worker rights grants. The budget proposal did not call for specific additional steps to create efficiencies and realize other cost savings in pursuing the agency's mission beyond those proposed in the fiscal year 2010 budget and cost savings realized to comply with the constraints of the continuing resolutions covering fiscal year 2011.

However ILAB intends to continue to pursue efficiencies and cost savings from measures that have been put in place during the current fiscal year, including prioritization of activities, targeted engagement with those governments that offer greatest promise of progress, limitations on staff travel and cautious hiring and replacement policies.

In addition, in fiscal year 2012 ILAB intends to undertake more assignment of staff across its offices in order to accomplish all high priority and mandated work

without addition staff resources, in case the fiscal year 2012 budget does not allow additional hiring. ILAB will also identify and eliminate additional lower priority activities, beyond those curtailed in fiscal year 2011, as needed to accomplish its mission with constrained resources. ILAB has started to identify such lower priority activities for possible elimination in fiscal year 2012. These measures will mean that ILAB is not able to sustain the current level of effort on all programs.

*Question.* Please describe the impact of not receiving the increase proposed in the fiscal year 2011 budget, particularly on activities related monitoring and enforcement of labor provisions of trade agreements.

Answer. Not receiving the increase proposed in the fiscal year 2011 budget has significantly reduced ILAB's intended impact on improving worker rights around the world. Without the fiscal year 2011 request for resources to monitor and enforce labor provisions of trade agreements, ILAB will be unable to increase its monitoring efforts. In fiscal year 2011, ILAB has been monitoring less than half the number of trade partner countries it would have monitored under the requested level of funding. It has also been impossible to establish and expand high priority trade related worker rights technical assistance, especially Better Work programs. A lower level of resources will lead to a reduction in ILAB's planned activities, particularly monitoring and enforcement, in the following specific ways:

*Monitoring*.—ILAB will not have the resources to systematically review, analyze and track labor problems in all FTA countries. ILAB has developed a set of standards and a systematized method for tracking progress on labor issues, but has only been able to apply this in-depth, systematic monitoring to six FTA countries. For the other 11 FTA partners, ILAB has been conducting ad hoc monitoring as problems arise. ILAB's responsibilities related to the labor provisions of FTAs are expected to rise significantly in the next year. The recently negotiated Colombia Action Plan Related to Labor Rights will require significant ILAB resources to monitor in the near future. In addition, the United States is currently negotiating the Trans-Pacific Partnership FTA (TPP) with seven countries. ILAB has not been able to invest the staff resources to engage the developing countries that are party to the TPP negotiations on labor issues to the extent we consider desirable. Negotiating new FTAs offers the best leverage for the necessary changes in labor regimes and institutions. Without the additional resources, ILAB's capacity to bring current and detailed knowledge to the negotiating process will be seriously constrained. TPP countries include Vietnam, Malaysia, and Brunei Darussalam, which have significant labor challenges.

*Enforcement*.—ILAB will not have the resources to expand enforcement beyond 2010 levels of the labor obligations of countries that benefit from U.S. trade agreements and preference programs. ILAB monitors and engages countries on labor rights law and practice if a labor petition is filed under GSP, free trade agreements, or as part of the annual review process of AGOA. ILAB had planned to expand its engagement to additional countries of concern to address areas where there were concerns they had not met their obligations. While ILAB has identified potential labor rights issues in trade partner countries, it has been unable to proactively initiate new labor consultations or reviews under trade agreements and preference programs because of the significant staff resources they would entail.

ILAB must divert resources from other functions. ILAB has already been compelled to re-assign staff from technical assistance and research functions to mandated monitoring and enforcement of FTA labor provisions. If monitoring activities increase, we will have to draw resources from other priorities.

ILAB also has not received requested resources to expand its worker rights technical assistance programs. These programs aim to create a level playing field for U.S. workers in the global economy and improve worker rights in U.S. trade partner countries. As part of this initiative, ILAB has established Better Work programs in Haiti, Lesotho and Nicaragua, and provided initial funding in fiscal year 2010 to establish a program in Bangladesh and support modest expansions in Vietnam and Cambodia. In fiscal year 2011, we plan to initiate a program in Egypt modeled on Better Work. However, without additional resources, these programs will not be able to be fully scaled up.

*Question.* What will the ILAB achieve in terms of workload and performance in fiscal year 2011?

Answer. The fiscal year 2011 information and data provided in the fiscal year 2012 congressional budget justification was based on an annualized continuing resolution at fiscal year 2010 enacted appropriations. While the final fiscal year 2011 appropriation approximated these funding levels, the delay in appropriations creates challenges in achieving workload and performance goals. At this point, we do not expect the performance for ILAB to differ from the fiscal year 2011 information in the fiscal year 2012 congressional budget justification.

WOMEN'S BUREAU (WB)

*Question.* What actions will the Women's Bureau take in fiscal year 2011 to create efficiencies and realize other cost savings in pursuing the agency's mission, beyond replacing staff with lower-paid employees?

Answer. The Women's Bureau works diligently to make the most effective use of its resources. Over 85 percent of the Bureau's budget is spent on salaries and benefits, rent and working capital fund, leaving very little discretionary funding. However, the Bureau continues to look for ways to create efficiencies in the way it does business. One way is by utilizing the Federal Strategic Sourcing Initiative to lower cost for supplies. Both the national and regional offices use this initiative to purchase supplies whenever possible.

In addition, the Bureau is attempting to reduce copying and printing costs and find "greener" alternatives when disseminating outreach and technical assistance materials. As part of our strategic outreach activities, the Bureau provides attendees with research papers, guides, manuals, and other materials. At meetings or events that require such extensive resource material, the Bureau has moved away from printing the documents to providing them on flash drives. The use of flash drives also allows the Bureau to include additional Departmental and governmental information and resources to the attendee at no additional cost. These flash drives also serve as a communications tool, as they are imprinted with Bureau's name and website.

*Question.* What additional steps are proposed in the fiscal year 2012 budget?

Answer. The Bureau will continue to look for efficiencies including use of technology to reduce travel costs. The Bureau is working with the Department for cost effective ways to implement video conferencing with our regional offices, which will reduce travel costs over the near future. Additionally we are looking to use social media tools to promote our message, products and programs and increase the turnout and impact of our initiatives.

*Question.* The budget proposes appropriations language to enable the Women's Bureau to make grants. How much funding and what purposes would this authority be used to support?

Answer. The Bureau anticipates that approximately $500,000 to $750,000 of funds currently spent on contracts will be spent on grants. The Bureau typically works closely with nonprofits, community and faith-based organizations, and educational institutions to meet its mission of helping women achieve economic security, providing them with the necessary tools to ensure their advancement in the labor force, and promoting fair and high-quality work-life environments. These informal partnerships have been productive, but grants and cooperative agreements would give the Bureau the tools to better achieve its public policy and programmatic goals and objectives. This authorization would allow the Bureau to fund research, publications, and educational efforts that will directly contribute to the Bureau's mission.

*Question.* What will the Women's Bureau achieve in terms of workload and performance in fiscal year 2011?

Answer. The fiscal year 2011 information and data provided in the fiscal year 2012 congressional budget justification was based on an annualized continuing resolution at fiscal year 2010 enacted appropriations. While the final fiscal year 2011 appropriation approximated these funding levels, the delay in appropriations creates challenges in achieving workload and performance goals. At this point, we expect the performance for the Women's Bureau to differ only slightly from the fiscal year 2011 information in the fiscal year 2012 congressional budget.

OFFICE OF DISABILITY EMPLOYMENT POLICY (ODEP)

*Question.* What actions will the Office of Disability Employment Policy (ODEP) take in fiscal year 2011 to create efficiencies and realize other cost savings in pursuing the agency's mission? What additional steps are proposed in the fiscal year 2012 budget?

Answer. In fiscal year 2011 ODEP will create efficiencies and realize costs savings by focusing on the priority activities that we believe will yield the greatest impact on low labor force participation and high unemployment rates. This will allow ODEP to shift resources to key problem areas and, in some cases, increase resources to conduct policy development and expand technical assistance and dissemination efforts. For example, we plan to transition some programs and initiatives to other Federal agencies who are better positioned to administer them. For example, ODEP efforts related to two initiatives—United We Ride and America's Heroes at Work—will be reduced as other agencies assume greater responsibility for these.

ODEP is proposing additional steps in fiscal year 2012 to concentrate its efforts on those key factors most likely to yield significant results. By utilizing proven

strategies focused on our priority areas, ODEP will direct and redirect its resources to maximize impact. Also, in fiscal year 2012, ODEP intends to increase its reliance on the National Employer Technical Assistance Center (NETAC) which has knowledge of ODEP's policy products and utilizes a consortium approach to leverage access of national organizations to employers and stakeholders. By relying on NETAC and its partners, ODEP can extend its reach and ability to rapidly disseminate information and provide technical assistance. ODEP expects to realize operational efficiency and cost savings by tapping into NETAC's existing knowledge, infrastructure and capacity to reach more than 4,000 employers (including the Federal Government and its contractors), service providers, and other stakeholders likely to adopt and implement effective practices.

DOL'S CIVIL RIGHTS CENTER (CRC)

*Question.* Please provide information on the findings from the new review process of State Methods of Administration and the assistance that will be provided to help States and the One Stop System meet the needs of all customers or potential customers, including individuals with disabilities.

Answer. The WIA nondiscrimination regulations require each Governor (or his/her designee) to prepare and submit to DOL's Civil Rights Center (CRC) a document known as a Methods of Administration (MOA) plan for ensuring that all WIA Title I financially assisted State programs comply with the civil rights laws enforced by CRC, including the laws protecting individuals with disabilities. Additionally, every 2 years, the Governor is required to review the MOA to determine whether it needs to be updated in order for the State to be in full compliance. If updates are necessary, the Governor must make and submit them; if no updates are necessary, the Governor must certify in writing that the previous MOA remains in effect.

Until recently, review of the MOA documents was CRC's primary method of assessing whether each Governor was satisfying his/her oversight responsibilities. Within the past 2 years, CRC has shifted the emphasis of its reviews to determining whether the actions described in the plans are actually being implemented.

CRC offers recipients a number of different types of technical assistance and training. The agency's website, which underwent a major reorganization in fiscal year 2010, contains compliance assistance tools and training courses on a number of nondiscrimination-related topics, including disability issues. CRC staff members provide individualized compliance assistance and information, upon request, to congressional staff, State- and local-level Equal Opportunity Officers, Disability Program Navigators, Job Corps administrators and staff, other DOL managers and employees, representatives from other Federal departments and agencies, members of the public seeking information about civil rights laws, and a host of other persons from CRC's internal and external customer base. This assistance and information is generally provided by phone or e-mail, and occasionally in person. (Note: The majority of technical assistance requests CRC receives are with regard to disability issues, such as the lawfulness of disability-related inquiries.)

With regard to training, CRC continues its policy of delivering training courses and workshops at State- or Local Area-sponsored training events, tailored to the specific issues of concern to the audience. In recent months, the agency has leveraged limited resources by providing these courses and workshops remotely, via webinar and audio conference; live delivery will take place as budgets permit. In addition, CRC will offer its 22nd Annual National Equal Opportunity Training Symposium from August 30 through September 2 in Crystal City, Virginia. The 2010 event drew approximately 350 State- and local-level EO Officers and staff, as well as administrators and staff of the One-Stop workforce development system; Job Corps staff and contractors; and other stakeholders.

*Question.* What will the ODEP achieve in terms of workload and performance in fiscal year 2011?

Answer. The fiscal year 2011 information and data provided in the fiscal year 2012 congressional budget justification was based on an annualized continuing resolution at fiscal year 2010 enacted appropriations. Since the final fiscal year 2011 appropriation closely approximated these funding levels, the delay in appropriations is not expected to create any significant challenges in achieving workload and performance goals. At this point, we do not expect the performance for the Office of Disability Employment Policy (ODEP) to differ significantly from the fiscal year 2011 information in the fiscal year 2012 congressional budget justification.

EMERGING INDUSTRIES AND HIGH GROWTH OCCUPATIONS

*Question.* The prediction of emerging industries and high growth occupations is essential to effective workforce development. What are the current ways that ETA

is using labor market information to improve workforce services such as job search, career counseling and training?

Answer. We agree that labor market information (LMI) including information about emerging industries and high growth occupations is necessary to ensure that job seekers, career changers, and strategic planners have the labor market intelligence they need to make sound training, education, and economic development investments. This past year, ETA launched two new creative and useful electronic tools: mynextmove.org which is a career exploration site for individuals entering the labor market and myskillsmyfuture.org which quickly shows unemployed workers what other jobs need their skill sets.

ETA takes several actions to assure that State and local workforce investment boards, One-Stop Career Centers, partner agencies, job seekers, and businesses have a wide variety of reliable and comparable labor market data and information. ETA provides annual funding from the Workforce Information-National E-Tools and Capacity Building budget line to the States and territories and consortia of States to support the collection and dissemination of state and local labor market information, including:

—Production at the State and local levels of 2- and 10-year industry and occupational employment projections;

—Population of the Workforce Information Database that facilitates the sharing among the States of comparable data sets on wages, licenses, credentials, military to civilian occupational cross walks, employer location and contact information, etc.;

—Maintenance and expansion of the occupational information network (O*NET) that documents occupational skills, competencies, and detailed work activities including new, emerging, or evolving occupations such as green jobs; and

—Universal access to the LMI data described above and a variety of other data through state LMI web sites and via national electronic tools including the Career One Stop portal at www.CareerOneStop.org and ONET Online at http://www.onetonline.org/. These websites and portals receive more than 38,000,000 customer visits per year.

In addition, in 2009, ETA provided nearly $50,000,000 in ARRA competitive grants for State LMI Improvement grants to 24 States and six consortia. While most projects continue to operate, to date the States have:

—Conducted numerous State- and local-level surveys to measure green jobs and the impact green jobs are having on their States' economies, and to identify education and training programs that support skills acquisition for emerging industries and occupations;

—Researched the use of "Real Time" LMI (job openings data collected daily and aggregated from the Internet job banks and corporate websites) to enhance 2-year and 10-year projections and to make more job opportunity data available to job seekers;

—Conducted research on green jobs skills with the goal of aiding dislocated workers' transition from declining to transforming and emerging industries; and

—Developed new tools and improved access to workforce and LMI data in the labor exchange operations within the One-Stop Career Centers.

*Question.* How is the Department working to improve the use or availability of this information to make quality and timely predictions?

Answer. One of the State LMI Improvement grants, noted in the response to SSEC 37, was awarded to the Projections Managing Partnership consortia of States to re-write and enhance the State and local industry and occupational short-term (2 years) and long-term (10 years) software suite that States use to inform training, education, and economic development investment decisionmaking. This is now available to all States to produce the occupational projections. In addition, the consortia made enhancements to add the skills that will be in demand by combining the projected occupational growth and O*NET-defined skills.

In September 2010, the Department released a new skill transferability tool specifically designed for direct use by dislocated workers who have skills and work experience but need to change jobs to adapt to the changes in their local economy. Called myskillsmyfuture.org, this site uses simplified navigation, language, and integrated information resources to provide a seamless experience for dislocated workers. Similarly, for individuals who are exploring careers, the Department released a site in February 2011 with simplified language, and an online 60-question interest assessment tool that makes the O*NET occupational profiles easier to access and use, while ultimately still linking to the additional detail available through O*NET OnLine. This tool is found at mynextmove.org.

ADULT EMPLOYMENT AND TRAINING ACTIVITIES

*Question.* The fiscal year 2012 budget request indicates that the Department will increase the rate of industry-recognized credential attainment among customers receiving training. What is the strategy for increasing credential attainment and how will the Department measure its progress on this goal?

Answer. The Secretary of Labor has set a high priority performance goal of increasing by 10 percent the number of workforce program participants who attain industry-recognized credentials. To support this goal, the Employment and Training Administration has issued guidance to the system (Training and Employment Guidance Letter 15–10), provided technical assistance through webinars and other means, and invested in promising program models. A summary of this activity follows:

ETA, with its partner agencies in Education and Health and Human Services, supports the increase of credential attainment through the development of career pathway systems. Through strong alignment of education, training and employment services among public agencies and with employers, career pathway approaches better enable low-skilled adults and other hard-to-serve populations, students, and workers, to succeed in postsecondary education and earn in-demand, industry-recognized credentials that place them on a career ladder. Through discretionary grants and technical assistance efforts, ETA is working with community colleges, State workforce systems and others to develop career pathway models that link education and training to advancement along a specific track. For example, one career pathway includes bridge programs to assist Certified Nursing Assistants to become Licensed Practical Nurses.

ETA also focuses on strengthening programs like Job Corps and YouthBuild that help young people earn valuable occupational credentials while completing high school and Registered Apprenticeship programs that provide participants a valuable credential while earning wages on the job.

Through the Trade Adjustment Assistance Community College and Career Training Initiative, the Department of Labor will make a large investment in building the capacity of community colleges and other eligible higher education institutions to design programs that meet the needs of trade-impacted workers. These programs will be designed to meet the needs of non-traditional, eligible students for flexible scheduling, easy entry and exit from programs, accelerated remediation through contextualization, integrated academic and occupational training, on-line courses, and more. They will reflect evidence-based strategies that have proven effective, or test strategies that have promise.

DISLOCATED WORKER EMPLOYMENT AND TRAINING ACTIVITIES

*Question.* Dislocated Worker National Emergency Grants (NEGs) are sometimes used to create employment opportunities for dislocated workers to assist with clean up from natural disasters. What portion of fiscal year 2010 NEGs was used for these purposes and how many dislocated workers received employment opportunities through these grants?

Has the use of NEGs for this function increased over time?

Answer. As fiscal year 2010 appropriations fund Program Year (PY) 2010 activity for National Emergency Grants (NEGs), we are providing responses based on disaster NEG activity thus far in PY 2010 (PY 2010 began July 1, 2010 and ends June 30, 2011).

Within the National Reserve, the fiscal year 2010 appropriation provided $190,919,666 for NEGs. As the table below shows, the Department has awarded 18 disaster NEGs and funded two increments for prior year disaster NEGs, for a total $79,893,327. Of the amount awarded, $69,041,816 was funded, which is about 36 percent of the almost $191 million available for NEGs in PY 2010 and 55 percent of the $126,544,605 awarded to date. An estimated 6,180 individuals will receive temporary employment opportunities and reemployment services through these NEGs. A number of these NEGs are too recent to have completed their final planning/hiring, so we have presented their participant estimates in italics.

Disaster NEG funds provide funding to create temporary jobs to support clean-up and recovery efforts. These efforts can fluctuate widely depending on the number, severity, and type of natural disasters that occur in any given year. Activity in PY 2010 is slightly above average. However, it doesn't compare to Hurricane Katrina/Rita efforts, where Louisiana alone spent $43,599,160 to provide 7,502 disaster affected workers temporary employment and reemployment services.

As indicated, we are still within the program year, and it is customary for State applications to come in late in the program year as formula funds are depleted. As a result of this practice, together with recent weather emergencies, the Department

currently has applications that exceed the remaining funds for NEGs and we expect the entire appropriation to be awarded.

| State | Project | New or incremental funding | Approval date | Amount approved (up to award) | Amount funded | Participants |
|---|---|---|---|---|---|---|
| KY | KY-Severe Storms, Tornadoes, and Flooding | New | 6/6/2011 | $4,276,514 | $4,276,514 | 317 |
| OK | Oklahoma Severe Storms and Tornadoes | New | 6/1/2011 | $471,150 | $471,150 | 26 |
| MO | MO Severe Storms, Tornadoes and Flooding 2011 | New | 5/27/2011 | $5,822,352 | $5,822,352 | 404 |
| AR | Severe Storms, Tornadoes and Associated Flooding | New | 5/26/2011 | $3,758,327 | $3,758,327 | 249 |
| TN | TN-Disaster-Storms, Tornadoes, Flooding | New | 5/23/2011 | $3,589,704 | $3,589,704 | 480 |
| CA | California Tsunami Waves | New | 5/11/2011 | $6,498,100 | $6,498,100 | 271 |
| GA | Georgia Tornado and Storm Disaster | New | 5/11/2011 | $5,000,000 | $5,000,000 | 300 |
| MS | MS-Disaster-Severe Storms, Tornadoes, Straight-line Winds, and Associated Flooding | New | 5/9/2011 | $7,000,000 | $7,000,000 | 525 |
| AL | Severe Storms, Tornadoes, Winds, & Flooding Disaster | New | 5/4/2011 | $10,000,000 | $10,000,000 | 800 |
| OR | Oregon Tsunami Wave Surge 2011 | New | 4/15/2011 | $284,023 | $94,674 | 15 |
| OR | STORMS 2011 | New | 3/18/2011 | $176,904 | $176,904 | 10 |
| CA | 2010 California Severe Storms | New | 2/23/2011 | $11,267,940 | $3,755,980 | 252 |
| AR | Storms October 2009 | Increment | 12/10/2010 | | $8,494 | 119 |
| PR | Tropical Storm Otto | New | 11/23/2010 | $4,000,000 | $4,000,000 | 607 |
| MN | Southern MN 2010 Flood | New | 11/8/2010 | $1,160,391 | $580,195 | 29 |
| IA | Severe Storms/Flooding/Tornadoes 2010 | New | 9/22/2010 | $5,800,000 | $2,000,000 | 126 |
| TN | Severe Storms and Flooding | Increment | 9/14/2010 | | $2,921,500 | 670 |
| TX | Hurricane Alex Flooding | New | 9/14/2010 | $5,849,481 | $5,849,481 | 416 |
| KY | Eastern Kentucky Severe Storms, Flooding and Mudslides | New | 8/27/2010 | $938,441 | $938,441 | 57 |
| PR | Severe Storms and Flooding | New | 7/22/2010 | $4,000,000 | $2,300,000 | 507 |
| | Totals | | | $79,893,327 | $69,041,816 | 6,180 |

YOUTHBUILD

*Question.* As you know, as a result of the significant funding constraints on the fiscal year 2011 continuing resolution, the 2011 funding level for YouthBuild represents a significant reduction to the program. Specifically, the program was funded at $80 million—a $23 million or 22 percent reduction. On May 17, 2011, the Department announced 74 grantees that will receive funding under the fiscal year 2011 appropriation for YouthBuild. How many existing YouthBuild grantees have lost funding as a result of the reduction and how many of the 74 awards are going to new grantees not previously funded by the Department?

Answer. With fiscal year 2009 and American Recovery and Reinvestment Act Funds (ARRA), a total of 183 grants were funded by the Department of Labor (DOL). In fiscal year 2011, a total of 74 grants were awarded, of which two went to organizations not previously awarded grants by DOL. This means that 72 previously funded grantees were refunded through the 2011 competition. Therefore, 111 grantees were not refunded in the most recent competition.

*Question.* In the past the Department has tended to fund YouthBuild grants on a 2-year basis. Has that approach changed as a result of the lower funding level in fiscal year 2011?

Answer. With fiscal year 2011 funds, the Department of Labor (DOL) awarded 74 YouthBuild grants that are for 2 full years of program services. These grants were provided the full amount from the fiscal year 2011 funds. This plan was outlined in Solicitation for Grant Application announced in October, 2010 and was not a result of the lower funding level.

JOB CORPS

*Question.* The fiscal year 2011 continuing resolution included a $75 million rescission to Job Corps construction and renovation funds. How will Job Corps implement that rescission?

What projects will it impact and will Job Corps go forward with the planned construction of centers in Wyoming and New Hampshire?

Answer. Job Corps had preliminarily identified $75 million from previously budgeted, but not obligated, projects. These projects have now been placed on hold, subject to available resources, and may be designated to receive funding in future Program Years. These projects are in one of three categories: (1) projects in which the budgeted amount includes the construction phase of the project, (2) projects in which the budgeted amount includes the design phase of the project, and (3) projects in which the budgeted amount was only partially rescinded.

The new centers in Wyoming and New Hampshire are still under consideration in light of the available funding. Final decisions will be made after the Department thoroughly assesses the impact of the rescission and concludes a re-evaluation of Job Corps' inventory of construction projects.

WORKFORCE INNOVATION FUND

*Question.* The fiscal year 2011 continuing resolution included $125 million for a new Workforce Innovation Fund to support innovative new strategies or expand evidence-based strategies that align programs and strengthen the workforce development system to improve the education and employment outcomes for job seekers and workers, youth, and employers. What are the Department's plans for these awards in terms of the timing of the solicitation and awards and the likely number of awards?

What benefits do you see these grants having for the workforce investment system and how would these initial grants tie to the President's fiscal year 2012 request for Workforce Innovation Funds?

Answer. While the precise timeline is still being discussed, ETA is pursuing an aggressive timeline to prepare for publication of the first Workforce Innovation Fund (WIF) Solicitation for Grant Applications. To ensure that our final product draws fully on the experience and knowledge of stakeholders and is capturing the most innovative and promising approaches, the Department has commenced an intensive stakeholder engagement strategy which includes outreach to Federal partners, including the Departments of Education and Health and Human Services and the Office of Management and Budget; State and local workforce organizations; intergovernmental organizations and associations; Senate and House Committees (Authorizing and Appropriations); and foundations and the research community. ETA is using a mix of face-to-face discussions and webinars to encourage broad participation; it has established a general e-mail account (workforce.innovation@dol.gov) where stakeholders can post ideas and feedback. ETA will

determine the size and scope of grants after analyzing information from the consultations.

The WIF offers a unique opportunity to test innovative workforce strategies that lead to system change. While the fiscal year 2011 budget provides only a brief description of the WIF, the fiscal year 2012 budget request provides additional information and outlines the intent and purpose. Specifically, the administration intends that the Fund:

—invest in projects that deliver services more efficiently and achieve better outcomes, particularly for vulnerable populations and dislocated workers;
—support both structural reforms and the delivery of services;
—emphasize building knowledge about effective practices through evaluation;
—translate into improved labor market outcomes and increased cost efficiency and other measures in the regular formula programs; and
—facilitate the use of waivers where necessary to achieve better outcomes and facilitate cooperation across programs and funding streams.

In fiscal year 2011, the Department is the sole contributor to the fiscal year 2011 Workforce Innovation Fund. Therefore, the first year of funding on innovation strategies will directly benefit Title I and III (Workforce Investment System and Wagner-Peyser Employment Service) programs, although proposals to improve coordination with Title II and IV, and other Federal programs would be in line with goals for system reform. If joint funding with the Department of Education is achieved in fiscal year 2012, the Department will have a solid framework from which to expand to the other WIA title programs.

COMMUNITY SERVICE EMPLOYMENT FOR OLDER AMERICANS (CSEOA)

*Question.* The President's fiscal year 2012 budget proposes the transfer of CSEOA to the Department of Health and Human Services' Administration on Aging. What has been the reaction to this proposal of the national nonprofit agencies who administer the majority of these grant funds?

Have you received a lot of comments from those entities, what are their concerns and how are you addressing their concerns in your transition planning?

Answer. The Department has received very few direct comments from grantees. However, we have arranged two conference calls for the Assistant Secretaries of the Department of Health and Human Services (HHS) Administration on Aging (AoA) and the Department of Labor Employment and Training Administration to speak with the national grantee directors and with all grantees to address any concerns. Questions in advance of and during the calls largely centered on how the program would work if it went to AoA, and what kind of changes AoA anticipated making in how the program is structured and funds are allocated. Both Assistant Secretaries assured grantees that the Departments would work collaboratively to ensure that the proposed transfer would be as seamless as possible, with collaboration and consultation at the staff level already underway. This would include coordination on the statutorily required national grantee competition planned for late 2011, with operations under these new grants effective in 2012.

*Question.* Also, as the budget notes, the majority of State CSEOA programs are housed within offices on aging, senior services or health and human services departments. What will the transfer of this program mean for the 17 States where that is not the case, where CSEOA programs are housed in labor departments and how will DOL and HHS ensure a smooth transition for those grantees?

Answer. Under the Older Americans Act, Governors have complete discretion on where within the State bureaucracy the CSEOA program is housed. Program services, performance goals, program structure, coordination requirements, etc., are not dependent on whether the program is administered at the State level by either a Labor or HHS State agency. Because CSEOA has a dual focus on job training and community service, it can be effectively run by either the Labor or HHS State agency.

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## QUESTIONS SUBMITTED BY CHAIRMAN DANIEL K. INOUYE

WORKFORCE INVESTMENT ACT (WIA) WORKFORCE INNOVATION FUND

*Question.* Are the innovation grants proposed in the fiscal year 2012 budget intended to inform the Employment and Training Administration's (ETA's) reauthorization efforts or are they a component of ETA's ongoing efforts to improve program functioning?

Answer. This Fund represents a small but crucial investment in innovative, evidence-based and cost-saving workforce strategies to strengthen outcomes for both

workers and employers. This Fund will benefit future WIA formula-funded activities by moving the public workforce system toward better results and more cost effective delivery that can be replicated broadly across the workforce system. In addition, while evidence developed over the next few years may not be available in time to inform an imminent WIA reauthorization, it would inform future WIA reauthorizations and administrative guidance issued by the Department.

*Question.* Are the proposed innovation grants multi-year grants and would they require funding in subsequent years? If these proposed innovation grants are intended as multi-year grants, what are the proposed periods (e.g., 3 years, 5 years)?

Answer. Grant funds are available for Federal obligation through September 30, 2012; the appropriation remains available for recording, adjusting, and liquidating obligations properly chargeable to the WIF account until September 30, 2017. Assuming a 1 year close out period, grants could be provided for a period of up to 5 years. Senators Harkin and Murray have recommended a 2–3 year period of performance. While this aligns with our typical grant award period, and will adequately accommodate front-line service delivery reforms, such a time period may not be sufficient for a State or regional partnership to make structural or systemic changes at the State or local level and observe how those changes increase efficiency or quality in service delivery. Currently, the Department is engaged in intensive stakeholder consultations for the WIF which will provide more information around a practical timeframe of grant availability.

*Question.* Will the proposed reduction in the Governors Reserve from 15 percent to 7.5 percent of State formula grant allocations affect the ability of Governors to carry out required statewide activities within the WIA system?

Answer. It is possible that the reduction in the Governor's Reserve will cause States to scale back on some statewide activities, including performance incentives to local areas. The fiscal year 2011 Full-Year Continuing Appropriations Act reduced the Governor's Reserve from 15 percent to 5 percent, which will provide a test case to determine how States prioritize their statewide activities with fewer available resources. For the fiscal year 2011 funds, the Department has advised States to consider investments in statewide activities central to State management such as reporting or those that provide direct services to participants ahead of other required activities. States that are unable to carry out all required activities due to a lack of funds may apply for a waiver to allow for a temporary exemption from the requirement to carry out some of the required statewide activities, such as performance incentives and evaluations.

UNEMPLOYMENT COMPENSATION (UC)

*Question.* What has DOL done to discourage States from reducing the number of weeks that unemployed workers can receive regular unemployment compensation (UC) benefits?

Answer. The Federal-State UC program is a cooperative arrangement between the Federal Government and the States providing income support to individuals who meet the eligibility requirements of State law. Federal UC law establishes broad requirements that State laws must meet. Otherwise, States are free to establish the requirements of their own UC laws. Federal law has never included any requirements concerning weeks of benefits payable. Thus, DOL has no official role in mandating the number of weeks of benefits that States provide; we implement laws passed by Congress. Additionally, we note that until the American Recovery and Reinvestment Act, Federal law had never included any requirements concerning weekly benefit amounts. Currently States that have agreed to operate the Emergency Unemployment Compensation (EUC) program on behalf of the Federal Government (and all States currently do) are prohibited from reducing their weekly benefit amounts. The EUC program is currently set to expire December 31, 2011, with phase out completed by June 9, 2012.

There are potential consequences if States reduce the number of weeks of benefits available. Specifically, the benefit amounts available under the permanent extended benefits (EB) program and the temporary emergency unemployment compensation (EUC) program are reduced if individuals received fewer than 26 weeks of regular UC. DOL has informed States considering such benefit reductions of the impact on EUC and EB benefit amounts that would be available to eligible individuals in their States.

*Question.* Will the administration support the reauthorization of the Emergency Unemployment Compensation (EUC08) program before it expires in January 2012? Would the administration support an extension of 100 percent Federal financing for Extended Benefits (EB) beyond January 4, 2012?

Answer. When people lose their jobs our Unemployment Insurance system provides crucial support for both the recipients and their communities. We've seen in every recession how important these benefits are not just in helping to keep food on the table and roofs over peoples' heads, but they provide an automatic stabilizer for our economy. Each dollar paid out in UI benefits generates $2 in economic activity, which means that helping the jobless prevents joblessness.

The extension of Emergency Unemployment Compensation (EUC) and 100 percent Federal financing of Extended Benefits—that we pushed for and passed as part of the broadly supported tax agreement in December—have been very important for our economy. They are helping 7 million Americans support themselves while looking for work who would otherwise have seen their benefits expire and supporting the businesses in their community. The Council of Economic Advisers estimates that these extensions of Federal support for unemployment insurance will create 600,000 jobs this year.

As we continue to work every day to put Americans back to work, we are looking at a wide variety of options. The extension of Unemployment Insurance benefits is also one of the ideas that should be analyzed economically and discussed with all Members of Congress as we go forward.

*Question.* Does the administration favor adding another Tier of emergency UC benefits to the Emergency Unemployment Compensation program (EUC08)?

Answer. Whether Unemployment Insurance benefits should be expanded is worth both analyzing economically and discussing with all members of Congress as we go forward.

DAVIS-BACON ACT

*Question.* What are Department of Labor's plans to improve implementation of the Davis-Bacon Act?

Answer. In fiscal year 2010, the Wage and Hour Division (WHD) re-engineered its Davis-Bacon wage survey processes to improve the quality and timeliness of wage determinations published by the agency. For example, we are now utilizing State prevailing wage determinations as the basis for issuing more current highway wage rates. This change, coupled with improvements to the survey process, has positioned the agency to complete during fiscal year 2011 all surveys that are currently in the pipeline.

WHD continues to improve the IT system used for Davis-Bacon wage determinations and to re-engineer its wage determinations processes in order to improve the timeliness and accuracy of wage determinations. We are also building upon previous efforts to revamp and enhance performance measures and goals, as well as increase our numbers of trained and experienced survey staff. We believe all these efforts will produce more responsive and representative survey results that will lead to more accurate and timely wage determinations.

*Question.* What resources would DOL need to ensure that Davis-Bacon wage determinations are accurate and up-to-date?

Answer. The Department's budget does not include a request for additional resources for Davis-Bacon wage determinations. Process changes in conducting wage surveys are currently being implemented. These changes should enable the Wage and Hour Division to update and to keep current wage determinations nationwide.

*Question.* How will the administration's proposed cut to the Community Service Employment for Older Americans program affect services to older, low-income Americans?

Answer. The fiscal year 2011 budget allocation has already reduced program funding to the level proposed in the fiscal year 2012 budget. It will mean an approximate 25 percent reduction in funding and services to unemployed, low-income seniors starting in PY 2011, as compared to PY 2010 regular funding. However, grantees are already implementing management strategies to help ensure that the impact of the severe funding reductions on current CSEOA participants is minimized in so far as possible. Grantee strategies include eliminating new enrollments, cutting back on hours of paid community service training for individual participants, and restricting any time extensions for current participants beyond the new statutory 48 month participation limit that starts on July 1, 2011.

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## QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

EVALUATIONS AND PERFORMANCE

*Question.* Duplicity and ineffectiveness are two claims that have been levied against Federal job training programs recently, mostly in response to the release of

a GAO report earlier this year. However, most of the inquiries I've heard into these claims never got to the heart of the matter. I believe that accountability and performance are too important not to address the issue fully.

I'd like to ask about the evaluation required under Sec. 172 of the law. To your knowledge, why, under the Bush administration, didn't the Department complete the multisite control group evaluation of WIA formula programs by fiscal year 2005 as required by statute?

Has the Obama administration made such an evaluation a priority?

Answer. While rigorous random assignment impact studies provide the most credible information on program effectiveness, these also are highly resource intensive and take a minimum of 5 years to implement and complete. The Bush administration had several policy proposals to change WIA, and while we cannot answer with certainty why decisions were made, it is our understanding that the Bush administration viewed the WIA program as a program undergoing a transition. It generally is advisable not to conduct an evaluation of a program undergoing transition, as it could result in incorrect conclusions.

While it is unfortunate that we do not have evaluation results from that period in time, in 2008, the Department commissioned the rigorous WIA Gold Standard Evaluation of the Adult and Dislocated Worker Programs (WGSE). This study will use a control group to measure the impact of the WIA adult and dislocated worker formula programs at nearly 30 randomly selected sites. The study's results will be available in 2016, although this schedule is dependent upon continued appropriations for the evaluation of WIA programs.

*Question.* I'd like to ask about the other evaluations that the Department has undertaken under the authority of Sec. 172. Another recently released GAO report noted that ETA released 34 reports to the public in 2008, 20 of which had waited between 2 and 5 years to be approved for public release. GAO goes on to note that several of those reports would have been useful for the workforce system.

To your knowledge, why didn't the Bush administration release those findings and reports earlier?

How has the Obama administration worked to address the criticisms leveled by GAO concerning it research and evaluation activities for WIA programs?

Answer. As I understand it, the Bush administration argued that those studies were flawed. What I can tell you is that the GAO's March 2011 report discussed the marked improvement in the dissemination of research reports by the Employment and Training Administration under my leadership at the Department of Labor. The GAO noted that, "The 34 research reports published by ETA in 2008 took, on average, 804 days from the time the report was submitted to ETA until the time it was posted to ETA's research database. By, contrast, from 2009 through the first quarter of 2010, the average time between submission and public release was 76 days, which represents a more than 90 percent improvement in dissemination time compared with 2008."

The Department has also worked diligently over the past 2 years to increase the rigor of its evaluation studies. For example, I created the Chief Evaluation Office (CEO), which was staffed in May 2010. The purpose of this office is to coordinate the Department's research and evaluation agenda in order to increase its capacity to conduct high quality, rigorous evaluations.

In addition, since 2009, about half the evaluations the Employment and Training Administration (ETA) has funded have been rigorous, random assignment impact evaluations. These include: (a) the Workforce Investment Act (WIA) Gold Standard Evaluation of the Adult and Dislocated Worker Programs (WGSE); (b) the YouthBuild Impact Evaluation; (c) the Reintegrating of Ex-Offenders Random Assignment Evaluation; (d) the Impact Evaluation of Green Jobs, Health Care and High Growth Training Grants; and (e) the Transitional Jobs Impact Evaluation. Each of these evaluations will examine net impacts on employment, retention and earnings, and include benefit-cost analyses. ETA was able to fund these evaluations through an increase in fiscal year 2010 appropriations and the large one-time infusion of funds made available to the Department through the American Recovery and Reinvestment Act of 2009.

While rigorous random assignment impact studies, such as the WGSE, provide the most credible information on program effectiveness, they also are highly resource intensive. Mindful of the statutory responsibility and to address the knowledge gap until the WGSE results are available, in 2009 the ETA released the results of a quasi-experimental net impact evaluation of the WIA Adult and Dislocated

Worker programs.[1] This study uses the next-best methodology when random assignment is not available. This evaluation found positive long-term earnings impact for both programs. ETA plans to publish interim findings of the WGSE in 2013, and the final report will be available in 2016.

In addition, random assignment evaluations may not always be possible when the law requires that people receive services as is the case in many entitlement programs such as the Unemployment Insurance (UI) program. In November 2010, ETA released a study which used nationally representative tax and benefit data in a prominent macroeconomic model, which provided new evidence reaffirming the value of UI as an automatic economic stabilizer during the latest recession.[2]

*Question.* I'd like to address the lack of performance information argument. Does the Department collect performance data on WIA formula programs? If so, how long has such data been collected and what does it reveal about the value of WIA programs?

Answer. The Department has collected performance information on WIA formula programs since its inception. The principal data set, known as the Workforce Investment Act Standardized Record Data (WIASRD), records a wide range of information about individual program participants, including program outcomes for participants after they have exited from the program. The outcomes recorded include employment, job retention, and earnings, as well as attainment of education, credentials, and skills.

Other information collected includes individual demographic information and data about participation in and services or other assistance received through WIA or partner programs. The full list of data elements collected by WIASRD is posted on-line at http://www.doleta.gov/performance/guidance/WIA/Appendix-A-WIASRD-Specifications-Expires-02282009.xls.

Since WIA's inception, the Department has used this information to produce and disseminate quarterly and annual performance reports. These reports provide aggregate summary information on program exiters and their outcomes with respect to the given time periods. These reports are available to the public on-line at http://www.doleta.gov/performance/results/Reports.cfm?#etaqr.

While this information is highly useful for monitoring program performance, it cannot directly provide information regarding the value of the programs. However, this information is the primary source of data on which program evaluations, cost-benefit analyses and/or impact studies are based. On the whole, these studies have provided evidence that WIA programs enhance both the employment prospects and future earnings of WIA participants.

As with any performance accountability system, WIA data systems and performance metrics could always be improved or expanded. However, WIA is certainly not lacking performance information as the WIASRD is a rich dataset.

INVESTMENT COMPARED TO NEED

*Question.* A recent GAO report noted $18 billion was invested in Federal employment and training programs in fiscal year 2009, an increase of $5 billion since an analysis in 2003. The same report goes on to note that after adjusting for inflation, the increase in funds equals $2 billion, which is approximately the same amount Congress invested in these programs in the American Recovery and Reinvestment Act to help address the impact of the Great Recession. I've seen some reports that public financing for our workforce development programs has actually fallen by 90 percent since the 1970s while our workforce has grown by 50 percent.

However, just looking at recent years, it's my understanding that the one-stop delivery system saw a marked increase in use over the last several years due to the downturn in the economy. In fact, it experienced nearly 234 percent increase in participants. Do you believe that Federal investments have matched the increasing need for services since 2003?

Answer. In calendar year 2010, ETA programs served more than 39.1 million people. The Wagner-Peyser Employment Services (ES) and Unemployment Insurance (UI) served 74.6 percent of this total, and 63 percent of those receiving Unemployment Insurance also received Wagner-Peyser funded Employment Services. ETA's other programs provided more comprehensive services to over 9.9 million people in 2010. The high level of participants reflects the continued demand for temporary in-

[1] The Workforce Investment Act Non-Experimental Net Impact Evaluation: Final Report may be found at ETA's Research Publication Database Web site.

[2] The Role of Unemployment Insurance As an Automatic Stabilizer During a Recession may be found at ETA's Research Publication Database Web site.

come support, training and employment services including job search assistance, and the impact of the American Recovery Act and Reinvestment Act funding.

While many of ETA's current workforce programs existed in 2003, we are not able to make a direct comparison between the number of individuals served in 2010 with those served in 2003 due to a changing number of workforce investment programs authorized and appropriated by the Congress. It also is important to note that the $18 billion invested in Federal employment and training cited by the Government Accountability Office includes the one-time $2 billion infusion of funding from the American Recovery and Reinvestment Act. Without these funds, there will be a significant decrease in individuals who receive WIA services.

Adequate funding is important; there are many individuals eligible for WIA services that the system could serve with additional funding. In addition, increasing the number of participants who acquire industry-recognized credentials through longer-term training means higher cost services; and funding evaluations to assess the effectiveness of alternative approaches requires significant resources. However, these needs must be balanced with the current economic environment, and the acknowledgment that the Federal Government must live within its means. This requires that investments be strategic and focus on increasing efficiency and alignment with existing Federal resources. For example, the new Workforce Innovation Fund supports the identification and replication of innovative, evidence-based and cost-saving workforce strategies.

The range of such investments can build on technological advances (e.g., using online resources to reach more people), system flexibility measures such as waivers, partnerships, and guidance on aligning or leveraging resources to help State and local workforce investment programs deliver cost effective and high quality services to job seekers and worker and employers.

ADMINISTRATIVE STRUCTURES

*Question.* Another claim we often hear about job training programs is multiple administrative structures and lack of strategic approach to planning at the State level. To help address this issue, we've heard about the value of unified planning and common performance measures as ways to reduce administrative burden while promoting a better understanding about the value of these programs. How does the Department propose to address these concerns?

What value do you see in unified planning and the use of common measures?

Answer. The Workforce Investment Act of 1998, Section 501 allows States to submit a single Unified Plan to satisfy the planning requirements of multiple employment and training programs. ETA currently is redesigning and streamlining the Unified State Plan requirements in order to improve strategy-focused planning and promote improved alignment and integration of workforce and other relevant programs. ETA is working with States to gather ideas and feedback on how the current State planning process could be improved without any changes in law. We hope that encouraging more strategic and joint planning among States will prepare the states for any reauthorized WIA that enhances planning provisions. ETA will encourage more States to engage in unified planning leading to improved outcomes across programs (as captured by the common measures) and resource utilization. Common measures and unified planning are complementary tools that can support State and Federal efforts to better align planning with performance measurement and make each process more effective and efficient.

ETA anticipates sending revised planning guidance to States in December 2011 that will facilitate the inclusion of multiple partners in the planning process and in the State plan submitted to the Department.

The goals of the effort to redesign State plans are to:

—Focus State planning on strategy instead of operations and compliance;

—Better align and integrate workforce programs and strategies with each other and other relevant programs (e.g., training providers, education, and economic development);

—Streamline various paperwork processes;

—Encourage strategic thinking and creating workforce strategies that focus on skills training and credential attainment; and

—Use current labor market information and economic indicators to place newly trained individuals into career pathway employment opportunities and track retention through wage record information.

QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

*Question.* Your testimony this morning reflects the administration's commitment to keep annual domestic spending low by building on the recently enacted continuing resolution that defined spending levels for the remainder of fiscal year 2011 and to make the tough cuts necessary to achieve these savings. Can you identify the additional cuts that would be needed to make the fiscal year 2012 DOL budget request before us consistent with the deficit reduction framework President Obama announced last month?

Answer. The President's fiscal year 2012 budget was transmitted before enactment of the final fiscal year 2011 appropriations bill. I am aware that there are ongoing bicameral, bipartisan discussions between the administration and congressional leadership on the Nation's long-term fiscal picture. These conversations, along with the enacted fiscal year 2011 appropriations, could impact eventual funding levels. The implications of both on the fiscal year 2012 request will be evaluated. Nonetheless, the fiscal year 2012 budget request reflects the administration's policy priorities and remains a good starting point for developing funding levels. We look forward to working closely with you as the process moves forward.

But while the administration is committed to making the tough cuts necessary to achieve these savings—including to programs we care about—we will not sacrifice the core investments we need to grow and create jobs and protect our workforce. We still believe that the fiscal year 2012 budget request is a disciplined approach, representing responsible spending that supports the most critical investments necessary to keep our workforce system moving forward to assist our country's businesses and workers. The budget includes key investments that are an essential part of the President's commitment to out-innovate, out-educate and out-build our global competitors, and to assure that our workplaces are safe and fair. In short, getting America back to work is a top administration priority. As you formulate your appropriations bill, I hope we can work together to ensure adequate funding for the programs that help us reach that goal.

VOLUNTARY PROTECTION PROGRAMS (VPP)

*Question.* Currently, there are approximately 96 Voluntary Protection Programs (VPP) sites in the State of Louisiana that are actively pursuing VPP status in the State of Louisiana. Collectively, these sites employ approximately 28,871 workers. The fiscal year 2012 budget request includes $4 million for Department of Labor's Occupational Safety and Health Administration (OSHA) to administer the VPP for 2012. How will President Obama's proposed deficit reduction framework impact the resources terms of their ability to administer the VPP?

Answer. The fiscal year 2012 request level includes sufficient resources to maintain the VPP program, which is included in the Federal Compliance Assistance budget activity.

*Question.* According to Government Accountability Office report on the VPP published in May 2009, approximately 80 percent of VPP worksites have fewer than 500 employees. Has OSHA studied and concluded separately on the impact on small businesses?

Answer. The 80 percent figure does not accurately capture the true number of actual small businesses because GAO was looking at the size of the worksite and not the size of the company owning the worksite. For example, many participating U.S. Postal Service worksites have been classified as small businesses because they employ 250 or fewer employees.

OSHA has not concluded a separate analysis of the impact of VPP on small business because only 99 out of the 1,644 Federal VPP sites (6 percent) of the total number of VPP sites meet the small business definition (250 or fewer employees and are not part of a corporation/organization with 500 or more employees.)

*Question.* What are OSHA's plans to review the impact on small businesses that participate in the VPP?

Answer. While at this time, there are no plans to review the impact on small businesses that participate in the VPP, OSHA has formed a VPP Workgroup to conduct a comprehensive evaluation of OSHA's VPP in response to the May 2009 GAO report. Comprised of Regional and National Office VPP personnel, the Workgroup will review such subject areas as consistency in VPP administration, response to fatalities and documentation following fatalities, effective use of limited resources, recertification of current VPP sites, and training, communication, and cost of administering the VPP. The review process will involve interviews of OSHA VPP staff (Region and National Office), VPP stakeholders (e.g., VPPPA, labor unions, VPP corporate participants, and congressional staff), and review of policy and procedure manuals. A first draft of the Workgroup's evaluation/report is to be completed by

the end of September 2011. Small business participation in VPP will be addressed as part of this comprehensive VPP evaluation.

Small businesses with exemplary safety and health management systems are more likely to be recognized under OSHA's Safety and Health Recognition Program (SHARP). These small employers have had a full On-site Consultation visit and meet other requirements. Upon receiving SHARP recognition, OSHA exempts worksites from OSHA programmed inspections during the period that the SHARP certification is valid.

*Question.* What is the current status of implementing the recommendations from the GAO report for assessing the performance of the VPP?

Answer. OSHA is continuing to evaluate and develop ways to improve internal controls and measurement of program performance and effectiveness as part of the ongoing VPP continuous improvement process. The Assistant Secretary's series of VPP policy memoranda (five to date, the earliest signed August 3, 2009, and the most recent, April 22, 2011) include instructions to strengthen nationwide consistency in OSHA's administration of VPP; improve the quality and documentation of OSHA actions following a fatality at a VPP site; strengthen internal controls, audit procedures, tracking, and proper documentation of OSHA actions; and improve annual data submissions required of all VPP participants and OSHA's review of the submissions and follow-up actions. And as mentioned above, in order to ensure successful implementation of these improvements, OSHA has formed a VPP Workgroup to conduct a comprehensive evaluation of OSHA's VPP.

*Question.* Some of my constituents have contacted me regarding the Department of Labor's (DOL) proposed rule for expanding the definition of the term "fiduciary" to include Employee Stock Ownership Plan (ESOP) annual appraisers. See 75 Fed. Reg. 65263 (Oct. 22, 2011). According to testimony submitted by the American Society of Appraisers at a hearing on this proposed fiduciary rule held last month, the proposed rule would impose "significant financial burdens" on ESOP appraisers because it would require ESOP appraisers to purchase special high-cost fiduciary insurance in addition to the standard errors and omissions insurance required under current law. These increased insurance costs will result in increases to the cost of ESOP valuations—costs that would be then transferred to the ESOP and inevitably to the customer. Has the DOL made a determination as to whether it will exempt annual ESOP appraisals from the new fiduciary rules?

Answer. Some stakeholders have asserted that the proposal would cause some appraisers to discontinue ESOP valuations and would significantly increase costs of appraisals for small businesses that sponsor ESOPs. The Department is carefully reviewing these and other comments with a view to avoiding unwarranted costs for ESOPs. In so doing, we must also keep in mind that ESOPs often use annual appraisals to calculate the dollar amount that participants who are leaving the employer will receive for their shares. Thus, such appraisals should be conducted in a prudent and impartial manner.

*Question.* Some constituents have also raised questions as to how the above-referenced proposed fiduciary duty rule will impact broker-dealers servicing individual retirement accounts. Constituents have expressed concern about the proposed rule having the effect of restricting affordable access to services for initiating and managing IRAs. Recent studies have illustrated that IRAs are the fastest growing accounts holding retirement savings. Specifically, IRAs are widely held by small investors. Small investors prefer brokerage relationships over advisory relationships. Ninety-eight percent of investor accounts with less than $25,000 are in brokerage relationships. The proposed rule would practically make every investment-related conversation with a client subject to fiduciary duty. Consequently, under this proposed rule firms and their associated representatives may not receive different levels of compensation based on the investment choices made by retail investors in protected IRA accounts. The current fee structure accommodates the needs of small investors by allowing firms to provide them with affordable investment services commensurate with their risk profile. Under the proposed rule, brokerage firms would be forced to offer investment services and guidance to IRA investors through fee based advisory accounts—which frequently require much higher fees. These higher fees make it uneconomical and unaffordable for the majority of IRA investors. What is DOL going to do to ensure small IRA accounts can continue to be served by broker-dealers in the same way they are being served now?

Answer. Today, the advice provided to workers, employers, and retirees about their retirement plans is too often tainted by conflicts of interest and therefore potentially harmful. There is strong evidence that unmitigated conflicts of interest cause substantial harm, and therefore the Department is confident that amending the fiduciary regulation to combat such conflicts will deliver significant benefits to plan participants and IRA holders. This evidence is found in academic research, IRA

underperformance, SEC examinations, and EBSA's own enforcement experience. Taken together, the available evidence more than establishes that such negative impacts are present and often times large. When the fiduciary proposal is finalized, plans, plan participants and IRA holders will be able to more readily access and benefit from impartial advice that puts their interests first.

The Department has received comments that the proposed fiduciary regulation would force brokers to convert their existing commission-based accounts into fee based advisory accounts, which would result in higher fees and widespread distributions from smaller account, as these advisory accounts would require higher minimum balances. The Department is carefully considering these comments. To be clear however, the proposal does not, by its terms, require brokers to restructure their compensation as wrap fees or to convert brokerage accounts to advisory accounts. Moreover, under already existing administrative exemptions broker-dealers that are fiduciaries can receive commissions for trading securities, insurance products, and mutual funds—which are the types of investments that make up the large majority of IRA assets today. These and other existing exemptions already create substantial space for brokers to provide fiduciary advice as fiduciaries under ERISA and the tax code while continuing to operate as brokers under the 1934 Securities Exchange Act. In addition, we have ample authority to grant additional exemptions if there are legitimate concerns that beneficial practices would be needlessly prohibited. We will attempt to provide this clarification in a more formal manner as we proceed in this process.

Further, the tax code itself treats IRAs differently from other retail accounts, bestowing favorable tax treatment, and prohibiting self-dealing by persons providing investment advice for a fee. In these respects, and in terms of societal purpose, IRAs are more like plans than like other retail accounts. Most IRA assets today are attributable to rollovers from plans.[3] The statutory definition of fiduciary investment advice is the same for IRAs and plans. It therefore makes sense to establish a single consistent definition for both by regulation, and then deal with the practical differences between the two by tailoring exemptions accordingly. In addition, while IRA holders have more choice, they may nonetheless require more protection. Unlike plan participants, IRA holders do not have the benefit of a plan fiduciary to represent their interests in selecting or compensating investment advisers. Compared to those with plan accounts, IRA holders have larger account balances and are more likely to be elderly. For all of these reasons, combating conflicts among advisers to IRAs is at least as important as combating those among advisers to plans.

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## QUESTIONS SUBMITTED BY SENATOR JACK REED

### WORKSHARE

*Question.* As you know, I introduced legislation last year to expand work sharing, which just over 20 States have adopted or implemented. I was pleased to see the administration include a work sharing proposal in its budget this year that builds off of my legislation. What can we do to encourage the remaining States to adopt work sharing and for more businesses to participate in work sharing as a means to avoid layoffs and help workers stay attached to the workforce?

Answer. The Department currently is limited in what it can do to actively encourage the adoption of worksharing or short-time compensation (STC) programs. Current legislative authority for STC does not authorize certain State practices, such as making the payment of STC contingent on the employer entering into a plan with its employees and making such plan subject to approval by the State UC agency. Amending Federal law would address these issues and allow the Department to more actively promote STC. The Department's Unemployment Compensation Integrity Act of 2011 that was recently sent to the Congress includes language that would provide the necessary legislative authority for the Department to more actively promote STC. The Department welcomes the opportunity to work with the Congress to develop additional strategies to encourage more states to adopt STC and more businesses to participate.

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[3] Peter Brady, Sarah Holden, and Erin Shon, *The U.S. Retirement Market, 2009*, Investment Company Institute, Research Fundamentals, Vol. 19, No. 3, May 2010, at http://www.ici.org/pdf/fm-v19n3.pdf.

WORKFORCE INVESTMENT ACT REAUTHORIZATION

*Question.* Public libraries are key access points in the workforce investment system. How can we strengthen these linkages in the Workforce Investment Act? Do you see the Innovation Fund that was included in the fiscal year 2011 CR as an avenue for supporting library-workforce partnerships?

Answer. We agree that public libraries are an important access point for all jobseekers to access workforce services. Under current law, libraries may serve as affiliate One-Stop Career Centers and this feature should be preserved in a reauthorized Workforce Investment Act. The Department has an agreement with the Institute of Museum and Library Services (IMLS) to support strong linkages between public libraries and the workforce investment system. Under this agreement, the Department has provided technical assistance and guidance specifically targeted to library workers on how to use the workforce electronic tools such as career exploration, résumé writer, job banks, etc. The Workforce Innovation Fund will test and support innovative practices and strategies in the workforce system and will contribute to the ongoing work of the Department to disseminate and replicate innovative, successful, and proven practices, which may include those supported by partnerships between the workforce system and other partners such as libraries. The Department has launched a broad consultation process regarding the WIF with the public workforce system and its stakeholders and partners, such as libraries, and this input will help shape the grant solicitation.

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## QUESTIONS SUBMITTED BY SENATOR SHERROD BROWN

UNEMPLOYMENT RATE FOR AFRICAN AMERICANS

*Question.* In 2010, the overall unemployment rate in the United States was 9.6 percent. However, the unemployment rate for African-Americans was 16 percent, which is nearly twice as much as the 8.7 percent unemployment rate for white Americans. We also know African-Americans are among highest of the long-term unemployed.

The numbers we use only include people who the Bureau of Labor Statistics considers officially unemployed; still more Americans want jobs and can't find one, yet they aren't considered unemployed. Many of these Americans, like discouraged workers, have likely been unemployed for a very long period of time as well.

Please explain what DOL is doing to address the especially high long-term unemployment rates among African-Americans?

Are there any programs geared specifically toward lowering the high unemployment rates among African-Americans?

Answer. DOL recently released a comprehensive report looking at the labor market situation for African-Americans since the 2007–2009 recession. Although most of the Department's programs are not specifically targeted to any one demographic, our programs are serving African-Americans who are unemployed and underemployed in significant numbers. The following provides an overview of how these programs have benefitted millions of African-Americans during these challenging economic times:

—Ensuring that training and employment services are serving African Americans and are providing a host of support services to hard-to-place workers.
  —Between October 2009 and September 2010, more than 4.3 million participants served by the Department's Wagner-Peyser program, employment services administered by the Department, were African-American. This figure represents over 19 percent of total participants served by this program.

—The Workforce Investment Act (WIA) served 570,000 self-indentified African-American Adult and Dislocated Worker participants who received staff-assisted services from July 2009 to June 2010. For PY 2009 (July 2009–June 2010), after receiving counseling or counseling and training services, over 330,000 Adult and Dislocated African-American workers exited their respective programs. In addition, of those being served by WIA, over 140,000 African-Americans found jobs during the corresponding timeframe.
  —As of September 30, 2010, 28,392 African-Americans have been served by the Department's Community Based Job Training grants and 13,060 African-Americans have been served through the Department's High Growth and Emerging Industry grants.
  —Between October 2009 and September 2010, 11,835 African-American workers impacted by trade were served by the Department's Trade Adjustment Assistance program.

—In January 2011, the Department of Labor announced the availability of approximately $500 million for the first round of Trade Adjustment Assistance Community College and Career Training Grants. The program will enable eligible institutions of higher education, including but not limited to community colleges, to expand their capacity to provide quality education and training services suitable for Trade Adjustment Assistance program participants and other individuals. The overarching goals of these grants are to increase attainment of degrees, certificates, and other industry-recognized credentials and better prepare workers, for high-wage, high-skill employment.

—The National Farm-Worker Jobs Program provides funding to community-based organizations and public agencies to assist migrant and seasonal farm-workers and their families attain greater economic stability. Between October 2009 and September 2010, nearly 1,000 individuals who exited the program after receiving core, intensive, and training services were African-American.

—Since its inception in spring 2006, the Reintegration of Ex-Offenders programs have assisted over 26,000 participants. Of these, 15,530 (60 percent) are African-Americans.

—The Federal-State Unemployment Insurance system (UI) served over 2,377,000 African-Americans from October 2009 to September 2010.

—Providing training opportunities for African-American workers to be involved in the clean energy economy. In 2010, DOL funded the following Recovery Act grant competitions designed to advance training and employment in these industries.

—"Pathways Out of Poverty" grants provided $150 million to support programs that help disadvantaged populations find ways out of poverty and into economic self-sufficiency through employment in energy efficiency and renewable energy industries.

—Among the awardees was the East Harlem Employment Services, which will work with foundations, unions, educational institutions, and minority contractors to provide education and training to 1,819 people and unsubsidized employment to 881 people in Flint, Michigan and Baltimore, Maryland.

—MDC, Inc. was awarded funds to train more than 700 persons, including 400 who will be placed into employment, in Orangeburg, Calhoun and Bamberg Counties in South Carolina. The Los Angeles Community College District will use funds to provide training to more than 925 persons, including 667 who will receive on the job training.

—"Energy Training Partnership" grants provided $100 million for job training in energy efficiency and clean energy industries, of which approximately $50 million reached communities of color. The grants support job training programs to help dislocated workers and other target populations, including communities of color, find jobs in expanding green industries and related occupations.

—Transitioning more African-American youth to employment through programs targeting individuals affected by high poverty and high unemployment.

*Job Cops and Youthbuild*

—Programs such as Job Cops and YouthBuild provide job training and educational opportunities for low-income or at-risk youth aged 16 to 24. As of September 2010, there are 8,380 African-American youth enrolled in YouthBuild, representing nearly 60 percent of the participants served in the program.

—African-American youth represented approximately 50 percent of Job Corps students. In addition, VETS and ETA recently announced a pilot for 300 veterans to participate in Job Corps.

*"Skills for America's Future" Initiative*

—Increasing college attendance and graduation rates among African-American youth and encouraging more African-American students to pursue careers in science, engineering and technology. The President's "Skills for America's Future" initiative seeks to increase the number of college graduates in science, technology, engineering, and mathematics (STEM), as well as improve industry partnerships with community colleges and other training providers by matching classroom curricula with industry standards and employer needs.

—Assisting workers interested in starting their own businesses. Entrepreneurship training is available to dislocated workers and other adults and youth through the public workforce system overseen by DOL. DOL is also currently conducting an experimental training program called Growing America Through Entrepreneurship (GATE). Project GATE connects individuals with entrepreneurship training and education to help them realize their dreams of business ownership. Project GATE, which is now in its second phase, has been shown to increase

the number of hours of business training participants receive, the speed of business opening among participants, and the longevity of their businesses.

—In eight States—Delaware, Maine, Maryland, New Jersey, New York, Oregon, Pennsylvania, and Washington—certain unemployed workers who participate in entrepreneurship training or business counseling but would otherwise be eligible for unemployment insurance can obtain weekly benefits through a program called Self Employment Assistance.

*Supporting Family-Friendly Workplace Policies*

—Examples of such policies include flexible work schedules and on-site child care, along with the Department's Wage and Hour Division's implementation of the break time for the nursing mothers' law, which became effective when the Patient Protection and Affordable Care Act was signed by the President in March 2010. This new law requires employers to provide reasonable break time and a place—other than a bathroom that is shielded from view and free from intrusion by coworkers or the public—to express breast milk while at work. The Department's role in this effort will undoubtedly help nursing moms achieve balance between their job and care for their children.

—Additionally, the Department has taken steps to ensure more workers can take advantage of the Family and Medical Leave Act (FMLA) by issuing an Administrator Interpretation clarifying that the definition of son and daughter includes someone who stands or stood "in loco parentis" to the child. This interpretation ensures that an employee who assumes the role of caring for a child receives parental rights to family leave regardless of the legal or biological relationship.

—Protecting workers through enhancing the Department's Wage and Hour Division and Office of Federal Contract Compliance Programs enforcement

—The WHD is working to prevent employee misclassification. Misclassification often results in the failure of employers to pay employees the proper minimum wage or overtime pay. Employers may also evade payroll taxes and often do not pay for workers' compensation or other employment benefits. As a result of misclassification, employees are denied the protections and benefits of this Nation's most important employment laws—protections to which they are legally entitled. Misclassification tends to be a pervasive problem in industries that employ a large number of vulnerable workers, such as construction, janitorial, staffing firms, restaurants, and trucking. The President requested funding in fiscal year 2012 for DOL to lead a multi-agency initiative to strengthen and coordinate Federal and State efforts to enforce statutory protections, and identify and deter employee misclassification. This initiative will help provide employees with their rightful pay and benefits.

—The Department recovered more than $176 million in African-American wages for nearly 210,000 workers in fiscal year 2010. Through the direct leadership of Secretary Solis, the Wage and Hour Division hired more than 300 new investigators—a staff increase of more than one-third. These increased staffing levels will help improve complaint investigations and more targeted enforcement.

—In 2010, the Office of Federal Contract Compliance Programs (OFCCP) completed 80 compliance evaluations where it identified discriminatory practices under Executive Order 11246, which bars race, gender, religious, and national origin discrimination by Federal contractors impacting minorities, which included African-Americans. One case of compensation discrimination against an African-American male resulted in an award of $24,894 in back pay. Overall, OFCCP also entered into more than 96 Conciliation Agreements with discrimination findings on behalf of more than 12,000 affected workers, resulting in back pay awards of more than $9 million, and more than 1,400 potential job offers to provide relief for affected workers who have been discriminated against under the Executive Order. Of these, 14 discrimination cases impacted 1,414 African-Americans.

WORKFORCE TRAINING STRATEGIES

*Question.* As we've discussed on several occasions, I've been working on sector partnership workforce training strategies for 4 years, along with Senator Olympia Snowe. This is the strategy of bringing multiple industry players together, along with labor, community colleges, and WIBs, to design a training curriculum and pipeline for future workers within that industry. It's a proven strategy many Governors have taken up, and we're seeing success in Ohio, especially in biosciences and healthcare.

I've introduced legislation—the SECTORS Act—that would amend WIA to create dedicated capacity for sector partnerships, and many States have used their 15 percent set-aside for statewide activities under WIA to support these strategies.

The fiscal year 2011 CR created a new Workforce Innovation Fund that will be used to support demonstration and replication projects that test innovative workforce service delivery strategies, and the fiscal year 2012 budget request proposed $380 million for the Fund.

Given the reduction in State-level funding under the recent CR, and while Congress continues to consider WIA reauthorization, can you assure me that new and existing sector partnerships will be eligible to receive support from the new Workforce Innovation Fund?

Answer. Eligible applicants for these competitive grants are States, State agencies eligible for assistance under Title I and III of the Workforce Investment Act, consortia of States, or partnerships, including regional partnerships (which ETA interprets to include partnerships of local Workforce Investment Boards). Applications submitted by an eligible entity should demonstrate appropriate and engaged partnerships that support the proposed innovation that leads to better employment outcomes for individuals, meets the skill needs of employers, accelerates learning and credential attainment, and increases efficiencies in the delivery of services. Depending on the relationship and types of activity, sector partners may be eligible to receive funding in support of the overall goals of the proposed innovation.

ETA is engaged in a consultation process with key stakeholders including the Federal partners, Congress, intergovernmental organizations, and the public workforce system in support of the SGA development. Your comment and others received through both formal and informal discussions will be taken under advisement as the Department refines the WIF.

PAYROLL FRAUD PREVENTION ACT

*Question.* I recently introduced, with Senators Harkin, Blumenthal, and Franken, the Payroll Fraud Prevention Act (S. 770) which would protect workers from being misclassified as independent contractors, thereby ensuring access to fair labor standards, health and safety protections, and workers compensation. The President's budget includes $46 million to combat worker misclassification.

What is DOL's plan for cracking down on worker misclassification and payroll fraud? How does making misclassification a violation of the Fair Labor Standards Act (FLSA) helpful to your efforts?

Answer. The administration recognizes that misclassification is a serious problem—it often deprives workers of rights and benefits to which they are entitled under the law; it results in a loss to Federal and State revenue, and underfunded unemployment insurance and workers compensation funds; and it creates an uneven playing field for those employers who obey the law. This is why the Department is participating in a multi-agency Misclassification Initiative, headed by the Vice President's Middle Class Task Force, that aims to coordinate the administration's efforts to enforce statutory protections, identify and deter employee misclassification, and mitigate future violations.

Internally, the Department's Initiative is headed by the Wage and Hour Division (WHD), which is working with the Department's Solicitor's Office to increase information sharing and coordination between DOL agencies, with other Federal agencies, and with State agencies that also enforce laws where employee misclassification is a significant issue. When WHD finds cases where misclassification has occurred, it will be referring those cases to the appropriate Federal and State agencies, such as the IRS and State agencies that oversee Unemployment Insurance and Workers Compensation programs.

WHD is also focusing its enforcement and compliance assistance resources on those industries with large numbers of vulnerable and low wage workers where misclassification is particularly prevalent. WHD is working on ensuring that employers, employees, and the public fully understand that misclassification, whether deliberate or as an unintended consequence of a business practice that seeks to reduce labor costs, frequently leads to violations of the laws we enforce, and effectively communicating to employers the risks of being found in violation. As part of this effort, WHD is actively seeking to work with local and national businesses and trade associations to make sure that our compliance assistance reaches their members.

Currently, misclassification is not a violation of any Federal labor or employment law, but the practice often leads to violations of those laws. We believe that, by making misclassification a violation of the FLSA, requiring notice to workers informing them whether they are classified as employees or not, and providing civil money penalties for violating the act's recordkeeping provision, the Payroll Fraud

Prevention Act would provide employers with important additional incentives to make the correct call when determining whether a worker is an employee and keep accurate records of how they treat those employees, which could reduce the number of violations that occur without WHD having to get involved.

*Question.* The administration is soon likely to submit to Congress the pending trade agreements with South Korea, Colombia, and Panama. The administration recently announced a "labor action plan" with Colombia.

The Colombian government, however, continues to fail at effectively prosecuting those responsible for anti-union violence. The United Steelworkers claim the Colombian government has prosecuted only 4 to 5.6 percent of the nearly 2,800 killings of trade unionists since 1986. And, it has not initiated investigations into more than two-thirds of these killings. What is your view of the labor action plan with Colombia? Has Colombia so far met obligations set forth in the labor action plan, including its April 22 commitments? How is the Bureau of International Labor Affairs at DOL involved in the implementation of the action plan?

Answer. The Colombian Action Plan Related to Labor Rights (Action Plan) and our partnership with the new administration of President Santos provide a concrete way forward to address the problems of violence and impunity as a matter of urgency and to improve protections for internationally recognized labor rights in Colombia.

Yes, Colombia has met the April 22 commitments and is on track to meet the additional commitments in the Action Plan. We are continuing to work with the Government of Colombia to ensure that Colombia continues to make the needed progress.

For example, the Action Plan includes strong and specific steps to increase investigation and prosecution of the perpetrators of earlier violence against union activists because the Santos administration recognizes that ending impunity is a major factor in deterring future crimes. In accordance with the Action Plan, President Santos has issued a directive to the National Police, which has already assigned 100 additional full-time judicial police investigators to support the investigation of violence against trade unionists. The Prosecutor General's office has issued directives, consistent with the Action Plan, to improve the investigation and prosecution of labor cases. It is also undertaking an analysis of past homicide cases of union members and activists, in order to extract lessons that can help improve the investigation and prosecution of future cases. Moreover, the Prosecutor General's office has analyzed its needs for additional investigators and prosecutors and submitted its plan and 2012 budget request to the Santos administration, which has committed to provide funding for the expanded staffing, including to strengthen capacity in regional offices. In addition, the Prosecutor General's office is working with the Colombian labor unions and the National Labor School (ENS) to reconcile the Government's and ENS' lists of union homicides since 1986 with that of the unions.

DOL's Bureau of International Labor Affairs (ILAB) has been closely involved in both the negotiation and implementation of the Action Plan. An interagency team comprised of DOL, the Office of the United States Trade Representative, and the Departments of State and Justice are working closely with the Colombian government to ensure that each commitment under the Action Plan is fulfilled.

NATIONAL LONGITUDINAL YOUTH SURVEY

*Question.* For the past 32 years, the Center for Human Resource Research at the Ohio State University has been tasked with conducting the National Longitudinal Youth Survey. This survey measures an array of important issues ranging from how families handle their financial affairs, the impact of training and education programs for reentry into the workforce, and what Federal programs are most effective over multiple decades.

As the Nation continues to recover from the 2008 economic downturn, this survey can help us better understand how long unemployment, high rates of youth unemployment term and foreclosure can impact youth in future decades.

How does the Department of Labor plan to utilize the National Longitudinal Youth Survey to best gauge the impact of the current recession?

Answer. The NLS records the labor force experiences of two cohorts of American men and women. The older cohort is the 1979 National Longitudinal Survey of Youth (NLSY79) that provides information on the "baby boomer" generation. The younger 1997 cohort is composed of individuals currently in their late 20s and early 30s. The NLS captures long-run changes in individual labor force behavior by interviewing the same individuals over extended time periods. As a result, it is uniquely designed to enable researchers and policymakers to examine how changing economic conditions, such as a recession, affect labor force experiences.

Policymakers can utilize information from past recessions to understand the effect of the recent recession. For example, a study using the NLSY79 measured the wage effects for people who graduated from college in a recession (Kahn, 2010). Another study used the NLSY79 from the years 1978 to 2006 to examine how State and national unemployment rates affected the likelihood of divorce (Arkes and Shen, 2010).

Another use of these data can be to study the recent recession and recovery. As the recession began, the nearly 10,000 members of the NLSY79 were aged 43 to 51 and had been followed for almost 30 years. Analysts will be able to examine how the recession affected this generation's retirement plans, health, ability to pay for their children's college education, and many other aspects of their lives. The 9,000 members of the NLSY97 were 23 to 28 when the recent recession started and had been reporting about their lives for over 10 years. This survey includes many veterans of the wars in Iraq and Afghanistan, and the Department's Veterans' Employment and Training Service already has used the survey to examine the challenges these young veterans have faced as they transition back to civilian life. Analysts will continue to use the NLSY97 to examine how the recession affected the career trajectories, educational attainment, health, families, and other aspects of the lives of veterans and nonveterans, both in the short-term and across the rest of their working lives.

INTERNATIONAL LABOR COMPARISONS (ILC)

*Question.* I was pleased that Congress saw fit in the fiscal year 2011 continuing resolution to maintain the International Labor Comparisons (ILC) office of the Bureau of Labor Statistics. I'm concerned, however, by the administration's proposal to eliminate this important office in its fiscal year 2012 budget.

As you know, the ILC program provides the only systematic data comparing labor costs in the United States with major trading partners, including China. As the volume of trade expands, particularly with developing countries, having reliable information on the competitiveness of our workers with those overseas is more important than ever before. While other agencies produce international data, none has the mission and expertise like the ILC to compare data across key countries on labor costs, GDP, unemployment, wages, and inflation. Therefore, it is disturbing that the administration would seek to eliminate this source of information.

If, as the President and you have stated, we are going to out-educate, out-innovate, out-compete in the global economy, it is imperative we do not sacrifice this source for effective policy making and analysis. I request that you share with me your views on maintaining the ILC in the fiscal year 2012 budget, and beyond.

Answer. The 2012 President's budget carries forward the proposal from the 2011 budget to eliminate the International Labor Comparisons (ILC) program. The BLS proposes to eliminate this program to fund other, more critical needs. In developing the 2012 budget, the administration committed to make tough choices that prioritize our Nation's most pressing needs during its economic recovery. As a result, programs that were funded in the 2011 budget were identified for reduction in the 2012 President's budget. The proposal to redirect ILC funding does not reflect on the quality and usefulness of the ILC data, but rather the administration's commitment to maintaining the quality and quantity of some of our Nation's most important economic indicators.

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QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

DOL FIDUCIARY RULES

*Question.* The Department of Labor's recent proposal to amend its fiduciary duty rule has raised many questions about potential unintended consequences of the rule. For example, a recent study by Oliver Wyman found that "the proposed rule will disproportionately negatively affect small balance IRA investors." What types of economic analyses does the Department intend to conduct to shed more light on how the proposal would affect small and large entities, including retirement plans, their sponsors and service providers, and individual retirement accountholders?

Answer. The proposed regulation included a regulatory impact analysis (RIA) that assessed the potential costs and benefits associated with the proposal. The Department's RIA satisfied applicable requirements and provided an appropriate economic basis for the proposal. The Department acknowledged in the RIA that its assessment was subject to uncertainty and solicited public comment to help it address areas of uncertainty. As we move forward with finalizing the proposed rule and developing an expanded RIA, the Department will take into account input received from stakeholders and consultations with other Federal agencies. The economic im-

pact of the final rule on both ERISA plans and IRAs will be carefully considered during this process.

Some private studies—including several have been commissioned by organizations opposed to the proposal—purport to demonstrate that the Department's proposal will hurt the very investors and workers that the Department is seeking to help. However, these studies are predicated on several deeply flawed assumptions. For example, one widely cited study builds its entire cost analysis on the assumption that commission-based compensation for servicing IRA's would no longer be allowed even though there are exemptions already in place that allow broker-dealers acting as fiduciaries to receive commissions for the sale of securities, mutual funds and insurance products.

The Department is always mindful of the impact its regulatory actions may have on the availability of investment products and services to employee benefit plans, IRAs, and to workers and retirees covered by those plans. For example, some commenter's have suggested that we consider the possible exercise of the Department's authority to issue additional administrative exemptions from certain prohibited transaction provisions of ERISA as a way of ensuring the continued availability of certain types of transactions that they say clearly benefit plan participants, beneficiaries, and IRA owners. Other commenter's urged that the effective date of the final regulation allow service providers transition time to adjust their business practices and systems for compliance. We will also be considering these comments and suggestions.

CFTC

*Question.* The CFTC has proposed rules under the Dodd-Frank Act that, when read together with the Department's proposed rule on fiduciary duty, may make it impossible for pension plans to find counterparties willing to engage in swap transactions with them. Does the Department of Labor plan to weigh in on the CFTC rulemaking or take steps in its own rules to ensure that pension plans are able to continue to use swaps in managing plan risks?

Answer. The Department has recently weighed in with the CFTC on the interaction between the fiduciary proposal and the CFTC rules proposed under Dodd-Frank by sending a letter from EBSA Assistant Secretary Phyllis Borzi to CFTC Chair Gary Gensler. As this letter says, it is the Department's view that "a swap dealer or major swap participant acting as a plan's counterparty in an arm's length bilateral transaction with a plan represented by a knowledgeable independent fiduciary would not fail to meet the terms of the proposed regulation's counterparty exceptions solely because it complied with the business conduct standards set forth in the CFTC's proposed regulation." The Department does not seek to impose ERISA fiduciary obligations on persons who are merely counterparties to plans in arm's length commercial transactions. Parties to such transactions routinely make representations to their counterparties about the value and benefits of proposed deals, without purporting to be impartial investment advisers or giving their counterparties a reasonable expectation of a relationship of trust. Accordingly, the Department's proposed regulation provides that a counterparty will not be treated as a fiduciary if it can demonstrate that the recipient of advice knows or should know that the counterparty is providing recommendations in its capacity as a purchaser or seller.

As we evaluate the comments we have received, we will continue to evaluate the particular terms used to define the scope of any exception to ensure that the regulation is as clear and effective as possible, and to avoid any unintended consequences.

Finally, the Department and the CFTC are actively consulting with each other and coordinating our efforts relating to the DOL fiduciary regulation and the CFTC business conduct standard. Our shared joint goal is to harmonize these initiatives to ensure that the regulated community has clear and sensible pathways to compliance. We are confident that this goal will be achieved.

*Question.* The Department of Labor is considering issuing a transparency rule under ERISA that would require service providers to disclose detailed financial information to health plans. If so, pharmacy benefit managers (PBMs) may be required to provide detailed disclosure of their proprietary cost structures (e.g., pharmacy discounts and drug manufacturer rebates) to thousands of PBM clients without sufficient confidentiality protections to safeguard against the anti-competitive effects repeatedly pointed out by the Federal Trade Commission in the context of state PBM transparency laws. As the Department is undertaking rule promulgation to require the disclosure of proprietary data of service providers of ERISA plans, what has the Department done to reconcile its proposal with the FTC's seemingly con-

trary position? Has the Department had high level, in-depth discussions with the FTC's Bureau of Competition?

Answer. Yes, the Department has met with senior policymakers at the FTC and had very productive and informative discussions. We will continue to work closely with our colleagues at the FTC on this regulatory initiative.

In March, the FTC's decided in a 5–0 vote to write Mississippi lawmakers about the anticompetitive effects of competitors learning each other's pricing information:

"These provisions could result in sharing competitively sensitive cost information among competing pharmacies and pharmaceutical manufacturers. In particular, such information sharing could undermine competition between pharmacies to be included in PBM networks and between pharmaceutical manufacturers to offer discounts to PBMs. Both outcomes could raise prescription drug prices for consumers. We note, however, that if there are appropriate confidentiality safeguards in place, health plan sponsors (and their consultants) may find specific cost information helpful as they seek to select among PBMs, understand their enrollees' prescription drug use, and ensure that they are receiving appropriate rebates from PBMs."

*Question.* How has the Labor Department calculated the additional costs of service provider disclosure in the absence of confidentiality?

Answer. The Department is aware of the FTC's March 2011 letter. We are still gathering information in advance of considering policy options for this rulemaking at this time and have not yet calculated the potential costs and benefits of service provider disclosure in the absence of confidentiality. The Department will take into account the FTC's concerns regarding competition, collusion, and appropriate confidentiality safeguards in developing the regulatory impact analysis for any rule that is promulgated in this area.

The FTC's March, 2011, letter also noted how certain disclosure could increase collusion.

"In some circumstances, sharing information among competitors may increase the likelihood of collusion or coordination on matters such as price or output. The antitrust agencies have explained how coordinated interaction harms consumers: coordinated interaction 'can blunt a firm's incentive to offer customers better deals by undercutting the extent to which such a move would win business away from rivals' and 'also can enhance a firm's incentive to raise prices by assuaging the fear that such a move would lose customers to rivals.'"

*Question.* What action is the Labor Department pursuing to mitigate collusion or price coordination among corporations?

Answer. The Department's objective in this area is to ensure that ERISA plan fiduciaries have sufficient information to fulfill their fiduciary responsibility of determining whether their contracts or arrangements with service providers, such as PBMs, are reasonable. We will consult closely with the FTC as we develop a regulatory framework that addresses concerns regarding collusion or price coordination.

TRADE ADJUSTMENT ASSISTANCE COMMUNITY COLLEGE TRAINING GRANTS

*Question.* Could you explain why the Trade Adjustment Assistance Community College Training Grants program (TAACCCT) calls for the development of Open Education Resources to meet the immediate training needs of students?

The National Center for Academic Transformation indicates that "high-quality course materials [are already available] at a reasonable cost," "reasonably priced software . . . is a non-problem," and that available software enables "faculty to focus on pedagogy rather than materials creation." Therefore, why do you believe the Federal Government should spend develop materials that appear to already exist in the marketplace?

Answer. The Department expects the Federal funding from the Trade Adjustment Assistance Community College and Career Training (TAACCCT) grant program to provide quality education and training services to Trade Adjustment Assistance (TAA) for Workers program participants as well as other individuals to improve their knowledge and skills, enabling them to obtain good, sustaining jobs. The program allows for development of materials, and it also can improve on existing courses that can be completed in 2 years or less. Ultimately, the goal of adoption and adaptation of courses is to increase industry-recognized credential or degree completion rates of participants through four key priorities and strategies including: (1) accelerating progress for low-skilled and other workers, (2) improving retention and achievement rates to reduce time to completion, (3) building programs that meet industry needs including the development of career pathways, and, (4) strengthening online and technology-enabled learning.

Across these strategies, DOL recognizes that grantees may use existing courses or programs when they are well suited to meet the project's objective. However, training and education needs vary by region and can change quickly. The marketplace does not support courses that meet every project need. In some cases courses may need to be tailored or augmented, and in other cases new materials altogether, not currently supported by the marketplace, may be developed.

As one of four strategies, community colleges and other education organizations have an opportunity to harness technology in their classrooms and modernize their curriculum. These projects are encouraged to improve or develop online or technology-enabled learning programs and courses that can be taken to scale beyond a community level to reach a national audience of diverse students over a larger geographic area. The programs and courses developed with these funds, particularly those developed by consortia of eligible institutions, will be produced to maximize interoperability and exchange, and made freely available for reuse and improvement by others. Online and technology-enabled learning courses not only ensure widespread usage but encourage continuous improvement of courses and learning materials. Most importantly, online learning allows for rapid deployment and the ability to meet employers' skilled workforce needs as they arise.

BUDGET DEFICIT

*Question.* Unemployment in our Nation is 8.8 percent. Madam Secretary, what is your Department doing to ensure that we are providing our workers with the type of assistance necessary to help our small businesses and entrepreneurs create well paying jobs?

Answer. While the Department's resources do not directly create jobs, they can help ensure workers acquire the skills that employers need to successfully compete in the global economy. The public workforce system focuses workforce development resources on the expressed needs of employers, both small and large, in the following ways:

Local and State workforce boards oversee WIA programs; they are required to be business-led and have majority business membership to connect the One-Stop service delivery system directly to the local employers to ensure workers and training providers are knowledgeable about what jobs/skills are needed in the regional or local economy.

The Department has strengthened connections between the public workforce system and local employers through initiatives such as:

Awarding $75,000,000 in competitive On-the-Job Training (OJT) where small businesses can be reimbursed up to 90 percent of the trainees' wages for up to 6 months to cover the extraordinary costs of training;

Requiring many of ETA's competitive grants to focus on employers' skill needs or require a partnership with employers, for example, H–1B technical skills training grants that may be competitively awarded to partnerships of private and public sector entities that may include business-related nonprofit organizations, such as trade associations;

Providing technical assistance such as training Business Service Representatives from the One-Stop Career Centers and Workforce Investment Boards to better address business needs and issuing guidance about Entrepreneurship (TEGL No.12–10).

The Department worked closely with businesses and trade associations to develop 19 competency models in such industry sectors as energy, advanced manufacturing, allied health and long-term care and supports, and entrepreneurship. These competency models document the foundational and technical skills and competencies required for workplace success in economically important industries and are available at www.careeronestop.org/competencymodel. Industry competency models provide a resource for the development of curricula, certifications, and the tests that assess work-related competencies. Most importantly, competency models support worker progression along career pathways.

WORKFORCE INVESTMENT ACT

*Question.* Under the Workforce Investment Act (WIA—pronounced WEE-a), all WIA funded initiatives were to be evaluated in 2005. It is now 2011 and we do not have any significant, concrete updates on WIA programs. Given the fiscal restraints in the fiscal year 2012 budget, unless we know that workforce programs are working, I do not think we should continue to fund them. It is my understanding the Department has started a comprehensive evaluation of WIA funded programs and interim results will be available in 2013. Secretary Solis, in the meantime, can you address ways this subcommittee can effectively evaluate these programs?

Answer. The value of training is illustrated by the entered employment rate, or how many individuals found jobs. For the 12-month period ending June 30, 2010, individuals receiving WIA Dislocated Worker program training found employment 1.6 times faster than those who did not receive training. Adults at program exit who participated in On-the-Job Training (OJT) found employment at a rate of 86 percent, while dislocated workers receiving OJT found jobs at 90.3 percent rate.[4] In the 6-month period after finding jobs, individuals who completed the WIA Adult program and Dislocated Worker program, and who were unemployed at program entry, helped stimulate the economy by earning just under $7.2 billion.[5]

However, such outcome data do not take into account what participants could accomplish without WIA. To do so, in 2008 the Department released the WIA Non-Experimental Study.[6] This study found that, although differences across States are substantial, participation in the WIA Adult program is associated with an increase in quarterly earnings of several hundred dollars. The analysis of participants who receive only core and intensive services suggests that their benefits may be as great as $100 or $200 per quarter over the period of study, which is substantial compared to the small costs of those services. The marginal benefits of training may exceed $400 in earnings each quarter.

The study also found that following entry into WIA, Dislocated Workers experience several quarters for which earnings are depressed relative to comparison group workers. However, their earnings do ultimately overtake the comparison group. The return they experience from training appears to be smaller than that obtained by Adult program participants. The study further found that women appear to obtain greater benefits than men for participation in both the Adult and Dislocated Worker programs.

The estimated effects for various subgroups examined—nonwhite non-Hispanics, Hispanics, those under 26 years of age, those 50 years of age or above, and veterans—are similar to the estimated effects for all WIA participants. In other words, there is essentially no evidence that any of the subgroups considered have experiences that differ from the average in important ways.

Because of serious concerns about the limitations of the methodology and data used in the non-experimental study, in 2008 the Department commissioned the WIA Gold Standard Evaluation (WGSE). This study will address the limitations of the 2008 study as shown in the table below and includes a cost-benefit component. The study's results will be available in 2016, although this schedule is dependent upon continued appropriations for the evaluation of WIA programs.

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[4] Workforce Investment Act Standardized Record Data (WIASRD) records from Program Year 2009 (July 1, 2009–June 30, 2010).

[5] Workforce Investment Act Standardized Record Data (WIASRD) records from April 1, 2008 to March 31, 2009.

[6] http://wdr.doleta.gov/research/FullText__Documents/Workforce%20Investment%20Act%20Non%2DExperimental%20Net%20Impact%20Evaluation%20%2D% 20Final%20Report%2Epdf.

| | WIA Non-Experimental Impact Study (aka 2008 Impact Study) | WIA gold standard evaluation |
|---|---|---|
| Evaluation Methodology | Quasi-experimental methods (propensity score matching) | Random assignment |
| Sample | Consisted of 12 purposively selected States | Will use a nationally representative sample of approximately 30 randomly-selected local workforce investment areas |
| Comparison Groups | Drawn from Unemployment Insurance claimants and Wagner-Peyser participants. | Will randomly assign from WIA applicants |
| Data Sources | Used administrative data (UI wage records) which limited the outcomes looked at to quarterly earnings and employment. | In addition to administrative data, will use survey data which will allow a full range of educational, employment, earnings, and self-sufficiency outcomes to be examined |
| Services Examined | Looked at three levels of services: Core, Intensive, and Training compared to persons not receiving WIA services. | Will look only at Intensive and Training compared to Core |
| Study Dates | Looked at participants who entered WIA between July 2003 and June 2005. | Will look at entrants between approximately September 2011 and December 2012 |

PROGRAM EFFECTIVENESS

*Question.* In March, GAO stated that the Employment and Training Administration's research and evaluation programs have "failed to conduct research that can answer urgent workforce policy questions and lead to an understanding of what works and what does not." What are the Department of Labor's plans to improve the efficiency and effectiveness of programs administered by the Department?

Answer. The Department of Labor is taking action in virtually all aspects of its operations to ensure that our programs will operate at the optimal levels of effectiveness and efficiency. We strongly believe in the importance of Federal fiscal responsibility and that part of this responsibility is identifying which programs and strategies efficiently provide the greatest benefit to participants.

The Department recently undertook a significant strategic planning process, publishing the U.S. Department of Labor Strategic Plan Fiscal Years 2011–2016 on September 30, 2010. The strategic planning process was highly inclusive, including formal opportunities for public comment. Further, each agency, including ETA, has formal Operating Plans that are used to guide and monitor its performance. Together, these plans harness and direct the Department's resources toward achieving five goals, which include: (1) preparing workers for good jobs and fair compensation, and (2) for those not working, provide income security. These planning processes are designed to maximize the use of evidence and results.

The Department relies on performance data and evaluations. In addition to our efforts to reassess performance measures to promote better outcomes for individuals of all skill and need levels, we believe that workers and employers should have easy access to information about program outcomes for past participants, so they can make informed decisions about which programs are most likely to meet their needs.

The Department has worked diligently over the past 2 years to increase the rigor of its evaluations. I established the Chief Evaluation Office (CEO) to coordinate the Department's research and evaluation agenda and increase its capacity to conduct high quality, rigorous evaluations. The CEO is working closely with all Departmental agencies, including ETA, to ensure that Departmental evaluations are appropriately rigorous and designed to yield clear and actionable information for policymaking purposes.

Since 2009, about half the evaluations the ETA has funded have been rigorous, random assignment impact evaluations. These include: (1) the Workforce Investment Act (WIA) Gold Standard Evaluation of the Adult and Dislocated Worker Programs (WGSE); (2) the YouthBuild Impact Evaluation; (3) the Reintegration of Ex-Offenders Random Assignment Evaluation; (4) the Impact Evaluation of Green Jobs, Health Care and High Growth Training Grants; and (5) the Transitional Jobs Demonstration Impact Evaluation. Each of these evaluations examines net impacts on employment, retention and earnings, and include benefit-cost analyses. ETA was able to fund these evaluations through an increase in fiscal year 2010 appropriations for evaluations and the funds made available to DOL by the American Recovery and Reinvestment Act of 2009. Random assignment evaluations are highly resource intensive and typically take a range of 3 to 7 years to implement. In addition, random assignment evaluations of our programs may not always be possible when the law requires that people receive services. Therefore, it is necessary at times to conduct other types of evaluations to gain as much information as possible with available resources.

Another key investment that the Department will maximize is the Workforce Innovation Fund (Fund). The Full-Year Continuing Appropriations Act of 2011 provides $124.7 (post rescission) for the Workforce Innovation Fund that will support competitively awarded grants to States; State agencies that are eligible for assistance under any program authorized under WIA; consortia of States; or partnerships, including regional partnerships. This Fund represents a small but crucial investment in innovative, evidence-based and cost-saving workforce strategies. This Fund will significantly benefit WIA formula-funded activities well into the future by obtaining results that can be replicated broadly throughout the workforce system. These results will inform administrative guidance issued by the Department and future workforce related legislative initiatives.

In addition, the Department has developed effective partnerships with other Federal agencies that encourage State and local synergies to improve the delivery of quality, cost effective services across programs and evaluate their performance. Finally, we look forward to continuing to work with Congress in support of a WIA reauthorization bill that meets the administration goals of streamlined service delivery, better meeting the needs of employers and regional economies, improving accountability, and promoting innovation.

SUBCOMMITTEE RECESS

Senator HARKIN. The subcommittee will stand recessed.

[Whereupon, at 11:03 a.m., Wednesday, May 4, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2012

**WEDNESDAY, MAY 11, 2011**

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 9:59 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Reed, Mikulski, Brown, Shelby, Kirk and Moran.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### NATIONAL INSTITUTES OF HEALTH

**STATEMENT OF DR. FRANCIS S. COLLINS, DIRECTOR**

**ACCOMPANIED BY:**

**HAROLD VARMUS, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE**

**ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES**

**SUSAN B. SHURIN, M.D., ACTING DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

**DR. GRIFFIN RODGERS, DIRECTOR, NATIONAL INSTITUTE OF DIABETES, DIGESTIVE AND KIDNEY DISEASES**

#### OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Senate Subcommittee on Labor, Health and Human Services, and Education will now come to order.

First of all, Dr. Collins, welcome back to the subcommittee. We welcome also Dr. Harold Varmus, Director of the National Cancer Institute; Dr. Tony Fauci, Director of the National Institute of Allergy and Infectious Diseases; Dr. Griffin Rodgers, Director of the National Institute of Diabetes, Digestive and Kidney Diseases; and Dr. Susan Shurin, Director of the National Heart, Lung, and Blood Institute.

This subcommittee holds an appropriations hearing on the NIH budget every year, and every year I am both inspired by the dedication of the scientists who testify before us and proud that their accomplishments have made America the world leader in biomedical research. But in recent years, our Nation's status in that regard has been threatened. While China and Singapore make

massive investments in research, here in the United States we're pulling back.

The fiscal year 2011 appropriations bill that Congress passed last month cut NIH funding by $322 million below the fiscal year 2010 level. When you consider how much funding was needed to keep up with inflation, the cut was more like $1.3 billion, taking inflation into account.

We should be thankful that the result wasn't significantly worse. H.R. 1, the spending bill passed by the House majority, would have cut NIH funding by $1.6 billion or $2.6 billion if you counted inflation. Fortunately, the Senate rejected that plan.

But even the compromise bill that was ultimately signed in law will result in a success rate for NIH research grants, I'm told, of just 17 or 18 percent, meaning just one out of every six peer-reviewed application will be approved. And, again, I am informed that that is the lowest success rate on record for NIH.

What a dismal downturn from what Senator Specter and I, and others did back in the late 1900s and early 2000 when we doubled the funding of NIH and we got the success rate up, I think—if I'm not mistaken. You correct me, Dr. Collins—up in the 20–30 percent range, somewhere in there. And we thought we were on a path to continue that kind of a success rate. Now, it's down lowest on record.

And there is cause to fear even bigger cuts next year. The budget plan approved by the House last month would cut health funding by 9 percent in fiscal year 2012. If that plan were approved, severe reductions to NIH research would be unavoidable.

That doesn't make sense. Let's set aside for a moment any thoughts about the moral value of trying to improve people's health, and just look at the issue from a purely economic standpoint. NIH research is one of the best investments this country can make.

A study released yesterday by United for Medical Research concluded that in fiscal year 2010, NIH funding supported almost 500,000 jobs across country. And I always have to remind people that only a small percentage of that goes to NIH in Bethesda, Maryland. I want Senator Mikulski to know that. Most is awarded to researchers at academic institutions all over the United States.

Another study by Battelle examined the specific impact of the Human Genome Project, which was overseen, again, by Dr. Collins and completed in 2003. The Federal Government spent a total of $3.8 billion on this historic initiative. A lot of money, but the return on the investment is staggering. According to the Battelle study that $3.8 billion translated into an economic output of $796 billion between 1988 and 2010. And, of course, we'll be seeing benefits from the Human Genome Project for many more decades to come. In fact, when I was reading all of your testimonies last night, what struck me in each one of them there were references made back to genomic research in every single case of the institutes who are represented here.

So the lesson is clear. Biomedical research is one of the engines that drive our economy. If we want our economy to grow, both immediately and in the long term, that engine needs fuel. Drastically cutting NIH, as the House budget would force us to do, would be

a classic case of penny wise and pound foolish thinking. That, again, is just on the economic side.

On the human side, though, the great advances that have been made in cancer research and what we have done to lessen the threat of cancer—young kids now with leukemia are being cured at an almost 100 percent rate. Maybe that's not quite right, but pretty darn close, things that were unheard of just a few years ago. The advances that we're making in infectious diseases, unheard of 20 years ago when I first came on this subcommittee. Well, that's been 25 years ago, but great advances have been made. Just stark.

So, from the human standpoint, in helping people have better lives and overcoming some of the dreaded diseases that have plagued mankind for so long, on both fronts, biomedical research is the place to go and we ought not to be penny wise and pound foolish on that.

And so now I'll recognize my ranking member, Senator Shelby, for an opening statement.

STATEMENT OF SENATOR RICHARD C. SHELBY

Senator SHELBY. Thank you, Mr. Chairman. I appreciate you holding this hearing today to discuss the vital mission carried out by the National Institutes of Health.

We live in a world where there are thousands of debilitating and life-threatening diseases, all that could use additional funding for research and clinical trials.

I support Federal investment in basic biomedical research and development. Research carried out by the NIH and its network of 325,000 researchers at 3,000 institutions across the country serves the Nation with the goal of improving human health. As research becomes more expensive and private capital dries up, I believe it's critical to ensure support for translational research; that is, research that moves a potential therapy from development to the market.

The NIH has developed an interesting proposal with the establishment of the National Center for Advancing Translational Sciences, NCATS. NCATS is intended to fill the gap between advances in scientific understanding of disease and the process to turn new scientific insights into products. I believe the need for an entity to straddle the world's research and industry is clear.

In the private market, pharmaceutical companies will abandon drug development projects that are not initially successful, become too complex or do not provide a lucrative path forward.

For example, since 1949, there have only been two major drug discoveries in mental health—lithium and Thorazine. Sixty years later, researchers still do not know why these drugs actually work. Hundreds of genes have been shown to play roles in mental illness, too many for focused efforts by drug developers.

Therefore, many drug manufacturers have dropped out of the mental-health field. In particular, pharmaceuticals for rare and neglected disease are often ignored because private companies avoid this small market with little profit appeal leaving patients with no treatment options.

Even promising new drugs discovered through basic research often struggle during the translational stage of the process because

it's expensive, time consuming and prone to failure. These barriers inhibit both the scientists dedicated to improving health and the patients who ultimately need improved cures and care.

The question remains, however, as to whether NCATS is the right approach to solving the issue. Will NCATS be the right mechanism for taking valuable discoveries that the taxpayer has funded and giving it a greater opportunity to make it in the marketplace? As we review this proposal, we need to consider the fact that NIH is not a drug developer or an expert in the therapeutics world.

Dr. Collins, I would like to continue to work with you to make a thoughtful, informed decision regarding the NCATS. Unfortunately, the fiscal year 2012 budget request, I believe, does not provide adequate details on the reorganization.

It is May 11 and we've not received a budget amendment or specific structural details of an NCATS, a program NIH wants to implement by October 1. How can the subcommittee be expected to support a program that does not yet exist in budget documents?

I understand that the transition from basic research to clinical application requires interdisciplinary and multidisciplinary expertise. Research that aims to transform science is inherently difficult. If it were easy, the need for transformation would not exist.

NCATS may be the answer to solve this complex issue, but it also may not be. We don't know. Dr. Collins, I believe that NCATS is a matter that we should contemplate, but we must ensure that the steps forward are measured and in the best interests of all stakeholders, especially those who are in need of treatment and care.

I look forward to working with you and the chairman on this very important issue. Thank you.

## INTRODUCTION OF WITNESS

Senator HARKIN. Thank you very much, Senator Shelby.

Now, welcome back to Dr. Collins.

Francis Collins was sworn in as the 16th Director of the National Institutes of Health in August 2009 after being unanimously confirmed by the Senate.

He is a physician geneticist noted for his discoveries of diseased genes and leadership, of course, of the Human Genome Project. Prior to becoming Director, he served as Director of the National Human Genome Research Institute at NIH.

Dr. Collins received his bachelor's degree from the University of Virginia, his Ph.D. from Yale and his M.D. from the University of North Carolina at Chapel Hill.

Dr. Collins, again, welcome, and first I want to say that your testimony, and all of the testimony of the Directors who are here, will be made a part of the record in their entirety.

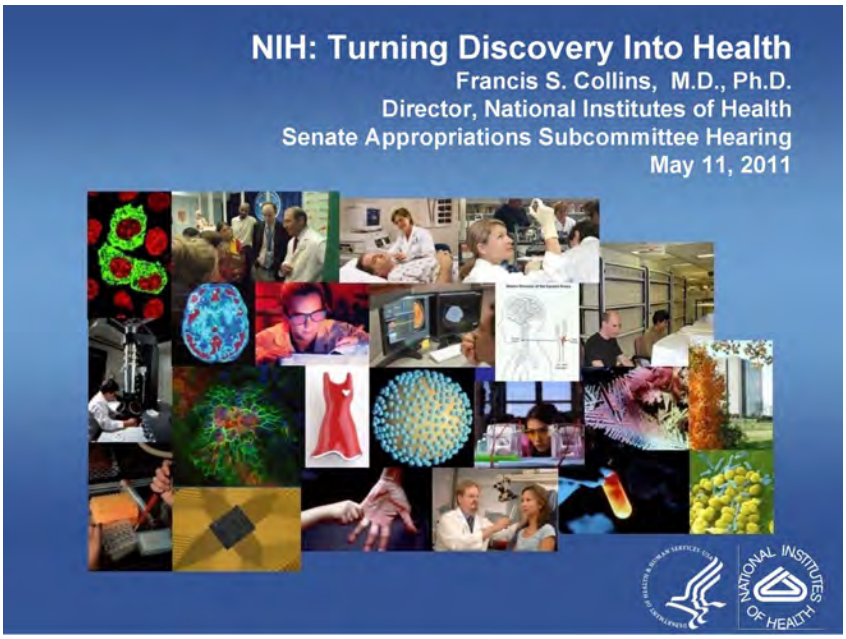
Again, due to time, Dr. Collins, we ask you to make a fairly comprehensive statement. I'm not going to get the clock going here, but if it goes too long and people start looking at me funny, then I'll probably ask you to close it out. But please take whatever time you need to give us an update on NIH and a concise summation of your written testimony.

SUMMARY STATEMENT OF DR. FRANCIS S. COLLINS

Dr. COLLINS. Well, thank you, Senator, and, Mr. Chairman, and distinguished members of the subcommittee, it's an honor to appear before you this morning, together with my colleagues, on behalf of NIH.

And I'll try not to talk so long that people start looking at you or looking at me, but I do have some things I really wanted to put in front of this distinguished subcommittee, because this is a very exciting time for biomedical research.

NIH is the largest supporter of biomedical research in the world, and we're here to present the President's budget request of $31.987 billion for fiscal year 2012.



## NIH Investments in Innovation

- Accelerating Discovery Through Technology
- Applying Science to Prevention
- Enhancing U.S. Economy and Global Competitiveness
- Advancing Translational Sciences

## Cost to Sequence a Human Genome 2001-2011

## The Cancer Genome Atlas (TCGA)

- Cancer is a disease of the genome
- DNA mutations in vulnerable locations cause cells to grow uncontrollably
- TCGA is developing a comprehensive molecular atlas of the driving mutations in the 20 most common cancers
- This will ultimately revolutionize the diagnosis and treatment of cancer

## NIH Investments in Innovation

- Accelerating Discovery Through Technology
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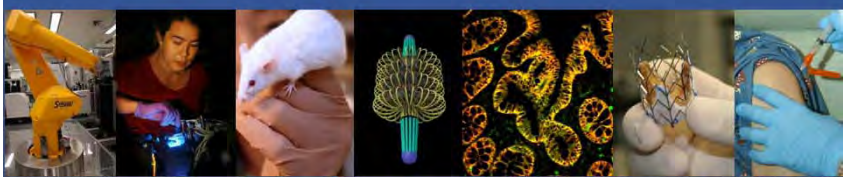
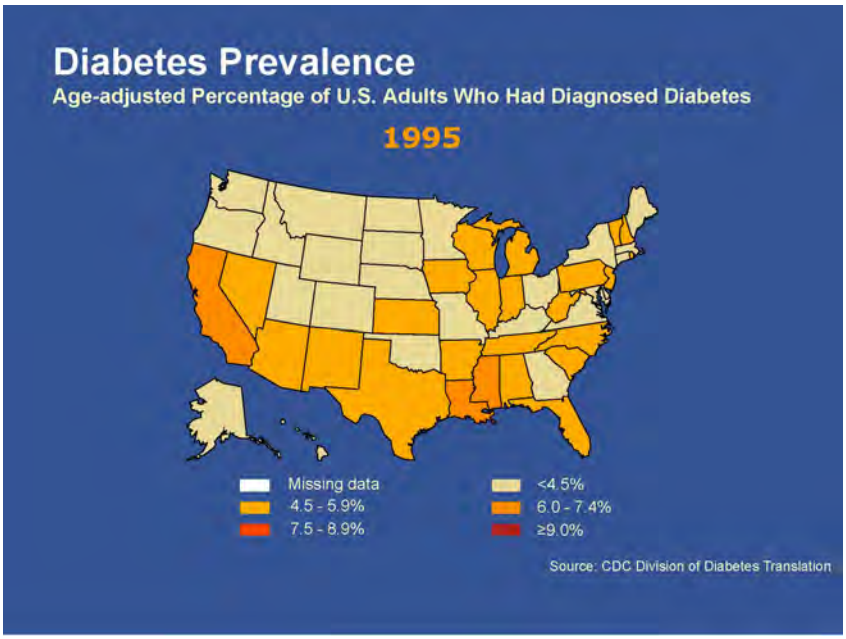
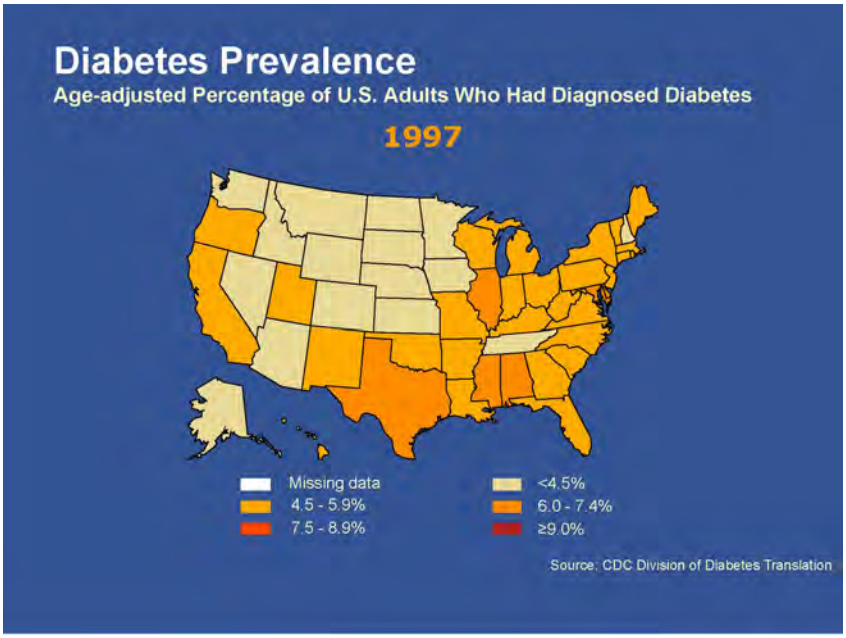



Diabetes Prevalence
Age-adjusted Percentage of U.S. Adults Who Had Diagnosed Diabetes
1995
Missing data
4.5 - 5.9%
7.5 - 8.9%
<4.5%
6.0 - 7.4%
≥9.0%
Source: CDC Division of Diabetes Translation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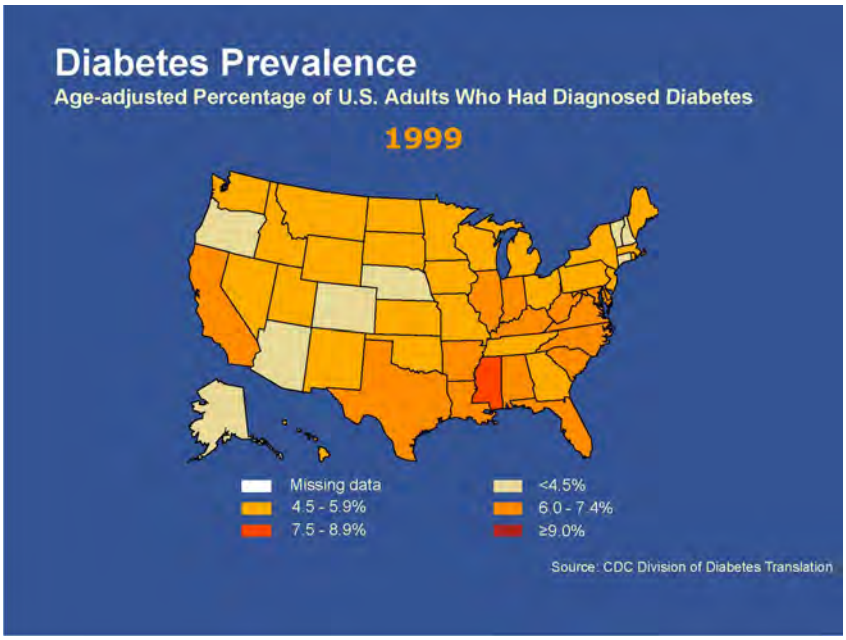
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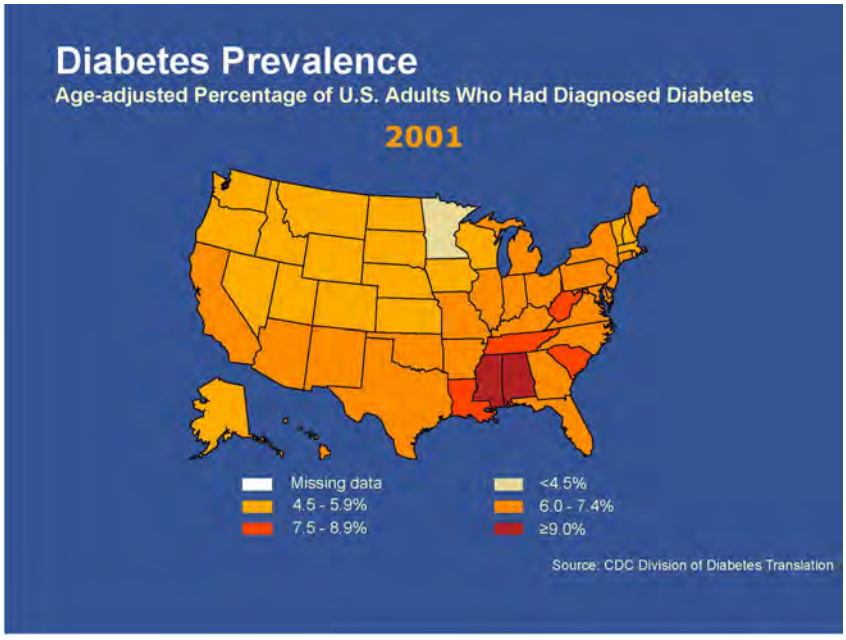
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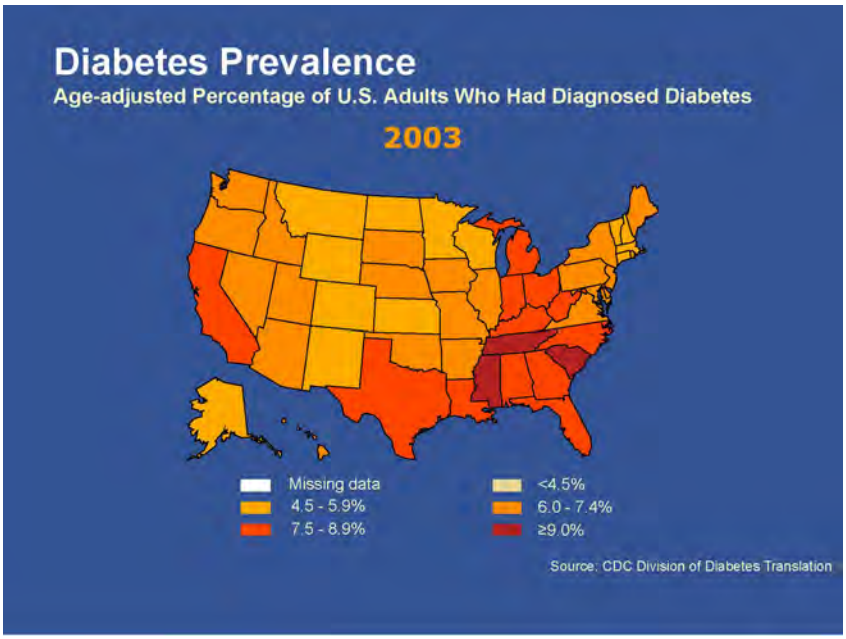
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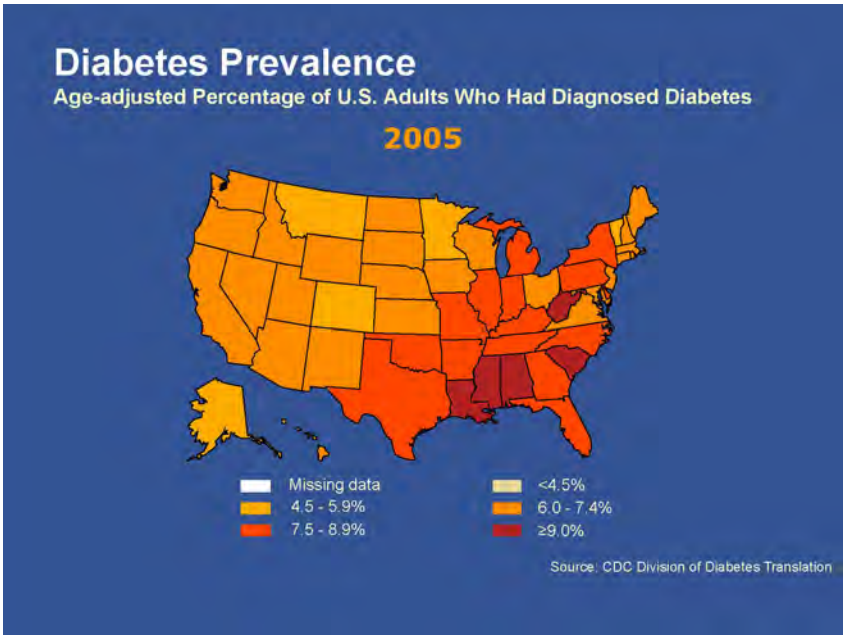
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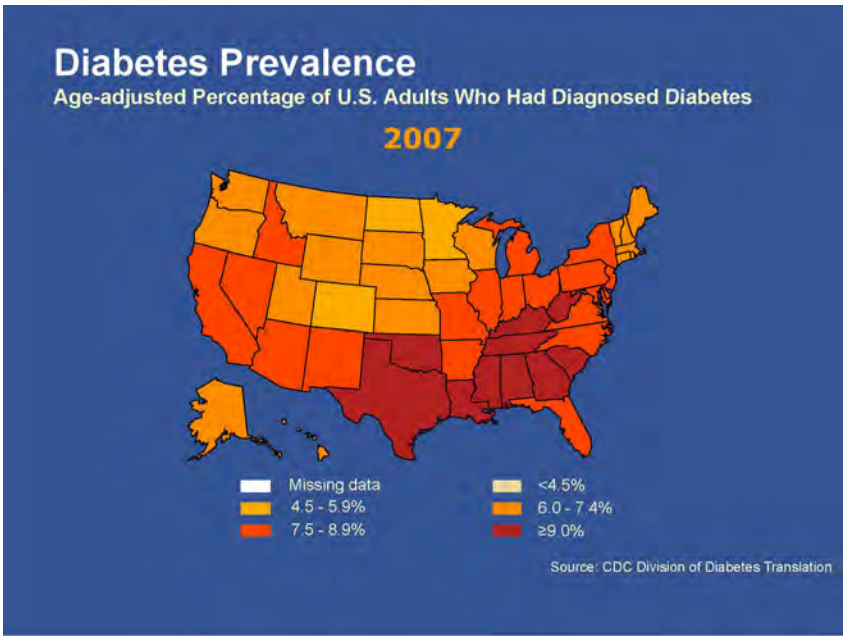
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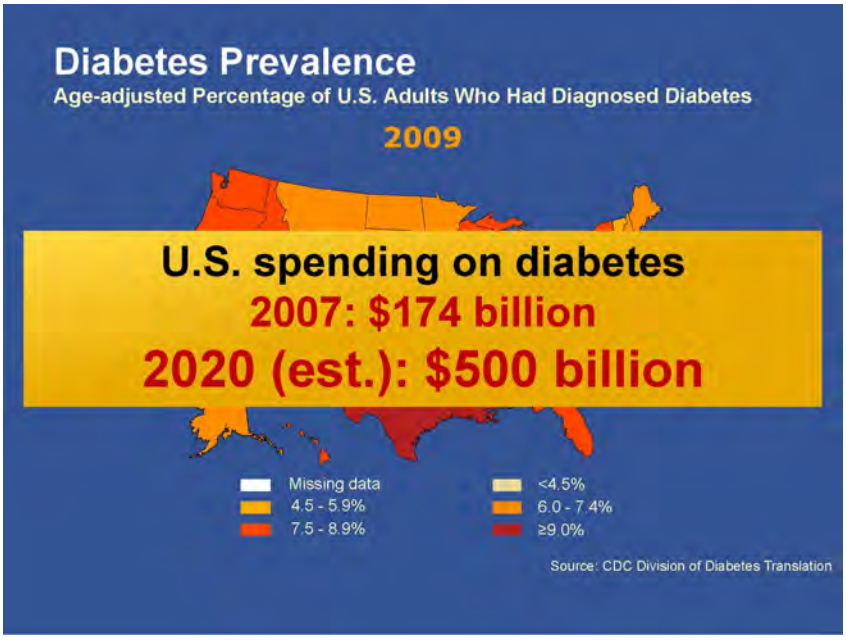
Source: CDC Division of Diabetes Translation


Diabetes Prevalence
Age-adjusted Percentage of U.S. Adults Who Had Diagnosed Diabetes
2009
U.S. spending on diabetes
2007: $174 billion
2020 (est.): $500 billion
Missing data
4.5 - 5.9%
7.5 - 8.9%
<4.5%
6.0 - 7.4%
≥9.0%
Source: CDC Division of Diabetes Translation

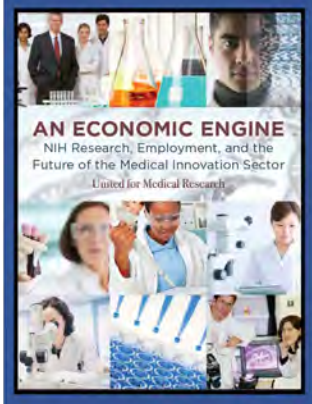
## Diabetes Prevention Program (DPP) Trial

- Adults with "pre-diabetes"
- Exercised 30 minutes a day, lost 7% body weight, were aided by a coach
- **Reduced diabetes risk 58%!**
- Many partners now taking this program to 13 communities in 10 states; CMS exploring ways to extend to Medicare and Medicaid

## NIH Investments in Innovation

- Accelerating Discovery Through Technology
- Applying Science to Prevention
- Enhancing U.S. Economy and Global Competitiveness
- Advancing Translational Sciences

## NIH's Contribution to U.S. Economic Growth and Global Competitiveness




NIH research funding supported an estimated 487,900 American jobs in 3000 institutions and small businesses in all 50 states…

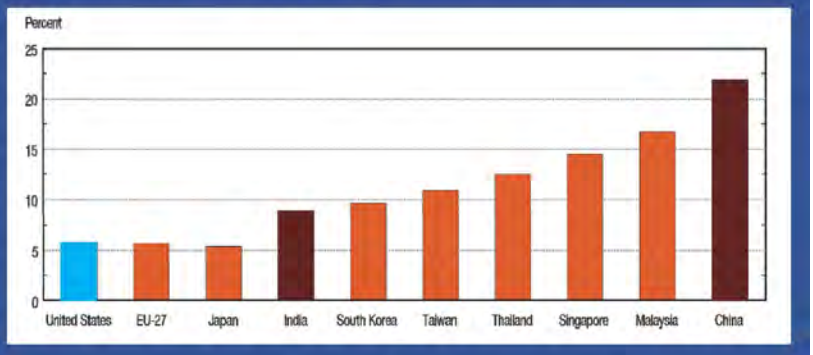
…EVEN WIDER IMPACT in its role as the foundation for the medical innovation sector…

…1 MILLION U.S. citizens employed…

…earning $84 BILLION in wages and salary…

…exporting $90 BILLION of goods and services.

## Average annual growth of R&D expenditures for United States, EU-27, and selected Asia-8 economies: 1996–2007




Source: National Science Board, *Science and Engineering Indicators 2010*

## Case Study in Competitiveness: The BGI Genome Center in Shenzhen, China


- BGI has procured technology to sequence >10,000 human genomes/year
- **This single Chinese institution now surpasses the DNA sequencing capacity of all U.S. genome centers combined**

## NIH Investments in Innovation

- Accelerating Discovery Through Technology
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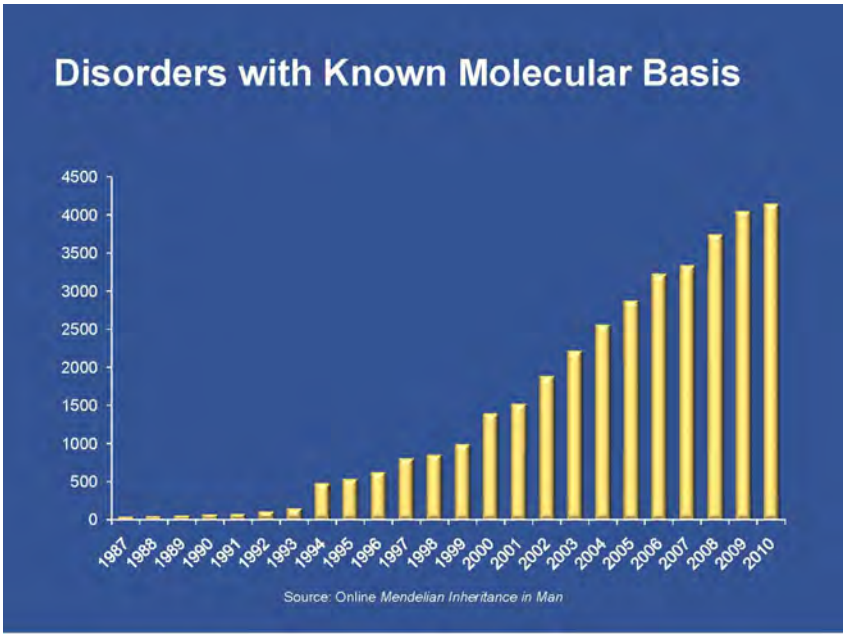
- Advancing Translational Sciences


Disorders with Known Molecular Basis
4500
4000
3500
3000
2500
2000
1500
1000
500
0
1987
1988
1989
1990
1991
1992
1993
1994
1995
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2004
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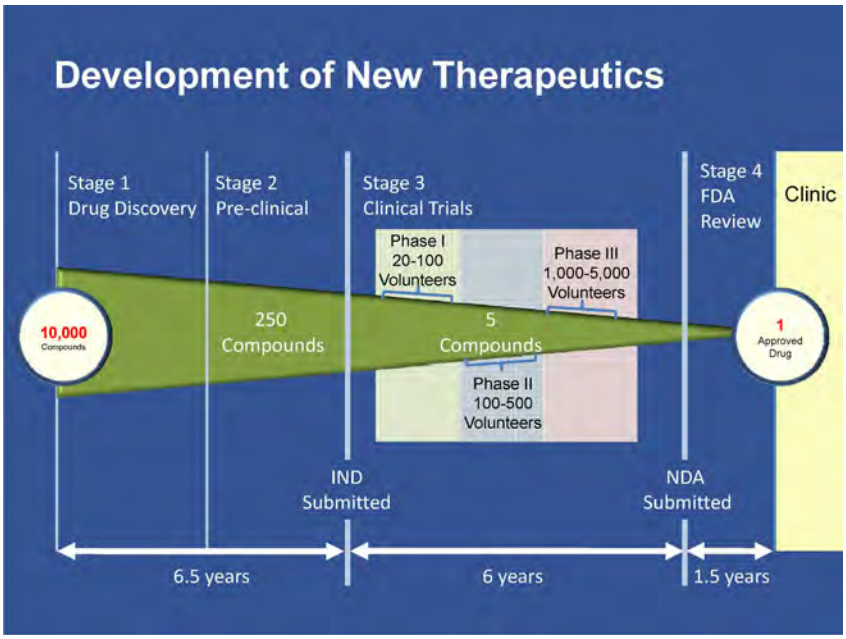
2007
2008
2009
2010
Source: Online Mendelian Inheritance in Man


Development of New Therapeutics
Stage 1
Drug Discovery
Stage 2
Pre-clinical
Stage 3
Clinical Trials
Stage 4
FDA
Review
Clinic
Phase I
20-100
Volunteers
Phase III
1,000-5,000
Volunteers
10,000
Compounds
250
Compounds
5
Compounds
1
Approved
Drug
Phase II
100-500
Volunteers
IND
Submitted
NDA
Submitted
6.5 years
6 years
1.5 years

## Creation of the National Center for Advancing Translational Sciences (NCATS)

*To advance the discipline of translational science and catalyze the development, testing, and implementation of novel diagnostics and therapeutics across a wide range of human diseases and conditions.*

## NCATS will:

- Complement – not compete with – the private sector
- Facilitate – not duplicate – the translational research activities supported and conducted by the NIH Institutes and Centers
- Reinforce – not reduce – NIH's commitment to basic science research

## NIH Investments in Innovation

- Accelerating Discovery Through Technology
- Applying Science to Prevention
- Enhancing U.S. Economy and Global Competitiveness
- Advancing Translational Sciences

## Nic's Story

*Credits: Milwaukee Journal Sentinel, Amylynne Santiago Volker, Medical College of Wisconsin*

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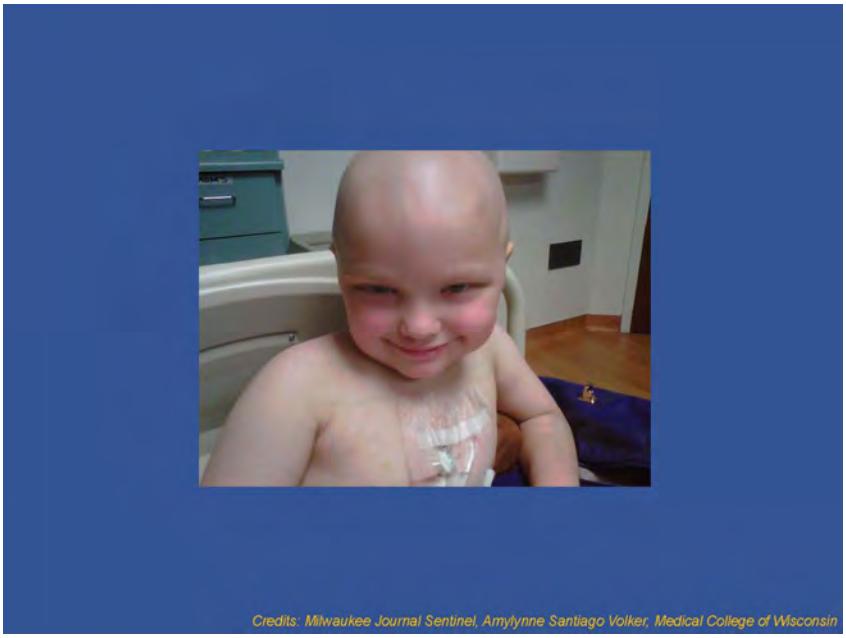
Credits: Milwaukee Journal Sentinel, Amylynne Santiago Volker, Medical College of Wisconsin


HAPPY MARROW DAY
NIC
Credits: Milwaukee Journal Sentinel, Amylynne Santiago Volker, Medical College of Wisconsin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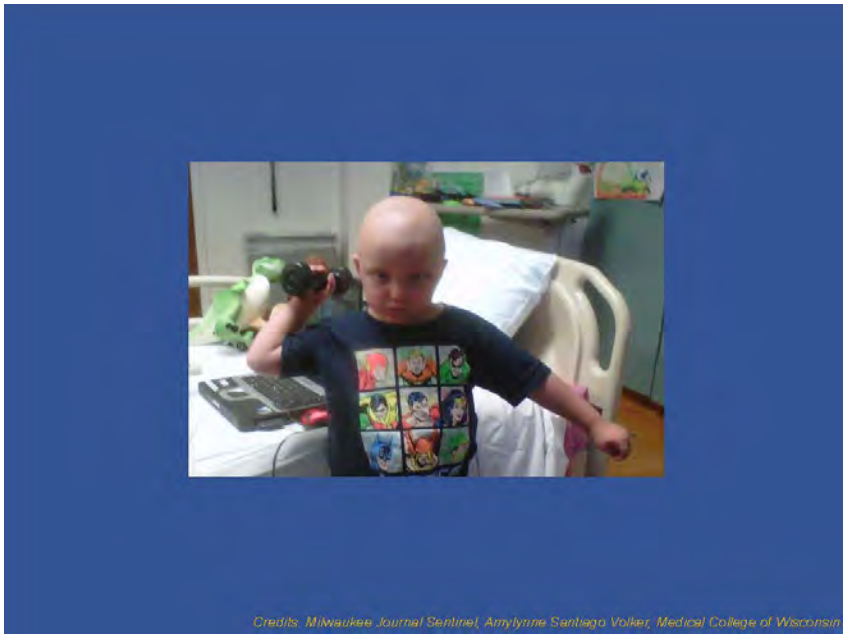
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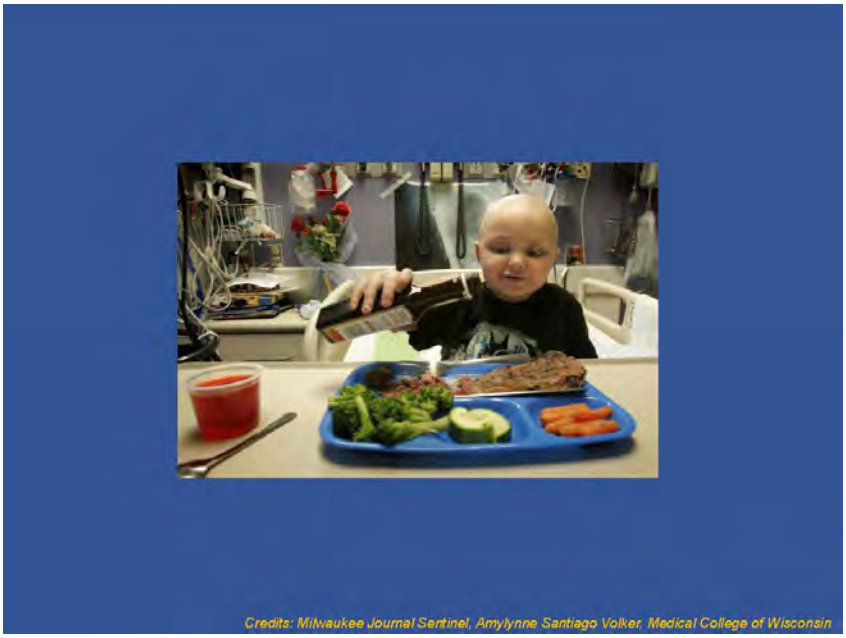

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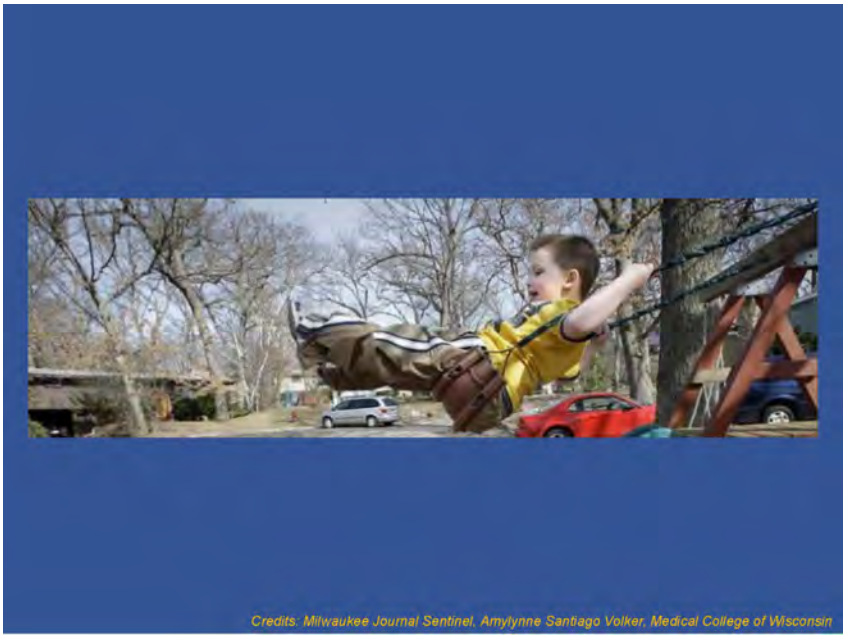

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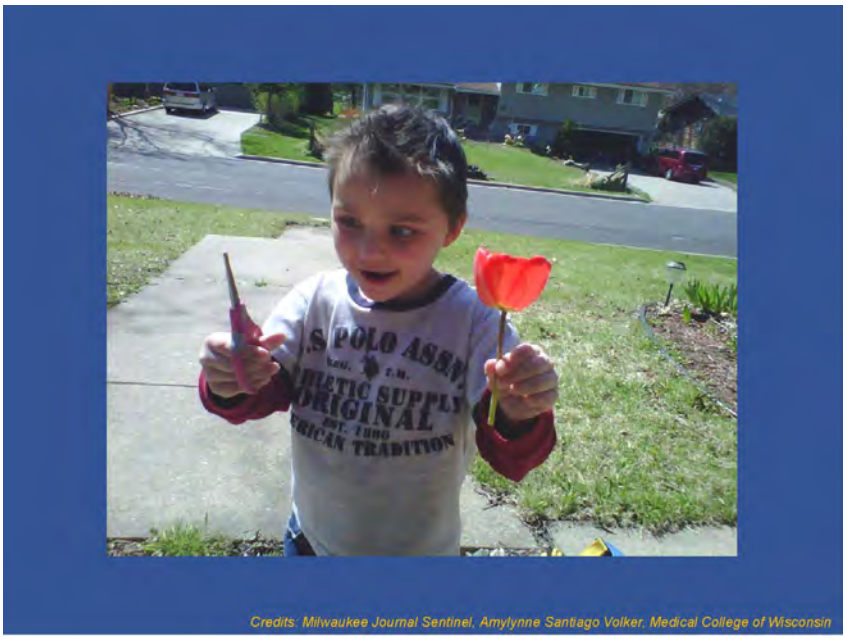
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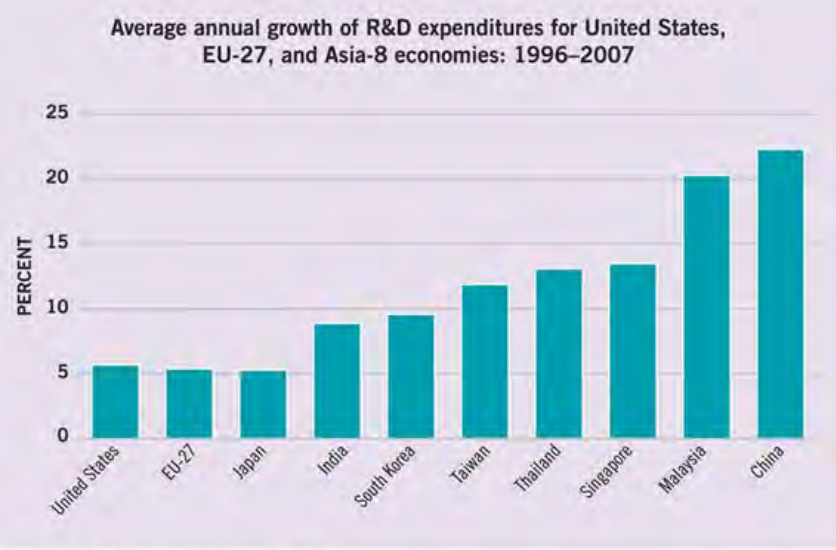
NIH
Turning discovery into health
U.S. Department of Health and Human Services

GLOBAL COMPETITIVENESS—THE IMPORTANCE OF U.S. LEADERSHIP IN SCIENCE AND INNOVATION FOR THE FUTURE OF OUR ECONOMY AND OUR HEALTH

The National Science Board's 2010 Key Science and Engineering Indicators, provide insight into how crucial decisions on R&D funding may affect our Nation's ability to thrive in an increasingly competitive and knowledge-driven global economy. While these trends apply not just to bimoedical reserch, but also to research in chemistry, physics, engineering, computer science, and many other fields, the conclusion of most observers is that the 21st century will be dominated by the life sciences, and the country that leads in this area will have much to gain. Unfortunatley, the United States, traditionally the dominant Nation in scientific resarch, has been slipping in leadership recently.

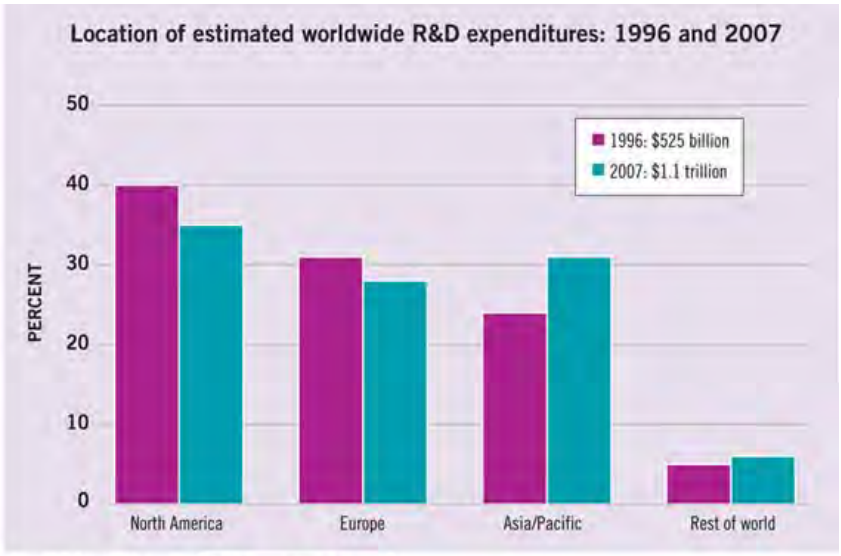
*Losing Ground*.—R&D investment growth rates are rising sharply in Asia.




*SEI 2010:* **Global Patterns of R&D Expenditures,** Chapter 4.

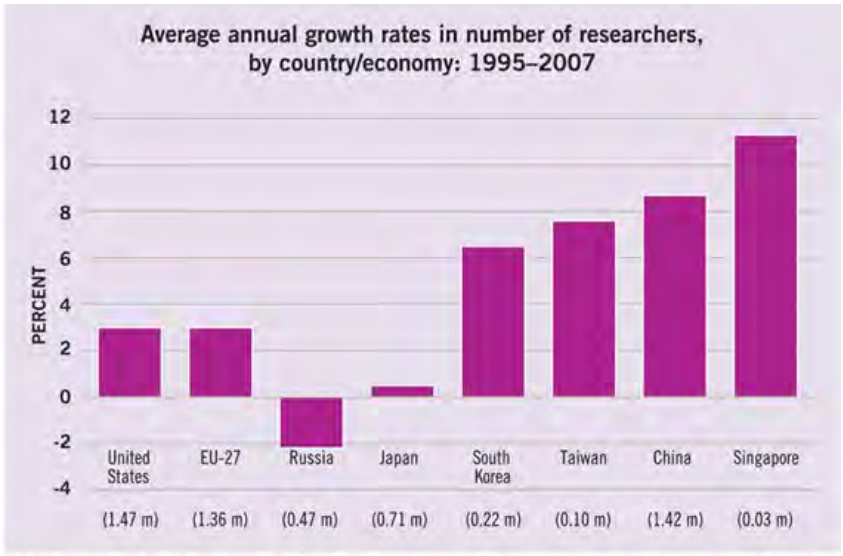
For example, China's growth rate is 4 times higher than the U.S. rate.

While the U.S. remains among the nations with the highest actual R&D expenditures, Asia is rapidly closing the gap.




*SEI 2010:* **Global Patterns of R&D Expenditures,** Chapter 4.

Employment Impact: The number of people engaged in scientific research in China has increased dramatically. In 2007, China had 1.42 million researchers, while the US had 1.47 million. In 2010, it is likely that China has surpassed the U.S. research workforce.

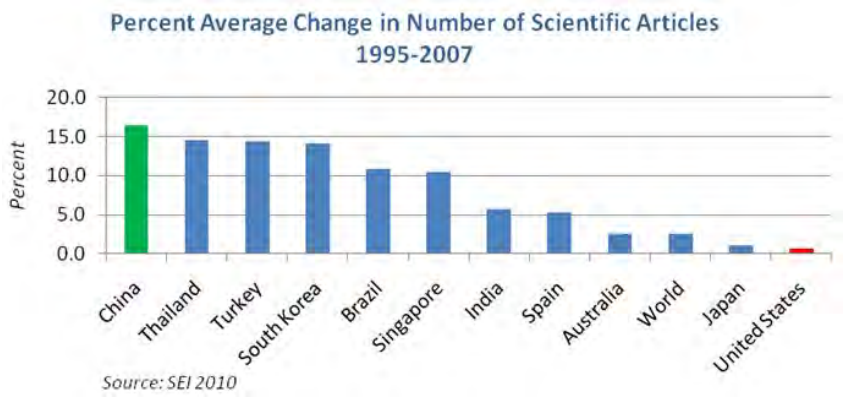



NOTE: Estimated number of researchers (in millions) is for 2007 and shown below country/economy. U.S. 2007 estimate based on long-term growth rate.

*SEI 2010:* **Global S&E Labor Force,** Chapter 3.

Knowledge Generation: The number of scientific articles published is a common measure of scientific productivity. The average increase in U.S. publications is significantly lower than for other key countries and also below the world average.

Meanwhile, China, Thailand, South Korea, and others show impressive growth rates.



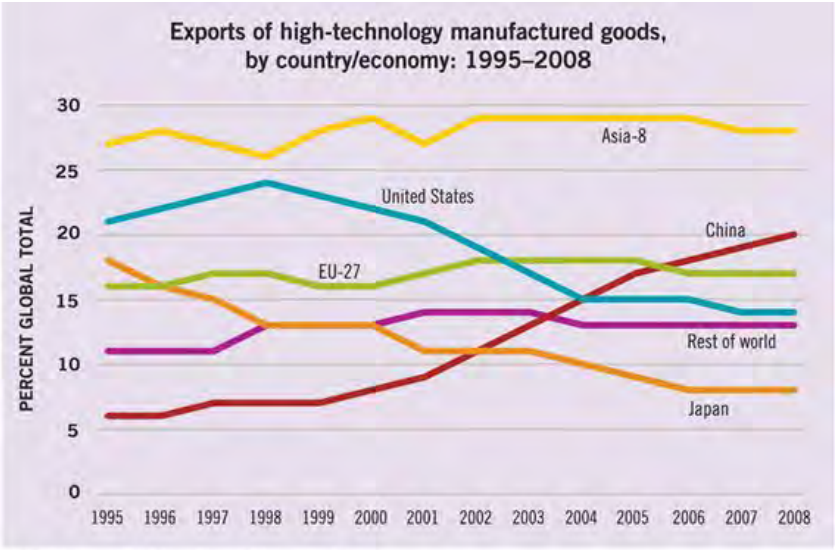

As a result of the previously mentioned trends, it is not surprising that the U.S. share of world publications has significantly decreased, and that China's share has grown.

| Country/Region | Share of world articles (Percent) | | Percent Change |
|---|---|---|---|
| | 1998 | 2008 | |
| United States | 34 | 28.9 | −5.1 |
| EU | 34.6 | 33.1 | −1.5 |
| China | 1.6 | 5.9 | 4.3 |
| Japan | 8.5 | 7.8 | −0.7 |
| Asia-8 | 3.6 | 6.8 | 3.2 |

Source: SEI 2010

The number of times a scientific article is cited indicates its scientific impact. One could argue that emerging countries are publishing articles with limited impact. While this may be the case from certain perspectives, the aggregate number of citations indicates a worrisome plunge in the U.S. share of worldwide citations, which fell 8.6 percent from 1998 to 2008. In contrast, China and Asia-8 countries displayed a noticeable increase in their share of citations, rising 3.7 percent and 3.1 percent respectively over the same time period.

Economic consequences: Reducing R&D investments when other nations are rapidly increasing them has already had significant consequences on exports, which are an important component of the U.S. economy and well being of Americans.




NOTES: China includes Hong Kong. Excludes intra-EU trade.
*SEI 2010:* **Trade of High-Technology Goods,** Chapter 6.

IMPACTS ON U.S. ECONOMY

NIH is the largest funder and conductor of biomedical research in the world.

The NIH fiscal year 2011 budget is $31 billion—84 percent of which is awarded to the Nation's finest universities, institutes, and small businesses through a rigorous peer review process. Every State, along with almost every Congressional district, benefits.

NIH extramural program supports more than 40,000 competitive research grants and 325,000 research personnel at more than 3,000 universities, medical schools, and other research institutions in all 50 states, U.S. territories, and around the world.

Approximately 10 percent of the NIH budget funds nearly 6,000 scientists working at the NIH campus in Bethesda, in laboratories in Rockville and Frederick, Maryland, at Research Triangle Park in Raleigh, North Carolina, and at the Rocky Mountain Laboratories in Hamilton, Montana.

NIH spending increases business activity directly and indirectly: According to Families USA, each dollar of NIH award money generates about $2.21 of new business activity within 1 year, while each grant awarded by NIH generates about 7 jobs.

NIH-driven advances have not only had profound effects on the health and quality of life for all Americans, but also yielded economic gains. The percentage of elderly with chronic disabilities has declined (from 27 percent in 1982 to 19 percent in 2005). Since 1970, life expectancy in the United States has risen from 71 to 78 years. Economists estimate that these gains in life expectancy have been worth approximately $95 trillion.

The economic potential of NIH-fueled advances in improved treatments for disease is also clear in this projection: a reduction in cancer deaths by one percent has a present value to current and future generations of Americans of nearly $500 billion. A full cure would be worth approximately $50 trillion—more than three times today's GDP.

Advances in disease diagnosis also illustrate the health-related and economic benefits of NIH research: approximately $100 million in health care costs annually are being saved through the use of a genomic test that determines whether a particular type of breast cancer is likely to be cured by surgery and radiation or by chemotherapy. As a result of this test, thousands of women are being spared needless exposure to toxic therapies—and millions of dollars are being saved.

NIH is an engine of innovation—and a crucial support for the global competitive stature of the United States. In fiscal year 2010, NIH filed 289 U.S. patent applications (of which 141 were new applications). These are now included in a total of 3,186 NIH patent applications in the United States and abroad that were pending approval.

*Key Facts on U.S. Competitiveness in the Global Research Arena*

The United States still is the world leader in science and engineering research. But that leadership role is being challenged by China, India, and other nations as they recognize the economic, health, and social benefits of investing in R&D.

Over the past decade, R&D intensity has grown in Asia, but remained flat in the United States.

Growth of R&D expenditures in the United States averaged 5–6 percent annually from 1996–2007, lagging behind the worldwide average of 7 percent per year. In contrast, growth in most Asian nations exceeded the worldwide average, and China's R&D expenditures grew more than 20 percent annually from 1996–2007.

The United States share of high technology exports fell by one-third from 1996–2007. China's share more than tripled.

India exported $8.3 billion in pharmaceutical products and services in fiscal year 2009, up 25 percent from the previous year.

About 277,000 people, ranging from scientists and to production workers, are currently employed by pharmaceutical companies in the United States, a decline of 5 percent from 2008. More than 340,000 people work in India's pharmaceutical manufacturing industry in 2009—and the industry is projected to grow by 13 percent in 2010.

Between 1995 and 2007, the worldwide share of researchers working in China, Singapore, South Korea, or Taiwan rose from 16 percent to 31 percent.

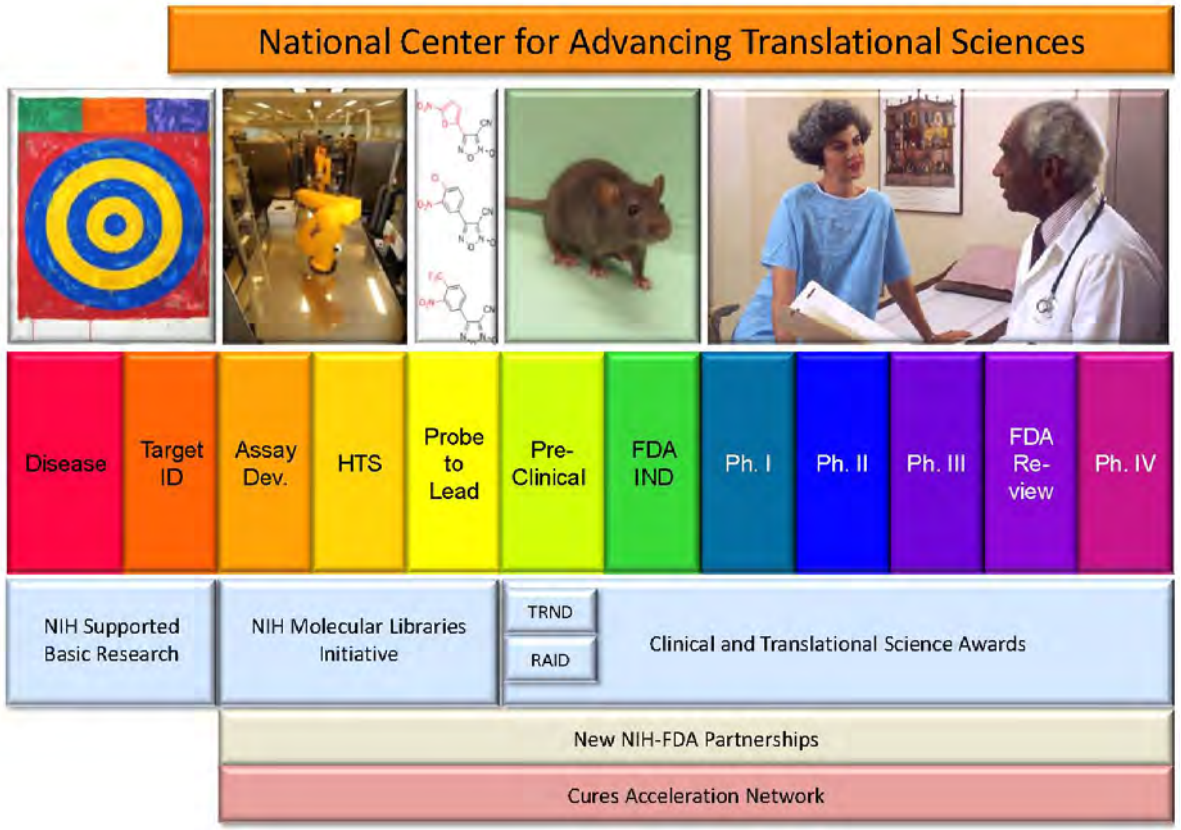
In 2007, the United States had 1.47 million people engaged in scientific research; China had 1.42 million—and it was generating R&D jobs at three times the rate of the U.S.

In the United States, the percentage of undergraduate students who major in science and engineering is 15 percent; in China, it is 50 percent.

In 1995, China ranked 14th in the world in the production of research publications. In 2008, it ranked second.

China's leading genome sequencing institute, BGI, is on track to sequence more than 10,000 human genomes a year. That would surpass the entire DNA sequencing output of the United States.

For more on how shifts in global research capacity are challenging the United States to actively focus on maintaining its competitive strength, go to http://www.nsf.gov/statistics/nsb1003/.


National Center for Advancing Translational Sciences
Disease
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Ph. III
FDA Re-view
Ph. IV
NIH Supported Basic Research
NIH Molecular Libraries Initiative
TRND
RAID
Clinical and Translational Science Awards
New NIH-FDA Partnerships
Cures Acceleration Network

## HEALTH IMPROVEMENTS

In the last 25 years, NIH-supported biomedical research has directly led to human health benefits that both extend lifespan and reduce illnesses:

—*Prolonging Life and Reducing Disability*.—Our Nation has gained about 1 year of longevity every 6 years since 1990. A baby born today can look forward to an average lifespan of nearly 78 years—nearly three decades longer than a baby born in 1900. Not only are people living longer, they are staying active longer. From 1982 through 2005, the proportion of older people with chronic disabilities dropped by almost a third.

—*Heart Disease*.—NIH research has generated new techniques for heart attack prevention, effective drugs for lowering cholesterol and controlling blood pressure, and strategies for dissolving blood clots. As a result, the death rate for coronary disease is 60 percent lower—and for stroke, more than 70 percent lower—than during the era of World War II. Better treatment of acute conditions, better medications, and improved health-related behaviors—all made possible by NIH research—account for as much as two-thirds of this reduction.

—*Chronic Disability*.—From 1982–2004, the reported chronic disability among American seniors dropped nearly 30 percent. Health improvements from NIH research played a major role in this, including better prevention and treatment of heart attacks and strokes, advances in treatment of arthritis, and improved technologies for cataract surgery.

—*Age-Related Macular Degeneration (AMD)*.—Forty years ago there was little or nothing one could do to prevent or treat advanced AMD and blindness. Because of new treatments and procedures based on NIH research, 750,000 Americans who would have gone blind over the next 5 years instead will continue to have useful vision.

—*Breast Cancer*.—The 5-year survival rate for women diagnosed with breast cancer was 75 percent in the mid-1970s. Because of NIH-supported research, the 5-year survival rate has risen to over 90 percent.

—*Cervical Cancer*.—Cervical cancer is a deadly cancer in women. Due to groundbreaking NIH research, an FDA-approved vaccine (Gardasil) now is available to prevent the development of cervical cancer.

—*Colon Cancer*.—From 1974–1976, in an NIH-sponsored study, the 5-year survival for patients with colon cancer was 50 percent. In 2009, based on NIH-supported clinical trials using new diagnostics and treatments, a comparable patient group has a 5-year survival rate of over 70 percent.

—*Cochlear Implants*.—Because of NIH-supported research, children who are profoundly deaf but receive a cochlear implant within the first 2 years of life now have the same skills, opportunities, and potential as their normal-hearing classmates.

—*Type 1 Diabetes*.—Thirty to forty years ago, 30 percent of patients died within 25 years of a diagnosis of type 1 diabetes. Today, due to tight blood glucose control, heart disease and stroke in patient with type 1 diabetes have been reduced by over 50 percent.

—*Hepatitis B*.—In the mid-1980s, hepatitis B infection caused untreatable and fatal illness. Due to intensive vaccination programs based on NIH research, the rate of acute hepatitis B has fallen by more than 80 percent.

—*HIV/AIDS*.—In the 1980s, the diagnosis of HIV infection was a virtual death sentence. Due to antiviral drugs developed by NIH, today an HIV-positive 20-year-old can be expected to reach the age of 70.

—*Infant Health*.—In 1976, the infant mortality rate was 15.2 infant deaths per 1,000 live births. By 2006, that rate had fallen to 6.7 deaths per 1,000 live births. Much of this progress can be attributed to NIH research in the areas of neonatal care unit procedures and new drugs administered to women at risk for premature birth.

—*Childhood Leukemia*.—Survival rates for children with the most common childhood leukemia (acute lymphocytic leukemia) is now 90 percent.

## ADVANCES IN KNOWLEDGE

NIH-funded research leads to thousands of new findings every year. These incremental advances and technological developments are the building blocks that ultimately yield significant improvements in health. Highlighted below are just a few of the many recent advances from NIH-supported research:

—*Studies find possible new genetic risk factors for Alzheimer's disease*.—Scientists have confirmed one gene variant and have identified several others that may be risk factors for late-onset Alzheimer's disease, the most common form of the disorder. In the largest genome-wide study, or GWAS, ever conducted in Alz-

heimer's research, NIH-supported investigators studied DNA samples from more than 56,000 study participants and analyzed shared data sets to detect gene variations that may have subtle effects on the risk for developing Alzheimer's. Until recently, only one gene variant, Apolipoprotein E-e4 (APOE-e4), had been confirmed as a significant risk factor gene for the common form of late-onset Alzheimer's disease, which typically occurs after age 60. In 2009 and 2010, researchers confirmed additional gene variants of CR1, CLU, and PICALM as possible risk factors for late-onset Alzheimer's. This newest GWAS confirms the fifth gene variant, BIN1, affects development of late-onset Alzheimer's. The genes identified by this study may implicate pathways involved in inflammation, movement of proteins within cells, and lipid transport as being important in the disease process.

—*NIH scientist advance universal flu vaccine*.—Significant progress was made toward the development of a universal flu vaccine that would confer longer term protection against multiple influenza virus strains. NIH-supported researchers have identified the regions of influenza viral proteins that remain unchanged among seasonal and pandemic strains. These findings will inform the development of influenza vaccines that might one day provide universal protection against the broad range of influenza strains. Such a universal influenza vaccine would provide broader protection against multiple flu strains and make yearly flu shots a thing of the past.

—*Early detection of cancer is critical to provide effective therapy*.—NIH-supported investigators recently reported the detection of a single metastatic cell from lung cancer in one billion normal blood cells. These circulating tumor cells (CTCs) may also be released into the bloodstream of patients with invasive but localized cancers. The presence of CTCs may be an early indicator of tumor invasion into the bloodstream long before distant metastases are detected. Identifying CTCs may be viewed as performing liquid biopsies, which can be especially advantageous for prostate cancer. Researchers plan to extend their work to develop a point-of-care microchip that would allow non-invasive isolation of CTCs from patients with many different types of cancer, to improve the management and treatment of this devastating disease.

—*Prenatal surgery reduces complications of spina bifida*.—NIH-supported scientists reported that a surgical procedure to repair a common birth defect of the spine, if undertaken while a baby is still in the uterus, greatly reduces the need to divert, or shunt, fluid away from the brain. The fetal surgical procedure also increases the chances that a child will be able to walk without crutches or other devices. The birth defect, myelomeningocele, is the most serious form of spina bifida, a condition in which the spinal column fails to close around the cord. The study, the Management of Myelomeningocele Study (MOMS), was stopped after the enrollment of 183 women, because of the benefits demonstrated in the children who underwent prenatal surgery. In spite of an increased risk for preterm birth, children who underwent surgery while in the uterus did much better, on balance, than those who had surgery after birth.

—*Progesterone reduces rate of early preterm birth in at risk women*.—Preterm infants are at high risk of early death and long term health and developmental problems including, breathing difficulties, cerebral palsy, learning disabilities, blindness and deafness. An NIH study found that progesterone gel reduces the rate of preterm birth before the 33rd week of pregnancy by 45 percent among women with a short cervix, which is known to increase the risk of preterm birth. Women with a short cervix can be identified through routine ultrasound screening, and once identified could be offered treatment with progesterone. In addition, infants born to women who received progesterone had a lower rate of respiratory distress syndrome than those in the placebo group.

—*Daily dose of HIV drug reduces risk of HIV infection*.—A daily dose of an oral antiretroviral drug, currently approved to treat HIV infection, was shown to reduce the risk of acquiring HIV infection by 43.8 percent among men who have sex with men. The findings, a major advance in HIV prevention research, came from a large international clinical trial supported by NIH. The study, titled "Chemoprophylaxis for HIV Prevention in Men" found even higher rates of effectiveness, up to 72.8 percent, among those participants who adhered most closely to the daily drug regimen. These new findings provide strong evidence that pre-exposure prophylaxis with an antiretroviral drug, a strategy widely referred to as PrEP, can reduce the risk of HIV acquisition among men who have sex with men, a segment of the population disproportionately affected by HIV/AIDS. Prophylactic antiretroviral therapy has already been proven to significantly reduce the transmission of HIV from a mother to a child during childbirth through breastfeeding.

—*Pocket-sized device makes medical ultrasound more accessible*.—NIH-supported research at General Electric supported the development of a low-cost, portable, high-quality ultrasonic imager. In the last year, this advance was extended even further with GE's production of "Vscan." This pocket-sized device makes medical ultrasound even more accessible and has enabled wireless imaging, patient monitoring, and prenatal care applications.

—*Lung cancer screening with CT scan reduces deaths*.—The National Lung Screening Trial found that screening with low-dose computed tomography (CT) can decrease lung-cancer deaths among current and former heavy smokers by 20 percent. Because of earlier identification of cancerous tumors, screening was found to reduce mortality from lung cancer, the most common cause of cancer deaths.

—*Nicotine vaccine shows promise in preventing tobacco addiction*.—Vaccines developed to combat drug addictions work by generating drug-specific antibodies that bind the drug while in the bloodstream and prevent its entry into the brain. A nicotine vaccine recently found to improve smoking quit rates is now in phase III trials to evaluate continued abstinence at 12 months.

—*Nanotechnology demonstrates advances in the realm of materials technologies*.—Carbon nanotubes have been used to deliver chemotherapeutic agents specifically to head and neck cancer cells, causing rapid death of the cancer cells, but leaving non-cancerous cells unharmed.

—*Certain lipid molecules that show promise in controlling pain could result in new treatments*.—Researchers have demonstrated in animal models that certain lipids called resolvins, which shut down inflammation, are more potent than morphine in controlling pain. Since these resolvins are normally found in the body, they are likely to be safe and non-addictive when used therapeutically. Additional research is under way to explore these compounds further and translate into new analgesics for pain management.

—*Combined treatment improves vision in patients with diabetic macular edema*.—A comparative effectiveness study for diabetic macular edema found that combined treatment with the drug ranibizumab and laser therapy was substantially better at improving vision in patients with diabetes than laser therapy alone, and better than laser therapy with a different drug (triamcinolone).

—*Scientists develop a system for making functional hair cells from stem cells, offering possible new treatment of deafness*.—In mammals, mechanically-sensitive "hair cells" in the inner ear, which are essential for both hearing and balance cannot regenerate when they die or are damaged. NIH supported scientists have used mouse embryonic stem cells as well as induced pluripotent stem cells and generated hair cells that respond to mechanical stimulation, offering a new avenue for the treatment of deafness.

—*Experimental medication lifts depression symptoms in people with bipolar disorder*.—NIH intramural researchers discovered that ketamine, an anesthetic medication, provides rapid and effective treatment for depressive symptoms among patients with bipolar disorders. While ketamine's side effects make it impractical for long-term use, this class of drugs may be invaluable for treating severe depressive symptoms in these patients during the weeks it usually takes for typical antidepressants to take full effect.

PROPOSED NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

NATIONAL INSTITUTES OF HEALTH

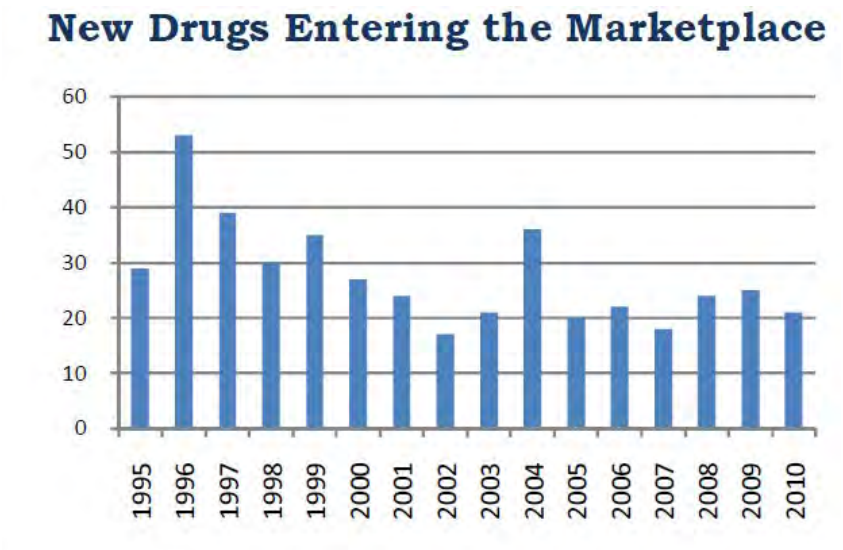
*Rationale*

The development of new diagnostics and therapeutics is widely recognized as a complex, costly, and risk-laden endeavor. Only a few of the thousands of compounds that enter the drug development pipeline will ultimately make it into the medicine chest.

MISSION

To advance the discipline of translational science and catalyze development and testing of novel diagnostics and therapeutics across a wide range of human diseases and conditions.

In recent years, there has been a deluge of new discoveries of potential drug targets, yet we still lack effective therapeutics for many conditions, especially rare and neglected diseases. A major problem is that the drug development pipeline is full of bottlenecks that slow the speed of development and add expense to the process. To address these challenges, the National Institutes of Health (NIH) has proposed establishing the National Center for Advancing Translational Sciences (NCATS).




Source: FDA

NCATS will study various steps in the drug development pipeline, identify bottlenecks amenable to re-engineering, and experiment with innovative methods to streamline the process. Promising therapeutic projects will be used to evaluate pipeline innovations.

NCATS will complement—not compete with— translational research being carried out elsewhere at NIH and in the private sector. In fact, through its mission to use the power of science to advance the entire discipline, NCATS will benefit all stakeholders, including academia, biotechnology firms, pharmaceutical companies, the Food and Drug Administration, and—most importantly—patients and their families.

*Functions*

NCATS will aim to improve the processes in the drug development pipeline by:
—experimenting with innovative approaches in an open-access model;
—choosing therapeutic projects to evaluate these innovative approaches; and

—promoting interactions to advance the field of regulatory science.

NCATS also will strive to catalyze the development of new drugs and diagnostic tests by:

—encouraging collaborations across all sectors;
—providing resources to enable therapeutic development; and
—enhancing training in relevant disciplines.

NCATS will:
—facilitate—not duplicate—other translational research activities supported by NIH;
—complement—not compete with—the private sector; and
—reinforce—not reduce—NIH's commitment to basic research.

*Programs*

NCATS will be formed by pulling together these existing NIH programs: components of the Molecular Libraries initiative, Therapeutics for Rare and Neglected Diseases, Office of Rare Diseases Research, Rapid Access to Interventional Development, Clinical and Translational Science Awards, and FDANIH Regulatory Science. In addition, the Cures Acceleration Network will be part of NCATS if funds are appropriated for fiscal year 2012. Relocated programs will have their respective budgets transferred to the new center.

Background

On May 19, 2010, the NIH Director asked the NIH Scientific Management Review Board (SMRB) to:

—identify the attributes, activities, and functional capabilities of a translational medicine program for advancing therapeutics development; and
—broadly assess the NIH landscape for existing programs, networks, and centers for inclusion; and recommend their optimal organization.


On Dec. 7, 2010, the SMRB recommended the creation of a new translational medicine and therapeutics center. It also urged NIH to undertake a detailed analysis, through a transparent process, to evaluate the new center's impact on existing NIH programs.

Informed by the SMRB's recommendations, NIH initiated a planning process to establish NCATS. The NIH Director established three panels to guide and inform the process: the Institute and Center Directors' (ICD) NCATS working group, the

Advisory Committee to the Director (ACD) NCATS working group, and the NIH Clinical and Translational Science Awards (CTSA) Integration working group.

On Jan. 4, 2011, Dr. Collins charged the ICD working group with making recommendations on the mission, functions, and organizational design of NCATS. This panel presented its recommendations to Dr. Collins on Feb. 17, 2011. The ACD working group, which has been asked to provide high-level advice on how NCATS can best engage the private sector in translational science, met for the first time on Feb. 4, 2011. This distinguished panel of outside experts will report its findings to the ACD later this year.

The final working group, composed of leaders from across NIH, was formed in mid-March to ensure a smooth transition of the CTSA program into NCATS.

*Next Steps*

At every point along the way, NIH has sought input on NCATS from a broad and diverse array of stakeholders. In addition, NIH will continue to inform all stakeholders on new developments and seek their comments through our interactive web site Feedback NIH.

Pending approval from the Health and Human Services Secretary, the Office of Management and Budget, and the Congress, NCATS will be included in the fiscal year 2012 budget and be formally established on Oct. 1, 2011.

So in this brief statement today, I'd like to tell you about four innovative areas, and I'm going to show some pictures up on the screen in which NIH is investing in order to carry out its mission of turning discovery into health.

First, dramatic advances in technologies, including imaging, nanotechnology, computational biology, and, yes, genomics, have recently made it possible for scientists to understand the details of health and disease in breathtaking new ways.

Consider this curve, the cost to sequence a human genome. Look at the profound reduction over the past decade. In 2001, it cost about $100 million to sequence a single human genome. That cost now stands at about $10,000, and we anticipate it will be less than $1,000 within the next few years.

That advance will give many Americans access to far more personalized strategies for detecting, treating and preventing disease than are now available.

Those new technologies not only reduce the cost of doing science, but open up whole new frontiers in medicine. I'll tell you about one of those later in a story about a 6-year-old boy named Nic that I think you'll find quite compelling.

But, first, let's turn to the effects that this technology has had on our understanding of cancer. Cancer is a disease of the genome, comes about because of mutations in DNA.

Through a bold initiative, called the Cancer Genome Atlas, or TCGA, my colleague, Harold Varmus, and others are analyzing the DNA of tumors of hundreds of patients to identify comprehensively the genetic mutations associated with the specific cancers.

Brain and ovarian cancers were the first ones selected for study through TCGA and the results have been stunning. Knowing the molecular drivers of cancer gives us a chance to make much more accurate diagnoses, prognoses, and predictions of response to therapy. And in the longer run, this approach will lead to development of a new generation of targeted therapies, those magic bullets so dreamed of to treat this disease.

The plan for the next few years is ambitious. TCGA will sequence, characterize, and understand the genomes of 20 different types of tumors.

New treatments are wonderful. Effective prevention can be even better. NIH is dedicated to use the latest science to improve America's health today by identifying effective new strategies for disease prevention. The grave threat of diabetes is a compelling example of how we are doing this.

This map shows the prevalence of diabetes in the United States in 1995. As you can see from the color code, in most States, less than 5 percent of adults were affected, but watch what happened over just 15 years. Prevalence of diabetes has gone up rapidly in every State, and it now stands at 9 percent or more in many parts of the country.

The total costs of the disease, including medical care, disability and premature death, were an estimated $174 billion in the United States in 2007. If current trends continue, one in three U.S. adults will have diabetes by 2020, just 9 years from now, and the annual cost of care alone will have risen to a breathtaking $500 billion.

But my colleague, Grif Rodgers, and I can offer some hope. NIH spearheaded a landmark clinical trial on how to prevent type 2 diabetes. The Diabetes Prevention Program, or DPP, involved adults with pre-diabetes. That refers to a modest elevation of glucose in the blood foreshadowing much worse to come if nothing is done, but not yet frank diabetes.

The study participants were assigned personal coaches who encouraged them to exercise about 30 minutes a day and to make modest dietary changes resulting in an average weight loss of just 7 percent. This simple approach lowered the chance of full-blown diabetes by a whopping 58 percent, and that has been sustained for more than 10 years.

Building on these results, NIH has joined with the Centers for Disease Control and Prevention (CDC), the YMCA, Walgreens, United Health Care and other partners to bring this program to communities in 10 States. And we are now working with colleagues at CMS to explore how a similar program could be used to great advantage in Medicare and Medicaid.

Now, I'd like to turn your attention to another important contribution of NIH research already mentioned by the chairman, enhancing the economy and U.S. competitiveness worldwide.

NIH will be a key engine driving the U.S. economy in the 21st century. Many call this the century of biology. As mentioned, just yesterday, a new economic impact study published by United for Medical Research suggests that in fiscal year 2010 NIH research funding supported an estimated 487,900 American jobs at 3,000 institutions and small businesses across all 50 States of this Nation.

More than that, nearly 1 million U.S. citizens are employed by the industries and companies that make up this sector of the economy, earning $84 billion in wages and salary and exporting $90 billion of goods and services annually. But despite this impressive track record, our Nation today is at serious risk of losing its position as the world's research leader.

As you can see in this slide, which shows the percent growth of R&D expenditures on an annual basis, China and India and other countries have been steadily increasing their R&D expenditures by 10 percent or more per year, highlighting China and India there.

Whereas, the United States has been at a substantially lower level. China's growth rate is now four times greater than ours.

Let me give you a personal example of what this means. Last fall, when I visited the BGI Genome Center in Shenzhen, China, I saw an amazing facility built in just 3 years from an abandoned shoe factory that is capable of sequencing more than 10,000 human genomes a year.

The capacity of that one Chinese institution now surpasses the combined capacity of all genome sequencing centers in the United States. This critical area of scientific innovation, stimulated by the U.S.-led Human Genome Project, is now being developed more aggressively in China than it is here, a sobering story indeed, and one that I hope would inspire our Nation to redouble its efforts on the research front.

A final area I wish to highlight in which our Nation faces exceptional challenges, as well as exceptional opportunities, is this field of translational science which Senator Shelby has specifically highlighted in his opening statement. As a result of years of steadfast support of NIH research by Congress and the American people, we find ourselves in a paradoxical situation.

This graph shows we've seen a deluge of discoveries about the molecular basis of disease, both rare and common, which provide us with the power to identify more therapeutic targets than ever before; more than 4,000 diseases now having their molecular basis discovered, much of that in the last decade.

But there's a serious problem. The process of taking those basic discoveries to the point of clinical advances, as here demonstrated by a diagram showing you what happens in the development of new therapeutics, is far too slow—14 years on the average—and the failure rate is far too high—more than 98 percent. We clearly need a new approach to therapeutic development and a new partnership with the private sector.

So to meet this need, NIH is proposing the establishment of a new national center for advancing translational sciences or NCATS. NCATS will allow us to study the various steps in the development of diagnostics, devices and therapeutics, identify bottlenecks that might be reengineered and experiment with innovative methods to streamline this process.

Through this new center, we can work in an open-access model that will allow stakeholders, including industry and academia, to access and apply the innovations that are developed. NCATS will also advance the field of regulatory science by promoting interactions among the NIH, FDA, patient advocates, and pharmaceutical and biotechnology companies.

Importantly, NCATS will complement, not compete with, the private sector. This is not Bethesda Pharm. It will facilitate translational research being carried out elsewhere at the NIH, extensive translational work already going on by many of the 27 Institutes, including those represented at this table. And it will reinforce, not reduce, NIH's commitment to basic science, a foundational part of our mission.

Most importantly, though, by advancing discipline of translational sciences, NCATS will benefit patients and their families.

So, Mr. Chairman, members of the subcommittee, I've spoken today about the great promise of new technologies, how we're applying science to prevention, NIH's role in maintaining U.S. economy—world leadership, and the unique opportunity to pursue a new paradigm in translation.

Let me close by sharing the story of one little boy to show you what NIH research advances now allow us to do. So meet Nic Volker, a brave boy from Monona, Wisconsin.

Starting about the age of two, Nic developed a mysterious life-threatening disease that ravaged his body, making it impossible for him to eat normally and causing unimaginable pain and suffering.

At a loss to explain Nic's terrible affliction, researchers at the Medical College of Wisconsin decided to sequence Nic's DNA instruction book hoping to find an answer. After exacting work over several months, the researchers identified a misspelling of just one single letter in a little-studied gene called XIAP. Now, glitches in this gene had been associated with rare blood disorders, but not with intestinal symptoms. Based on this new insight, the research team had an idea that, as with the rare blood disorders, Nic's disease might be curable with a bone-marrow transplant.

Transplantation of cord blood cells from—stem cells from a matched donor occurred in July of last year. Although Nic is still receiving some immunosuppressant drugs to prevent rejection of the donated cells, his symptoms have largely disappeared, and, today, as you can see here, he can eat normally and vigorously.

What's more, he's now attending kindergarten, enjoying outings with his family and friends, signing up for a T–Ball team, and, this past Sunday, presenting his mother with a flower for Mother's Day. Nic has given us all a glimpse of the future.

PREPARED STATEMENTS

Thank you, Mr. Chairman. This concludes my formal remarks.

[The statements follow:]

PREPARED STATEMENT OF FRANCIS S. COLLINS, M.D., PH.D.

INTRODUCTION

Good morning, Mr. Chairman and distinguished Members of the Subcommittee. I am Francis S. Collins, M.D., Ph.D. and I am Director of the National Institutes of Health (NIH).

It is a great honor to appear before you today to present the administration's program level request of $31.987 billion for NIH in fiscal year 2012, and to discuss the contributions that NIH-funded biomedical research has made in improving human health. NIH is the largest supporter of biomedical research in the world, providing funds for more than 40,000 competitive research grants and more than 325,000 research personnel at more than 3,000 research institutions and small businesses across our Nation's 50 States. I also want to offer a vision of how NIH will catalyze innovation in basic and translational sciences, and will ensure future U.S. economic strength and global competitiveness.

On behalf of NIH and the biomedical research enterprise, I want to thank you as Members of the Senate for sparing NIH from deeper cuts in the final fiscal year 2011 continuing resolution (CR). We know that, even as Congress and the administration wrestled with cuts of more than 3 percent to the Labor-HHS portion of the CR, NIH received a 1 percent, or $321.7 million, cut from the fiscal year 2010 level, while other programs and functions were cut more deeply.

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance human health, lengthen life, and reduce the burdens of illness and disability. I can report to you that NIH continues to believe passionately in that mission and works tirelessly to achieve it.

Due in large measure to NIH research, our Nation has gained about 1 year of longevity every 6 years since 1990. A child born today can look forward to an average lifespan of nearly 78 years—nearly three decades longer than a baby born in 1900. And not only are people living longer, but their quality of life is improving: in the last 25 years, the proportion of older people with chronic disabilities has dropped by almost one-third.

NIH research has enabled new techniques to prevent heart attacks, newer and more effective drugs for lowering cholesterol and controlling blood pressure, and innovative strategies for dissolving blood clots and preventing strokes. As a result, the U.S. death rate for coronary disease is 60 percent lower—and for stroke, more than 70 percent lower—than three generations ago. Better treatment of acute heart disease, better medications, and improved health-related behaviors—all underpinned by NIH research—account for as much as two-thirds of these reductions.

In recent years, largely as a result of NIH research, we have succeeded in driving down mortality rates for cancer in the United States. This progress comes despite the fact that cancer is largely a disease of aging and our population is growing older. Over the 15-year period from 1992 to 2007, cancer death rates dropped 13.5 percent for women and 21.2 percent for men. According to an American Cancer Society report released in July 2010, the continued drop in overall mortality rates over the last 20 years has saved more than three-quarters of a million lives.[1] And in cancers that strike children we have made near-miraculous progress—the 5-year survival rate for children with the most common childhood cancer, acute lymphocytic leukemia, is now 90 percent.[2]

I would also like to offer a shining example of the Senate's strong and consistent support of biomedical research at NIH by note that we are celebrating a significant anniversary. This year marks the 10th anniversary of the establishment of the Dale and Betty Bumpers Vaccine Research Center (VRC) at NIH. Groundbreaking research performed at the VRC is making great progress toward developing a universal flu vaccine that confers longer-term protection against seasonal and pandemic influenza strains.

Today, scientists have to make an educated guess about the make-up of the coming winter's influenza viruses. These educated guesses become the basis for the manufacture of each year's flu shot and mean that everyone has to be re-immunized in anticipation of next year's strain of flu. Recently, NIH scientists have identified pieces of influenza viral proteins that consistently appear among seasonal and pandemic flu strains. These findings raise the possibility that we might soon develop an influenza vaccine that provides near-universal protection against a broad range of current and future strains of influenza,[3] as well as make yearly flu shots a thing of the past. Most of this exciting work was performed at the VRC. Scientists at that same center are making important strides toward the development of the long-hoped-for vaccine against the human immunodeficiency virus (HIV), the cause of acquired immune deficiency syndrome (AIDS). While after so many frustrations, no one would want to predict success just yet, recent discoveries of VRC scientists about how to encourage production of neutralizing antibodies against HIV have provided renewed hope that this pressing problem may ultimately be solved.

### NIH AND ECONOMIC GROWTH

Mr. Chairman and Members of the Subcommittee, I recognize that, given our Nation's fiscal situation, and the extraordinarily tough decisions that you will have to make about our Nation's finances, you need to be assured that NIH remains a worthwhile national investment. Even as you make these decisions and even as our country recovers from financial recession, I want to offer evidence that NIH and its research provide two strong and ongoing benefits to our economy.

First, NIH research spending has an impact on job creation and economic growth. A new economic impact study by United for Medical Research suggests that in fiscal year 2010, NIH research funding supported an estimated 487,900 American jobs, including researchers and spin-off employment.

Second, NIH research funding has a longer term impact in its role as the foundation for the medical innovation sector. Nearly 1 million U.S. citizens are employed by the industries and companies that make up this sector of the economy, earning $84 billion in wages and salary in 2008, and exporting $90 billion of goods and services in 2010. NIH support for biomedical research institutions catalyzes business ac-

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[1] http://pressroom.cancer.org/index.php?s=43&item=252.

[2] http://seer.cancer.gov/csr/1975__2008/browse__csr.php?section=28&page=sect__28__table.08.html.

[3] http://www.niaid.nih.gov/news/newsreleases/2010/Pages/UniversalFluVax.aspx.

tivity in other ways as well. Such institutions constitute reservoirs of skilled, knowledgeable individuals and, thereby, attract companies that wish to locate their operations within such "knowledge hubs."

For example, in the 1990s, Federal funding through research grants and the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs transformed the academic research environment and helped to launch new industrial sectors in Silicon Valley and elsewhere that are flourishing today. Federal funding has been crucial in stimulating the formation of start-up companies and collaborations among academia and the private sector in the development of innovative technology. A prime example is the company Affymetrix.

In the late 1980s, a team of scientists led by Stephen P.A. Fodor, Ph.D., developed methods for fabricating DNA microarrays, called GeneChips, using semiconductor manufacturing techniques, melded with advances in combinatorial chemistry to capture vast amount of biological data on a small glass chip. In 1992, the first of several NIH grants was awarded to Affymetrix; with this and an SBIR grant from the Department of Energy, Dr. Fodor was able to demonstrate proof of principle of using large arrays of DNA probes in genetic analysis. Affymetrix and similar companies are building the machine tools of the genomic revolution. In 2009, Affymetrix had annual revenue of $327 million and employed more than 1,100 people.

Furthermore, NIH research leads to better health outcomes that not only ease human suffering, but also produce an economic return. A 2006 study by Kevin Murphy and Robert Topel of the University of Chicago shows that a permanent reduction of 1 percent in cancer deaths has a present value to current and future generations of Americans of nearly $500 billion. The article states that if we were able to defeat cancer completely, such cures would be worth approximately $50 trillion—more than three times today's Gross Domestic Product.[4]

We face a similar economic threat from diabetes. If current trends continue, by 2050 as many as one in three U.S. adults will be diagnosed with diabetes.[5] Total costs of diabetes, including medical care, disability, and premature death, reached an estimated $174 billion in the United States in 2007.[6] According to analysis from the UnitedHealth Center for Health Reform & Modernization, more than 50 percent of Americans could have diabetes or pre-diabetes by 2020.[7] Furthermore, the center's analysis predicts diabetes and pre-diabetes will account for an estimated 10 percent of total healthcare spending by the end of this decade, at an annual cost of almost $500 billion.

But I can offer some hope. NIH spearheaded a landmark clinical trial on type 2 diabetes prevention that showed that people at high-risk for diabetes can dramatically reduce their risk of developing type 2 diabetes through modest exercise and dietary changes that achieve modest weight loss. Called the Diabetes Prevention Program (DPP), the clinical trial included 3,234 adults at high risk for developing type 2 diabetes, including those with a family history of diabetes, as well as other risk factors. One-third of these individuals participated in a lifestyle program that included exercise training and dietary change implemented under the guidance of lifestyle coaches. The DPP research team found that this approach lowered risk of diabetes by 58 percent.[8] The DPP trial also demonstrated that the cost of the lifestyle intervention was $3,540 per participant over 3 years, which was significantly offset by the lowering of other healthcare costs as lifestyle participants became healthier.[9] The cost effectiveness of the DPP has continued to be followed and 10-year results will be published in the near future. Building on these critically important results, NIH partnered with the Centers for Disease Control and Prevention (CDC) and more than 200 private partners, including the YMCA, Walgreens, and UnitedHealthcare, to bring these evidence-based lifestyle interventions to communities in Ohio, Indiana, Minnesota, Arizona, Oklahoma, New Mexico, New York, New Jersey, Connecticut, and Georgia. In addition, the DPP Lifestyle Intervention is being used by the Indian Health Service in a large demonstration project on many American Indian reservations.

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[4] Murphy, K.M., & Topel, R.H. (2006), The value of health and longevity. Journal of Political Economy, 114(5), 871–904.

[5] http://www.cdc.gov/media/pressrel/2010/r101022.html.

[6] CDC National Diabetes Fact Sheet. http://www.cdc.gov/diabetes/pubs/pdf/ndfs__2011.pdf.

[7] http://www.unitedhealthgroup.com/hrm/UNH__WorkingPaper5.pdf.

[8] Knowler WC, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metiformin. N. Engl J Med 346:393–403, 2002.

[9] *Diabetes Care*. 2003 Jan;26(1):36–47.

INVESTING IN BASIC SCIENCE

At NIH, we have always put our greatest percentage of our resources into basic research. This is because the fundamental observations made today become the building blocks of tomorrow's knowledge, therapies, and cures. NIH's history has repeatedly demonstrated that significant scientific advances occur when new basic research findings, often completely unexpected, open up new experimental possibilities and therapeutic pathways. Historically, NIH has put more than 50 percent of its budget into basic research and the research discoveries that led to the 132 Nobel prizes won by our intramural and university scientists are evidence of the wisdom of this investment.

Basic research is precisely the type of work that the private sector, which must see a rapid return on invested capital, cannot afford to support. NIH provides the fundamental observations that pharmaceutical and biotechnology companies can turn into diagnostics, therapies, and devices that eventually reach patients. As the Congressional Budget Office put it, "Federal funding of basic research directly stimulates the drug industry's spending . . . by making scientific discoveries that expand the industry's opportunities for research and development." [10]

Because we simply cannot predict the next scientific revelation or anticipate the next opportunity, our basic research portfolio must be diverse. We set scientific priorities by considering a wide array of biomedical questions that we might try to answer. It is rather like facing a series of doors, some of which lead to vast treasures and others to much more modest payouts, without any sure way of knowing what lies behind any particular door. To improve our odds of striking scientific gold, we need a broad basic research portfolio that enables our Nation to open as many doors as our resources allow.

Not all disease or scientific problems are equally ripe for new advances, nor do such advances come at the same rate across the portfolio, no matter how pressing today's public health challenges are. We can only be sure that without a strong commitment to basic research today, the new knowledge of tomorrow will remain hidden behind those unopened doors and future therapies and cures will remain out of our reach.

Let me offer a few of the exciting insights that NIH's support of basic research have provided. On April 3, 2011, the online issue of Nature Genetics presented the findings by a team of NIH-supported scientists who had identified five new genetic variants that are risk factors for late-onset Alzheimer's disease, which is the most common form of the disorder. These findings doubled from 5 to 10 the number of gene variants that we know are associated with Alzheimer's disease.[11]

What is even more compelling is that these newly identified genes strongly implicate inflammation and high cholesterol as risk factors in the development of Alzheimer's disease. Although each of these newly identified genes increases a given individual's risk of developing the disease by no more than 10 to 15 percent, the unanticipated insight that cholesterol and inflammation are contributing factors opens up new research avenues to understand the disease process, and increases the likelihood that we can glimpse potential preventions or therapies.

NIH's commitment to basic research has also provided us with one of the most promising therapeutic strategies we have seen to date for the deadliest form of skin cancer, melanoma. Since 2002, we have known that many melanoma tumors exhibit a mutation in the BRAF gene and that this mutation might provide a target for therapeutic intervention. A team that included NIH-supported investigators used high-throughput screening in combination with structural biology, to identify compounds that inhibit the activity of the mutant form of the BRAF gene found in most melanomas, but have little effect on the BRAF gene found in normal cells. This basic cancer research supported by NIH contributed to the development of the drug PLX4032, a drug designed to inhibit the activity of a mutant form of the protein called BRAF. This is a powerful example of how support for basic research can be translated into therapeutic potential. In August 2010, Plexxikon, a small drug development company, announced that PLX4032, had elicited a positive response in more than 80 percent of melanoma patients in early phase clinical trials. PLX4032 caused the tumors in 24 of the 30 trial participants to shrink by at least 30 percent, while the tumors of two patients disappeared. Another clinical trial involving hundreds of participants across many institutions demonstrated that metastatic melanoma pa-

[10] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, October, 2006, p. 3.

[11] Naj, A.C. et al. Common Variants of MS4A4/MSA6E, CD2AP, CD33 and EPHA 1 are associated with late-onset Alzheimer's Disease. Nature Genetics, EPUB April 3, 2011, and Holligworth, P., et al. Common variants at ABCA7, MS4A/MS4A4E, EPHA 1, CD33 and CD2Ap are associated with Alzheimer's disease. Nature Genetics. Epub April 3, 2011.S

tients treated with PLX4032 lived 6 to 8 months longer than those who had been given the chemotherapy drug dacarbazine, which is the current standard of care.

Whether it is with the hope of finding new ways to treat cancer, prevent Alzheimer's disease, or help people suffering from countless other rare and common conditions, we at NIH invest in basic research because of our conviction that it will benefit our Nation in the long term.

ADVANCING TRANSLATIONAL SCIENCE

NIH also has a longstanding commitment to translating fundamental knowledge into cures and therapies for human disease. It should not be surprising that NIH-supported science underpins many of the most transformative drugs and therapies that have benefited millions of Americans and people around the world, including statins to lower cholesterol and drugs to treat depression. In 2010, we conducted a trans-NIH inventory of therapeutics development activities and found more than 550 such projects, of which approximately 65 percent were pre-clinical and 35 percent were clinical research.

An analysis published in the February 10, 2011 issue of the New England Journal of Medicine (NEJM) underscores the depth and breadth of NIH's support for translational science that benefits patients.[12] The article's authors describe a new emphasis on "public sector research" that is almost exclusively supported or conducted by NIH, noting "the boundaries between the roles of the public and private sectors have shifted substantially since the dawn of the biotechnology era, and the public sector now has a much more direct role in the applied-research phase of drug discovery."

Drugs that represent a major advance in treatment or offer treatments for diseases for which no adequate therapy currently exists are granted "priority review" by FDA. According to the NEJM article, between 1990 and 2007, 20 percent of the FDA approvals of novel compounds granted priority review were given to drugs discovered by NIH. Examples include AZT for HIV/AIDS and the targeted leukemia therapy Gleevec. Over the past 40 years, 153 new FDA-approved drugs, vaccines, or new indications for existing drugs were discovered through work carried out by NIH-supported biomedical research institutions.

Despite NIH's historic and growing commitment to translational sciences, far more remains to be done. Millions of people still suffer from diseases, such as cancers and diabetes, for which we have no adequate treatments. There are nearly 7,000 rare diseases, yet we have therapies for fewer than 200 of them. This staggering public health need and attendant human suffering continues even as the pharmaceutical industry, beset by economic stress, is investing less in research and development, and the pool of venture capital needed by the biotech industry is drying up.

At the same time, a deluge of discoveries about the molecular basis of disease has been made possible by the sequencing of the human and many other genomes, as well as breathtaking advances in research technologies, such as high-throughput screening and bioinformatics. These discoveries reveal hundreds of tantalizing potential therapeutic targets. As the result of years of steadfast support of NIH research by Congress and the American people, we find ourselves in a paradoxical situation: we can uncover the molecular basis of common and rare diseases better than ever before and we can more readily identify therapeutic opportunities than at any point in history, but the pipeline through which these new therapeutic agents must pass is crimped and, in some places completely blocked.

Consequently, a new approach to therapeutic development, and a new partnership with the private sector, is needed. That is why we have proposed the establishment of NIH's new National Center for Advancing Translational Sciences beginning in fiscal year 2012.

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

As previously noted, NIH has a long and rich history of significant contributions to therapeutic development. In particular, the National Cancer Institute (NCI) and the National Institute for Allergy and Infectious Diseases (NIAID) have made major contributions over many years to the discovery of new treatments. However, now is the time to consider the therapeutic development process itself as a scientific problem that is ripe for innovation. The mission of the National Center for Advancing Translational Sciences (NCATS) will be to advance the discipline of translational science and catalyze the development and testing of novel diagnostics and thera-

[12] Stevens, Ashley J. et al. The role of public-sector research in the discovery of drugs and vaccines. New England Journal of Medicine, 364,:6, February 10, 2011.

peutics across a wide range of human diseases and conditions. NIH has no intention of entering the drug development arena that is rightly the province of private sector companies. Indeed, given that it costs in the range of $ 1.3 billion to $1.8 billion to bring one drug to market, it is clear that it would be impossible for NIH to compete with private industry.[13] What NCATS intends to do is advance the science of therapeutic development and determine if there are ways we can re-engineer the drug development pipeline; creating new approaches and methods that will benefit everyone interested in speeding the delivery of new medicines.

Today, the development of new diagnostics and therapeutics is a complex, costly, and risky endeavor. Only a few of the thousands of compounds that enter the drug development pipeline will ultimately make it into the medicine chest or to the patient's bedside. NCATS will study the various steps in the drug development pipeline, consult with the private sector to identify bottlenecks amenable to re-engineering, and experiment with innovative methods to streamline the process.

To offer one example of the kind of pipeline challenge we might address, new ideas about assessing the toxic potential of drug candidates using sophisticated cell-based methods, instead of animal toxicology testing, hold out the promise of revolutionizing this step in validating a new therapeutic agent—and such research can be catalyzed by NIH in ways that might otherwise not be possible.

NCATS will attack the bottlenecks in the drug development pipeline by experimenting with innovative approaches in an open-access model so that all stakeholders, ranging from industry to patients, will be able to access and apply its innovations. NCATS's open access operating framework will also advance the field of regulatory science by promoting interactions among the Food and Drug Administration (FDA), NIH, patient advocates, and pharmaceutical and biotechnology companies. NCATS will encourage collaboration across all sectors, provide resources to enable therapeutic development, and support and enhance training in the relevant translational science disciplines.

NCATS will complement—not compete with—translational research being carried out elsewhere at NIH and in the private sector. In fact, in pursuing its mission of using the power of science to advance the entire discipline of translational science, NCATS will benefit all stakeholders, including academia, biotechnology firms, pharmaceutical companies, the FDA, and—most importantly—patients and their families.

NCATS will pull together existing NIH programs such as the Therapeutics for Rare and Neglected Diseases program, the Office of Rare Diseases Research, the Rapid Access to Interventional Development program, the Clinical and Translational Science Awards, the FDA–NIH Regulatory Science grants program, and components of the Molecular Libraries initiative. These relocated programs will have their respective budgets transferred to or implemented by the new center. In addition, we are hopeful that funding for the new Cures Acceleration Network will be provided within the NCATS appropriation in fiscal year 2012. The intent of this innovative program and its exceptional DARPA-like flexibilities for supporting projects are a natural fit with NCATS.

Aside from the new funding requested in fiscal year 2012 for the Cures Acceleration Network, resources for NCATS will come from the combination of already existing and appropriated programs and so be budget neutral.

NCATS will bring the scientific method to bear on today's drug development process and aim to improve and speed the therapeutic development process of tomorrow.

## CONCLUSION

This statement has provided you with a brief overview of NIH's past successes and future commitment to basic and translational sciences, along with a quick look at the important role that NIH plays in our domestic economy and U.S. global economic and scientific leadership.

But I would like to close my testimony today with an example that demonstrates the benefits to be reaped from our continuing pursuit of "personalized medicine." It is the story of one individual, 6-year-old Nic Volker of Monona, Wisconsin. Starting about the age of 2, Nic developed a mysterious, life-threatening disease that ravaged his intestines, making it impossible for him to eat normally and causing unimaginable pain and suffering. At a loss to explain this terrible, inflammatory condition, researchers and clinicians at the Medical College of Wisconsin decided to sequence Nic's entire exome, that is, all the parts of the genome that code for the proteins

[13] DiMasi, JA, Hansen RW, Grabowski HG. Extraordinary claims require extraordinary evidence. Journal of Health Economics 2005;24(5):1034–1044. Tonkens, R. An Overview of the Drug Development Process. The Physician Executive May-June 2005.

that become life's building blocks. After exhaustive work over a period of months, the researchers identified a mutation in Nic's XIAP gene. Such mutations had been associated with rare blood disorders, but not with bowel symptoms. Based on this new insight, the research team had an idea that, as with the rare blood disorders, Nic's disease might be curable with a bone marrow transplant.

NIH investment over the years in the sequencing of genomes—and the technologies associated with such sequencing—has put us at the threshold of "personalized medicine." Young Nic Volker is one of a handful of individuals who has crossed that threshold, and it was made possible because of years of research and development supported and performed by NIH.

Transplantation of cord-blood stem cells from a matched donor occurred in July of last year and, although Nic is still on immunosuppressant drugs to prevent rejection of the donated cells, his symptoms have largely disappeared and today he can eat normally. Hot dogs are his favorite!

The local newspaper, the Milwaukee Journal Sentinel, was so struck by the saga of Nic and his family that they devoted a series of articles to the little boy's struggles and therapy, coverage that included posting photos, videos, blogs, and many other resources to the web. The five Journal Sentinel journalists did such a good job that they were awarded the Pulitzer Prize for Explanatory Reporting on April 18. Now, that is truly putting a face on the promise of today's biomedical research, tomorrow's personalized medicine, and NIH's role in making this promise possible.

Thank you Mr. Chairman. This concludes my formal remarks.

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PREPARED STATEMENT OF HAROLD VARMUS, M.D.

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2012 budget request for the National Cancer Institute (NCI) of the National Institutes of Health (NIH). The fiscal year 2012 request includes $5,196,136,000 for NCI, which reflects an increase of $141,899,000 over the comparable fiscal year 2011 level of $5,054,237,000.

We now know that cancer is a collection of diseases reflecting changes in a cell's genetic makeup and thus its programmed behavior. Sometimes the genetic changes occur spontaneously or are inherited; sometimes they are caused by environmental triggers, such as chemicals in tobacco smoke, ultraviolet radiation from sunlight, or viruses. While cancers constitute an incredibly diverse and bewilderingly complex set of diseases, we have at hand the methods to identify essentially all of the genetic changes in a cell and to use that knowledge to rework the landscape of cancer research and cancer care, from basic science to prevention, diagnosis, and treatment. The funds in the President's budget for NCI represent a bold investment strategy critical for realizing that goal.

The emerging scientific landscape offers the promise of significant advances for current and future cancer patients, and for preventing cancer so that many never become cancer patients. And it offers scientists at the National Cancer Institute—and in the thousands of laboratories across the United States that receive NCI support—the opportunity to increase the pace of lifesaving discoveries dramatically.

In the past year alone, we have seen powerful examples of how research dollars have translated into concrete advances against cancer through basic science, prevention and early detection, and treatment.

*Basic science*.—In collaboration with NHGRI, the NCI is leading The Cancer Genome Atlas (TCGA), the largest and most comprehensive analysis of the molecular basis of cancer ever undertaken. TCGA aims to identify and catalog all of the relevant genetic alterations in many types of cancer. For instance, building on their recent reclassification of glioblastoma multiforme (GBM), an aggressive form of brain cancer, this year TCGA investigators discovered that about 10 percent of patients with one of the four subtypes of GBM are younger at diagnosis and live longer than patients with other subtypes of the disease, but their tumors are unresponsive to current intensive therapies. The molecular profile of this subtype offers new targets for developing drugs to treat this form of the disease more effectively. TCGA scientists are also preparing to publish similarly important findings about the major form of ovarian cancer in mid-2011 and are in the midst of analyzing nearly 20 other types of cancer.

*Prevention and early detection*.—NCI's intensive efforts to study and reduce the use of tobacco products have contributed to a sustained annual reduction in age-adjusted cancer mortality rates over the past decade and more. But current and former heavy smokers remain at high risk of developing lethal lung cancers, which are the leading cause of cancer mortality. In late 2010, NCI announced initial results from the National Lung Screening Trial, a large, multi-year randomized trial

that enrolled more than 53,000 subjects. Because early detection provides the potential to intervene at the earliest, most treatable stages of disease, thus reducing potentially difficult to treat outcomes seen in more advanced disease, current and former smokers who were screened with low-dose helical computed tomography were 20 percent less likely to die of lung cancer than were peers who received standard chest x-rays. These results provide the first clear demonstration that a screening procedure can be effective in reducing mortality from lung cancer—a finding that could save many lives among those at greatest risk. Over the course of the $240 million study, NLST investigators collected samples of early and advanced lung cancers from enrolled subjects, and these specimens will be invaluable for determining genetic alterations that may be used to predict which tumors are likely to progress to an advanced stage.

*Cancer treatment*.—The potential therapeutic impact of basic discoveries made by TCGA and other efforts in cancer genomics has been dramatically illustrated this year by the development of effective drugs against the most deadly form of skin cancer, melanoma. Almost a decade ago, studies of cancer genomes first uncovered a common mutation in a gene that encodes an enzyme called BRAF. Last year, early stage clinical trials at NCI-designated Cancer Centers of drugs targeted against the mutant BRAF enzyme showed that most melanomas with the relevant mutation regressed dramatically. Although tumor regression generally lasted less than a year, NCI-supported investigators have already pinpointed some causes of resistance to BRAF inhibitors, outlining a pathway to more sustained control of this lethal disease.

Another benefit of a prolonged and broad-based investment in cancer research has also been realized in the context of malignant melanoma this year, with the recent approval by the FDA of an antibody, ipilimumab, which extends the lives of patients with metastatic melanoma. Ipilimumab stimulates the immune system to act against cancer by blocking natural inhibitors of the immune response, an approach that would not be possible without a profound understanding of the immune system and one that promises to harness immunological tools against other cancers.

These examples of NCI's progress in understanding, treating, and detecting different forms of cancer illustrate what can be achieved at an accelerated pace with sustained investments across the cancer research spectrum, such as proposed under the President's budget. While those perspectives are only beginning to inform the American public's perception about cancer and its treatment, the downward trajectory of cancer deaths—reported by NCI and its partners in March—reflects real and sustained reductions over more than a decade for numerous cancers, including the four most common: breast, colorectal, lung, and prostate. We have identified proteins and pathways that different cancers may have in common and represent targets for new drugs for these and many other cancers—since so often research in one cancer creates potential benefits across others.

Additional progress against cancer also will require building these research advances into clinical treatments and diagnostic tools for better patient care and by our many connections with public and private sector partners. The Institute's investments in translational research are broad and deep, and will receive NCI's full energies, recognizing that the publicly announced proposal for reorganizing services that support translational science in general could give NIH additional focus in this important area.

### REVITALIZING THE CANCER CLINICAL TRIALS SYSTEM

For today's new understandings of cancer biology to benefit cancer patients on a broad scale, they must be coupled with a modernized system for conducting cancer clinical trials. This system must enable clinical researchers across the Nation to acquire tumor specimens and conduct genetic tests on each patient, to efficiently analyze molecular changes in those samples, to manage and secure vast quantities of genetic and clinical data, and to identify subsets of patients with tumors that demonstrate changes in specific molecular pathways—pathways that can be targeted by a new generation of cancer therapies.

As part of its effort to transform the cancer clinical trials system, NCI asked the Institute of Medicine (IOM) in 2009 to review the Clinical Trials Cooperative Group Program. This program involves a national network of 14,000 investigators currently organized into nine U.S. adult Cooperative Groups and one pediatric cooperative group that conduct large-scale cancer clinical trials at 3,100 sites across the United States. The IOM report, issued in April 2010, noted that the current trials system—established a half-century ago—is inefficient, cumbersome, underfunded, and overly complex. Among a series of recommendations, the report urged that the existing adult cooperative groups be consolidated into a smaller number of groups,

each with greater individual capabilities and with new means to function with the others in a more integrated manner.

In December 2010, NCI announced its intent to begin consolidating the current nine adult cooperative groups into four state-of-the-art entities that will design and perform improved trials of cancer treatments, as well as explore methods of cancer prevention and early detection, enhance the ability of the cooperative groups to assess the molecular characteristics of individual patients' tumors, and study quality-of-life issues and rehabilitation during and after treatment. The sole pediatric cooperative group was created by consolidating four pediatric cooperative groups almost a decade ago, and that group will not be affected by the current consolidation effort.

PROVOCATIVE QUESTIONS

This has been a challenging and hopeful time for NCI to lead the Nation's cancer research program. Over the past two decades researchers have unraveled some of the damage that occurs in the genome of a cancer cell and how a cancer cell behaves in its local environment as a result of those changes. With this better understanding of cancer and recent technological advances in many fields, such as genomics, molecular biology, biochemistry, and computational sciences, progress has been made on many fronts, and a portrait has emerged for several cancers. With sustained and accelerated funding, and NCI's strong leadership in defining cancer research priorities, we can build upon today's cancer advances with provocative thinking by asking better questions.

To that end, NCI is asking researchers in various disciplines to pose and articulate "provocative questions" that can help guide the Nation's investment in cancer. Provocative questions may be built on older, neglected observations that have never been adequately explored, or on recent findings that are perplexing, or on problems that were traditionally thought to be intractable but now might be vulnerable to attack with new methods.

Many of these provocative questions are being asked—and answered—by young scientists who are early in their careers. The 2012 budget will support NCI's commitment to ensuring that an equitable share of our research grants will go to the young men and women, who are at the forefront of understanding cancer.

We are now reaping the rewards of investments in cancer research made over the past 40 years or more, even as we stake out an investment strategy to realize the potential we see so clearly for the future. The public has benefitted from past generous congressional stewardship of biomedical research funding; cancer research over the past four decades has provided the evidence required to lower the incidence and mortality of many kinds of cancer, to improve the care of cancer patients, and to establish the new understanding of cancer that is now beginning to revolutionize control of cancer throughout the world.

No matter what the fiscal climate, NCI will strive to commit the resources necessary to bring about a new era of cancer research, diagnosis, prevention, treatment, and survivorship.

Thank you for the opportunity to provide you this testimony, and I would be pleased to answer any questions you might have.

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PREPARED STATEMENT OF SUSAN B. SHURIN, M.D.

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). The fiscal year 2012 budget of $3,147,992,000 includes an increase of $80,903,000 over the comparable fiscal year 2011 level of $3,067,089,000.

The NHLBI provides global leadership for a research and education program to promote prevention and treatment of heart, lung, and blood diseases. Our vision is to enhance the health of all individuals and thereby enable them to enjoy longer and more productive lives. The Institute advances its objectives through an innovative program of excellent science that addresses urgent public health needs, capitalizes upon extraordinary opportunities, leverages strategic assets, balances and integrates basic and clinical research approaches, and calls upon the creativity, expertise, and dedication of thousands of scientists here and abroad. The American people have generously supported this work for many years, and tremendous progress has resulted.

This testimony highlights three areas of particular current emphasis: (1) genetics and genomics; (2) regenerative medicine; and (3) translational medicine.

GENETICS AND GENOMICS

NHLBI-funded gene-sequencing projects and genome-wide association studies have been extraordinarily productive. Scanning the genomes of more than 100,000 people from all over the world, scientists recently reported the largest set of genes yet discovered that underlie blood lipid variations known to be major risk factors for coronary heart disease. Altogether, the gene variants explain between one-quarter and one-third of the inherited portions of cholesterol and triglyceride measured in the blood. Of the variants, 59 had not been previously identified and thus provide new clues for developing effective medicines to combat heart disease. This exciting discovery follows upon similar research, reported in 2009, regarding another heart disease risk factor—hypertension. Using genomic analysis of over 29,000 participants from the Framingham Heart Study and other cohorts, an international research team identified a number of unsuspected genetic variants associated with systolic and diastolic blood pressure. Although hypertension has long been known to run in families and have a substantial genetic component, previous attempts to identify genes associated with blood pressure had met with only limited success. The new findings from both the lipid and the blood pressure studies illustrate the potential of large-scale genome-wide scans to identify genes that play roles in a complex disease of widespread public health importance.

Smaller-scale genome-wide scans are also providing valuable new information about less common disorders, such as thoracic aortic aneurysm and dissection—a condition that is often asymptomatic until an unpredictable catastrophic cardiovascular event occurs. Researchers comparing 418 patients with non-familial thoracic aneurysms to normal controls identified a number of genetic variants that appeared more frequently in the patients. Many of the variants exist in genes that are in some manner involved in contraction of smooth-muscle cells, suggesting that genetic variants governing smooth-muscle cell function are a potential target of predictive tests that could be developed in the future.

Although genome-wide scans and sequencing have identified many genetic variations that contribute to disease risk, much more research is needed to understand the mechanisms underlying gene disease associations. NHLBI is advancing this area by supporting a new program, Next Generation Genetic Association Studies, to investigate cells that have been reprogrammed into induced pluripotent stem cells to model heart, lung, and blood diseases and explore the functional consequences of genetic variation.

Another initiative, Getting from Genes to Function in Lung Disease, will support characterization of the function of lung-disease associated genes and their variants that have been identified through GWAS or other genetic approaches. Multidisciplinary teams will use a variety of experimental methods and tools to elucidate the mechanisms that contribute to diseases such as asthma, chronic obstructive pulmonary disease (COPD), sarcoidosis, and idiopathic pulmonary fibrosis and thereby generate knowledge that may lead to more effective ways to prevent and treat them. In fiscal year 2012, the Institute plans to solicit research projects to study two severe and poorly understood conditions that affect the lungs: The Genomic Research in Alpha-1 Antitrypsin Deficiency and Sarcoidosis program will conduct state-of-the-art genomic, microbiomic, and phenotypic studies with the goals of understanding the molecular and cellular bases of the diseases, facilitating classification of subtypes, and developing new drug therapies.

Because genome-wide scans are not well suited to discovery of extremely uncommon genetic variants, the Institute is pursuing other avenues to explore the contributions of infrequent variants to both common and rare diseases. A program planned for fiscal year 2012 in collaboration with the National Human Genome Research Institute, Life After Linkage: The Future of Family Studies, will use data from existing family studies to identify and characterize genes, including rare variants, that influence complex diseases. The potential success of such an approach is illustrated by a recent breakthrough resulting from a collaboration between the NHLBI intramural program and the NIH Undiagnosed Diseases Program. Researchers identified the genetic cause of a rare and debilitating vascular disorder, not previously explained in the medical literature, that involves severe arterial calcification. Analysis of DNA from members of three affected families revealed that the variant is in a gene responsible for a product that protects arteries from calcifying. It is hoped that this understanding of the underlying defect will enable discovery of improved treatment for the patients.

REGENERATIVE MEDICINE

Body components can malfunction because of inherent defects, catastrophic or accumulated damage, or senescence, and chronic disease is often the result. Restoring

healthy function via delivery of "replacement parts" and helping organs repair injury with functional tissue instead of scarring are high priorities of NHLBI. Recent progress gives much reason for optimism. For example, heart attacks cause permanent damage to heart muscle cells (cardiomyocytes) that renders them useless for pumping blood. Although cardiomyocytes cannot themselves be rejuvenated, NHLBI-supported scientists were able to induce other heart cells (fibroblasts) to become pluripotent stem cells that, in turn, were induced to become cells that looked and behaved much like cardiomyocytes. The finding suggests the possibility that fibroblasts—cells widely available throughout the body—could be directly reprogrammed into functional cells to treat or prevent heart failure and other adverse consequences of cell damage. Other NHLBI-supported researchers recently reported progress toward engineering lung tissue in a rat model, creating a scaffold populated with multipotent neonatal rat cells to produce a transplantable organ capable performing the fundamental lung function of gas exchange. The success of this study and others using cadaveric human lung tissue and immortalized cell lines suggests that such an approach might one day be beneficial for patients who are awaiting lung transplant.

NHLBI is making considerable investments to advance regenerative medicine research for cardiovascular, lung, and blood diseases. A collaborative solicitation with the National Institute of Biomedical Imaging and Bioengineering, New Strategies for Growing 3D Tissues, will support highly integrated, multidisciplinary research to improve understanding of how cells respond to their environment and how cell-communication systems that enable blood-vessel and organ development can be used to engineer 3D human cellular aggregates. Translation of Pluripotent Stem Cell Therapy for Blood Diseases will promote the development of technologies for translation of recent stem cell advances into treatments for sickle cell disease and other blood disorders. This new program will build upon the expertise, resources, and infrastructure of the ongoing NHLBI Progenitor Cell Biology Consortium, and it will encourage collaboration with two other Institute initiatives—Production Assistance for Cellular Therapies and the Gene Therapy Resource Program, which is slated for renewal in fiscal year 2012.

A major initiative planned for fiscal year 2012, Consortium of Lung Repair and Regeneration: Building the Foundation, will establish an interactive group of multidisciplinary teams to formulate and test innovative hypotheses about the mechanisms that control lung repair and regeneration. The program will seek to leverage innovative technologies such as tissue engineering, biomaterials and scaffolds, induced pluripotent stem-cell technology, cell-directed therapy, and humanized animal models that are not used widely in lung-regeneration research but are being applied to investigate regeneration and repair in other organ systems.

### TRANSLATIONAL MEDICINE

NHLBI continues to place strong emphasis on translating basic science findings into better diagnostic, therapeutic, and preventive approaches and fostering their use in real-world clinical practice. A number of initiatives are supporting these efforts. For example, a program called Science Moving Towards Research Translation and Therapy (SMARTT) has been launched to facilitate transition of potential new therapies for heart, lung, and blood diseases from discovery in the lab to the testing needed to establish their safety and effectiveness in people. Pre-clinical development—that is, readying products for testing in humans—is the first step in turning discoveries into cures, but the processes involved can be expensive and baffling to academic scientists. Connecting academic researchers with industry, the SMARTT program will offer help with manufacturing, pharmacology and toxicology testing, pre-clinical and early-phase clinical study design, and administrative and regulatory matters.

The Translational Research Implementation Program, or TRIP, is intended to facilitate well-designed clinical trials in heart, lung, or blood diseases to demonstrate the safety and efficacy of promising interventions that have emerged from fundamental studies. Its initial phase, which began in fiscal year 2010, supported the planning of trials; the second phase will fund the most promising of them beginning in fiscal year 2012. A second new program will provide planning grants to establish the feasibility of pivotal clinical trials with a major focus on hemoglobinopathies such as sickle cell disease and thalassemia. Another solicitation, planned for fiscal year 2012, would provide an innovative mechanism for the development of clinical trials for hemostatic and thrombotic disorders, including access to expertise in clinical trial methodology and design through existing institutional resources.

Several exceptionally promising new translational efforts in lung diseases are also under way. Research Education in Sleep and Circadian Biology is promoting the use

of innovative educational tools and programs to accelerate the transfer of recent scientific advances and health knowledge in sleep and circadian biology into clinical and public-health practice. Renewal of a solicitation titled Utilization of a Human Lung Tissue Resource for Vascular Research will advance translational efforts in lung vascular disease, using previously collected biospecimens from patients with pulmonary hypertension. An initiative slated for fiscal year 2012 would support dosing and efficacy trials of promising but untested therapies for lung diseases, including agents that have already been approved for use in treating other diseases and combinations of common drugs with low toxicities, neither of which would be likely candidates for testing by industry. Such small proof-of-concept trials are vitally important for translating basic research advances into clinical research, providing a foundation for larger efficacy trials, and advancing understanding of disease processes.

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PREPARED STATEMENT OF GRIFFIN P. RODGERS, M.D., M.A.C.P.

I am pleased to present the President's fiscal year 2012 budget request for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH). The fiscal year 2012 budget includes $1,837,957,000, which is $47,272,000 more than the comparable fiscal year 2011 level. Complementing these funds is an additional $150,000,000 also available in fiscal year 2012 from the Special Statutory Funding Program for Type 1 Diabetes Research. The NIDDK supports research on a wide range of common, chronic, costly, and consequential diseases and health problems that affect millions of Americans. These include diabetes and other endocrine and metabolic diseases; digestive and liver diseases; kidney and urologic diseases; blood diseases; obesity; and nutrition disorders.

UNCOVERING THE GENETIC AND ENVIRONMENTAL CAUSES OF DISEASE TO INFORM THERAPY AND PREVENTION

Unprecedented discoveries in genetics continue to lead the way toward the development of personalized treatments and prevention of devastating diseases and disorders. Scientists revealed that certain variants in the APOL1 gene may be responsible for the differential risk of developing kidney disease for African Americans. These variants also provide a degree of protection against African sleeping sickness, a degenerative and potentially fatal condition caused by a parasite that is endemic to Africa. This could explain why these variants are more commonly found in individuals of African descent, despite the increased risk of kidney disease they confer.

Many of the diseases within the NIDDK research mission result from the interaction between multiple genetic and environmental factors. Research on the human microbiome—the microorganisms associated with the body—has demonstrated that the composition of bacterial communities is determined mostly by their location on or in the body and varied between people. In a separate study, scientists reported that bacteria in the mouse gut contributed to changes in appetite and metabolism. Therefore, excess calorie composition and obesity may be affected by these bacterial populations. Researchers in The Environmental Determinants of Diabetes in Youth are using newly developed technologies to study the microbiome of children at high risk for developing type 1 diabetes and explore whether viral or bacterial-based treatments could be used to prevent or treat the disease. NIDDK will continue to capitalize on recent genetics and environment discoveries to transform prediction, prevention, diagnosis, and treatment of diseases within the Institute's mission.

IMPROVING PATIENT CARE THROUGH RESEARCH

Obesity is a major health epidemic in the United States, and it increases the risk for type 2 diabetes; kidney, heart, and liver disease; and other health issues. Therefore, efforts to curb this rising trend are vitally important. The NIDDK's HEALTHY study revealed that while a middle school-based intervention did not reduce obesity school-wide, it lowered the obesity rate in students with the highest risk for type 2 diabetes. This important result will inform future school-based efforts to reduce overweight and obesity in children. Research also shows that weight loss can improve the health of people with diabetes. NIDDK's Look AHEAD study showed that weight loss in overweight and obese people with type 2 diabetes can lead, with lower medication requirements, to long-term favorable effects on diabetes control and cardiovascular risk factors.

NIDDK continues to support efforts to test potential treatments for NIDDK-related diseases and disorders. Investigators demonstrated in a preliminary trial that

salsalate, an anti-inflammatory drug used for years to manage arthritis pain, can help people with type 2 diabetes control blood glucose levels. If the expanded trial is successful, it could lead to a safe and inexpensive way to treat the disease. Nonalcoholic steatohepatitis (NASH) is a form of fatty liver disease associated with overweight and can lead to liver cirrhosis and liver failure requiring a transplant. Currently, there are no specific, FDA-approved treatments for NASH. NIDDK scientists compared vitamin E, the insulin-sensitizing drug pioglitazone, and placebo for treatment of adult NASH, and reported promising improvements in response to 2-year therapy, especially for vitamin E.

It is important to compare available, effective treatments and combine this knowledge with a patient's history to identify the best option for treating an individual. A recent NIDDK study demonstrated that, on average, a lower blood pressure goal was no better than the standard goal at slowing progression of kidney disease among African Americans who had chronic kidney disease resulting from high blood pressure. However, the lower blood pressure goal did benefit patients who had protein in their urine, a sign of kidney damage. In light of the APOL1 results I described earlier, this and other findings suggest that genetic traits more common in African Americans may subtly alter the pathogenesis of kidney disease in this population, and new classes of drugs that target these pathways might be more effective in preventing the onset and progression of chronic kidney disease in these patients.

Millions of American women suffer from stress urinary incontinence, an underdiagnosed public health problem that is associated with diminished quality of life. An NIDDK trial demonstrated that two different surgical approaches were equally effective—although they had different side effects—in treatment for stress urinary incontinence, a major milestone in treatment for this condition. This information will enable women and their doctors to weigh more accurately the benefits and risks of available treatment options. In concert with identifying the best treatment options, NIDDK research aims to ensure that patients are able to take advantage of these results to improve their health and care.

### DISSEMINATING RESEARCH RESULTS TO IMPROVE PUBLIC HEALTH

It is critical that the results of research reach the American public quickly and clearly to translate to real improvements in health. NIDDK supports a number of public health campaigns such as the National Kidney Disease Education Program, the Weight-control Information Network, a Celiac Disease Awareness Campaign, and the National Diabetes Education Program (NDEP).

Diabetes continues to be a growing worldwide public health concern; rising rates of obesity and an aging populance are driving the increasing prevalence of type 2 diabetes. There is hope, however: research has shown that it is possible to delay—or even prevent—the disease. The NIDDK's landmark Diabetes Prevention Program (DPP) was a tremendous success, demonstrating that loss of 5–7 percent of an individual's body weight—or treatment with the drug metformin—can delay type 2 diabetes. By eating less fat and fewer calories and doing moderate exercise, such as brisk walking, DPP participants were able to lose body weight and maintain the loss. These lifestyle changes worked particularly well for participants age 60 and older, and were equally effective for all participating ethnic groups and for both men and women.

To transfer the lessons of the DPP to the community level, NIDDK supports translational research, which included a trial of less costly delivery of the DPP intervention in YMCAs in group settings. The results have led CDC and private organizations to fund the intervention at more Ys and United Health Group to cover the cost for plan participants to use the intervention at Ys. Additionally, the NDEP is disseminating the good news from the DPP follow-up study that development of type 2 diabetes continued to be reduced 10 years after the intensive lifestyle change or treatment with metformin. NDEP has partnered with NIH's Office of Research on Women's Health to also raise awareness of the increased risk of type 2 diabetes for women who have a history of gestational diabetes.

### GENERATING RESEARCH OPPORTUNITIES

The future of public health depends critically on the development of the next generation of scientists and the pursuit of scientific opportunities. NIDDK continues to vigorously support new investigators, and training and mentorship in biomedical research. NIDDK held its second annual New Investigators' meeting to enhance their ongoing research and spur future success. NIDDK also held its eighth annual workshop for the Network of Minority Research Investigators to encourage and facilitate participation of members of underrepresented racial and ethnic minority groups in the conduct of biomedical research in NIDDK-relevant fields. These new investiga-

tors will be poised to take advantage of a wealth of opportunities to improve the health of Americans; such opportunities have been identified by a number of recent strategic planning efforts undertaken by the NIDDK.

The development and application of new technologies will also improve patient care. Through support for small business innovation research grants and other efforts, NIDDK will foster cutting-edge research in this area. New technologies could facilitate analysis of organs, tissues and biological molecules, and, with mobile communication, help convey critical information quickly to patients and healthcare providers. This research would enhance our ability to monitor disease progression or how a therapy is working and would improve diagnosis of disease or risk, to enable earlier intervention.

In closing, Mr. Chairman, NIDDK will continue to emphasize my guiding principles: support a robust portfolio of investigator-initiated research; vigorously support clinical trials to identify better ways to prevent and treat disease; preserve a stable pool of new investigators; disseminate science-based knowledge from research through education programs; and foster research training and mentoring.

Thank you Mr. Chairman and members of the Committee for the opportunity to share with you a few highlights of NIDDK's research and outreach efforts to improve the health of Americans. I will be pleased to answer any questions you may have.

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## PREPARED STATEMENT OF ANTHONY S. FAUCI, M.D.

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2012 budget request for the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH). The fiscal year 2012 budget includes $4,915,970,000, which is $144,100,000 more than the comparable fiscal year 2011 level of $4,771,870,000.

NIAID conducts and supports biomedical research to understand, treat, and prevent infectious and immune-mediated diseases, including HIV/AIDS; tuberculosis; malaria; influenza; emerging and re-emerging infectious diseases; asthma and allergies; autoimmune diseases; and the rejection of transplanted organs. NIAID makes a major investment in translational research, which seeks to accelerate the findings from basic research into healthcare practice. This decades-long commitment, together with NIAID's multidisciplinary collaborations with experienced as well as new investigators at academic centers, the private sector, and other governmental and non-governmental partners, continues to help improve domestic and global health through the development of diagnostics, therapeutics, and vaccines for infectious and immune-mediated diseases. I appreciate the opportunity to highlight just a few of our research successes and to describe some of our most promising research programs aimed at improving public health and quality of life.

### GLOBAL HEALTH

NIAID has been a leader in both basic and clinical HIV/AIDS research ever since the disease emerged as a devastating public health crisis 30 years ago. In 2010, NIAID support for HIV/AIDS research resulted in landmark scientific advances in HIV prevention. The NIAID-supported iPrEx study demonstrated that a daily dose of an oral antiretroviral medication, a strategy known as pre-exposure prophylaxis or PrEP, was effective at reducing the risk of HIV acquisition among men who have sex with men. This finding was selected by the prestigious journal The Lancet as one of the top six medical discoveries in the world in 2010 and was named by Time magazine as the number one medical breakthrough in 2010. A second important study, and another of The Lancet's selections, CAPRISA 004, showed that a vaginal microbicide gel of an antiretroviral drug could give women a measure of protection against HIV infection. This important trial was funded by the U.S. Agency for International Development and carried out using a research infrastructure developed with NIAID support. In the area of HIV vaccine development, researchers in NIAID's intramural Vaccine Research Center and NIAID-funded extramural investigators discovered human antibodies that can block a wide range of HIV strains from infecting human cells in the laboratory and are now zeroing in on their precise mechanisms of action. Coupled with last year's success from the RV 144 HIV vaccine clinical trial conducted in Thailand, which found a "prime-boost" vaccine candidate to be safe and modestly effective in preventing HIV infection, NIAID is making important strides in developing a robust package of prevention modalities that can be used in combination. In addition, research supported under NIAID's new initiative, the Martin Delaney Collaboratory: Towards an HIV Cure, will provide insights into how HIV hiding places in the body—so-called "reservoirs"—are formed,

where they are located, how they are maintained despite effective antiretroviral therapy, and how they might be eliminated.

NIAID makes a significant investment in research on the co-infections and co-morbidities that often accompany HIV infection. Tuberculosis (TB) occurs in about one-third of HIV-infected individuals and is the leading cause of death in this group. The NIAID-sponsored CAMELIA study demonstrated that survival of untreated HIV-infected adults with weak immune systems and newly diagnosed TB can be prolonged by starting antiretroviral therapy 2 weeks after beginning TB treatment, rather than waiting the standard 8 weeks. This finding will help to optimize treatment strategies for people co-infected with HIV and TB and promises to save many lives in the developing world. A significant number of adults at risk for HIV infection are also at risk for hepatitis B and C infection. NIAID supports a robust research program to understand the pathogenesis of and immune response to hepatitis viruses and to develop novel therapeutics and vaccines against the diseases caused by these viruses.

In 2009, there were approximately 9.4 million TB cases and 1.7 million TB deaths globally according to the World Health Organization (WHO). NIAID has accelerated its TB research activities and is applying 21st century technology to a field that has lagged behind the study of other infectious diseases. NIAID supports the development of several promising TB vaccine candidates, and basic and clinical research has contributed to both new and repurposed therapeutic approaches and candidates. With NIAID support, researchers also have developed a tool for diagnosing TB that provides more specific, sensitive, and rapid results than currently available diagnostics.

In 2009, approximately 225 million cases of malaria resulted in more than 780,000 deaths, 90 percent of which occurred in Africa, according to WHO. More than a decade has passed since the newest class of antimalarial drugs, artemisinins, entered widespread use worldwide; unfortunately, malaria parasites are becoming increasingly resistant to these medications. There is a pressing need for new malaria therapies due to the constant threat of the emergence of drug resistance, which NIAID is addressing by supporting domestic and international research. For example, NIAID-supported researchers identified NITD609 as a promising antimalarial drug with a mode of action that differs from the current drugs used to treat malaria. NIAID-supported scientists also discovered a novel metabolic pathway of the malaria parasite Plasmodium falciparum that could lead to new drug targets. In 2010, NIAID established ten International Centers of Excellence for Malaria Research in malaria-endemic regions. In addition to research on HIV/AIDS, TB, and malaria, NIAID supports research devoted to better understanding, preventing, and treating other important diseases that cause a significant burden of illness and death globally, including neglected tropical diseases such as lymphatic filariasis, trachoma, and leishmaniasis.

### EMERGING AND RE-EMERGING INFECTIOUS DISEASES

NIAID continues its critical focus on advancing drugs, vaccines, and diagnostics from concept to product development to fight emerging and re-emerging infectious diseases. In response to the 2009 H1N1 influenza pandemic, NIAID played a key role in developing and testing the 2009 H1N1 influenza vaccines, and in assessing their safety and potential effectiveness in a variety of populations. NIAID researchers also made important strides in the development of broadly protective influenza vaccines. NIH intramural researchers in the Vaccine Research Center demonstrated that a "prime-boost" vaccine strategy could protect animals from infection with multiple strains of influenza. NIAID-supported scientists also determined that individuals infected with pandemic 2009 H1N1 influenza generated antibodies that neutralized many different influenza virus strains. This adds to the evidence base that a universal influenza vaccine may be possible, which would obviate the need to modify the influenza vaccine each season. NIAID-supported investigators also showed that vaccinating children against influenza protects the wider community, underscoring the public health importance of widespread vaccination with current and improved vaccines. The Lancet chose this study as its top scientific advance of 2010.

Building on the experience and challenges of the 2009 H1N1 influenza pandemic, the Department of Health and Human Services conducted a review of the Federal Government's efforts to develop medical countermeasures (MCMs) such as drugs and vaccines for public health emergencies, including bioterror attacks, culminating in a new vision for MCM development. As part of this vision, NIAID—in coordination with the Biomedical Advanced Research and Development Authority and the Department of Defense—will lead the Concept Acceleration Program to stimulate

the translation of new scientific concepts and discoveries to the development of MCMs for biodefense and emerging infectious diseases.

The dengue epidemic in Puerto Rico and dengue cases in Florida and Hawaii, as well as the cholera outbreak in earthquake-ravaged Haiti, demonstrate the importance of understanding the factors that contribute to disease emergence and re-emergence. NIAID dengue research includes basic research, vector biology, translational research, as well as the development of research tools, resources, and services. With NIAID support, scientists are developing several vaccine approaches for dengue. NIAID research on cholera spans basic research, genomics, studies of environmental and climactic factors, and the development of vaccines and therapeutics. An NIAID-supported study pinpointed the genetic lineage of the cholera microbe that is causing the epidemic in Haiti.

NIAID continues to support a robust basic, translational, and clinical research portfolio to address the public health issue of antibiotic resistance for key pathogens, including methicillin-resistant Staphylococcus aureus (MRSA) and Gram-negative bacteria. For example, NIAID scientists recently identified a toxin from a community-acquired strain of MRSA that could be a factor in the severity of MRSA infections. NIAID also supports research to preserve the effectiveness of currently used antibiotics, including studies to examine optimal treatment of community-acquired pneumonia and infections caused by Gram-negative bacteria such as Pseudomonas and Acinetobacter. NIAID-supported researchers settled a medical controversy by recently showing that antibiotics clearly reduce the severity and duration of acute middle-ear infections in toddlers that were diagnosed using consistent criteria.

### IMMUNE-MEDIATED DISORDERS

NIAID is committed to furthering our understanding of the immunologic mechanisms underlying autoimmune diseases, asthma and allergic diseases, rejection of transplanted organs, and other immune-mediated disorders; and to translating this knowledge into new approaches for diagnosis, prevention, and treatment. In 2010, an NIAID-sponsored expert panel produced much-needed comprehensive guidelines for medical practitioners for the diagnosis and management of food allergy that will be helpful to clinicians across a range of medical specialties. NIAID also launched the Human Immunology Project Consortium to better understand the human immune system and how it reacts to infection or vaccination. The information gained from this effort will provide insights into the development of safer and more effective vaccines, including those for young children and the elderly. In addition, researchers in the NIAID Immune Tolerance Network demonstrated that Rituxan® is a safe and effective therapy for two forms of severe vasculitis, a rare and devastating disease of the blood vessels. These data were instrumental in the recent Food and Drug Administration-approval of Rituxan® for this indication, representing the first licensed treatment for this disorder in 40 years. Also, the NIAID Inner-City Asthma Consortium determined that the addition of Xolair® to NIH guidelines-based asthma therapy for young children and adolescents resulted in fewer asthma symptoms and severe asthma attacks.

### CONCLUSION

For more than 60 years, NIAID has conducted and supported basic and clinical research on infectious and immune-mediated diseases leading to the development of vaccines, therapeutics, and diagnostics that have significantly improved the health and saved the lives of millions around the world. NIAID will continue to support the highest quality research with the aim of translating fundamental discoveries into improved public health.

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## PREPARED STATEMENT OF JOSEPHINE P. BRIGGS, M.D., DIRECTOR, NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2012 budget request for the National Center for Complementary and Alternative Medicine (NCCAM) of the National Institutes of Health. The fiscal year 2012 budget includes $131,002,000, which is $3,399,000 more than the comparable fiscal year 2011 appropriation of $127,603,000.

The National Center for Complementary and Alternative Medicine (NCCAM) is the Federal Government's lead agency for scientific research on complementary and alternative medicine (CAM). CAM includes a group of diverse medical and healthcare interventions, practices, products, or disciplines that are not generally

considered part of conventional medicine (sometimes called Western or allopathic medicine). The boundaries between CAM and conventional medicine are not absolute; instead, they are constantly evolving: interventions such as hospice care or relaxation and breathing techniques in childbirth that were once considered unconventional are now widely accepted. Furthermore, there is growing interest in more integrative approaches that use both CAM and conventional interventions. For example, both the Departments of Defense [1] and Veterans Affairs are integrating select CAM modalities into treatments for pain, stress, and sleep disorders.

CAM is used by many in the United States, both in treating health problems and in promoting better health and well-being. Data from the 2007 National Health Interview Survey [2] (NHIS), developed under NCCAM leadership in collaboration with the National Center for Health Statistics at the Centers for Disease Control and Prevention (CDC), show that nearly 40 percent of adult Americans and 12 percent of children are using some form of CAM. The data also show that in 2007 out-of-pocket expenditures for CAM totaled $33.9 billion. While this amount accounted for only 1.5 percent of total healthcare expenditures, it was more than 11 percent of out-of-pocket expenditures. Finally, NHIS data indicate that a large portion of CAM use is best described as "self-care" in that it occurs outside of the framework of a relationship with a healthcare professional. The scope, associated costs, and self-care nature of CAM use in the United States reinforce the need to develop reliable, objective scientific evidence concerning the usefulness and safety—or lack thereof—of CAM interventions, and to ensure the public has access to accurate and timely evidence-based information.

NCCAM is shaping its research directions through our third strategic plan, which was developed with considerable input from our diverse stakeholder community and released in February 2011. The strategic plan, Exploring the Science of Complementary and Alternative Medicine (available at www.nccam.nih.gov), was built around three long-range goals aimed at improving the state and use of scientific evidence regarding the two major reasons for use of CAM in the United States—treating health problems and supporting or promoting better health and well-being. The three goals are to (1) advance the science and practice of symptom management; (2) develop effective, practical, personalized strategies for promoting health and well-being; and (3) enable better evidence-based decisionmaking regarding CAM use and its integration into healthcare and health promotion.

### PAIN AND SYMPTOM MANGEMENT

CAM approaches, as treatments for health problems, are used most often to manage symptoms such back or neck pain, arthritic or other musculoskeletal pain, headache, and insomnia. These are all difficult problems and there is broad agreement that existing options are less than fully satisfactory for many patients. For example, chronic back pain is, by far, the most frequent health problem for which Americans turn to CAM. They might try CAM approaches after exhausting other options such as opioids, injections, surgery, or physical therapy. More often, however, they pursue CAM treatment options, including spinal manipulation, yoga, acupuncture, and massage, in conjunction with conventional approaches. Individuals suffering from chronic pain conditions, their healthcare providers, and health policymakers all need better evidence regarding the value and safety of these complementary and integrative approaches in alleviating pain, and in improving quality of life.

To address this critical need, NCCAM is intensifying its focus on determining whether and how CAM interventions add value to existing approaches and on understanding their biological mechanisms. In order to advance the science and practice of symptom management, NCCAM plans to support Centers of Excellence for Research on CAM for Pain in fiscal year 2011. NCCAM is also working with our colleagues at the Department of Defense to explore ways that CAM mind and body approaches can be used in integrative approaches to treat pain, stress disorders, and other symptoms. For example, we recently sponsored a joint workshop on acupuncture for the treatment of acute pain. We are also investigating potential collaborations with the Department of Veterans Affairs to advance CAM research and to maximize our investments in bringing relief to our wounded warriors.

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[1] Pain Management Task Force Final Report: *Providing a Standardized DOD and VHA Vision and Approach to Pain Management to Optimize the Care for Warriors and Their Families*, Office of the Army Surgeon General, Department of Defense, May 2010.

[2] Nahin RL, Barnes PM, Stussman BA, et al. *Costs of complementary and alternative medicine (CAM) and frequency of visits to CAM practitioners: United States, 2007*. CDC National Health Statistics Report #18. 2009.

STRATEGIES FOR PROMOTING HEALTH AND WELL-BEING

It is generally accepted and well established that sustaining healthy behaviors (e.g., good eating habits and regular physical exercise) and modifying unhealthy behaviors (e.g., smoking) reduce risks of major chronic diseases. Many CAM and integrative medicine practitioners and disciplines employ various interventions (e.g., meditation or yoga) to help motivate people to adopt and sustain health-seeking behaviors, or to encourage dietary practices (sometimes grounded in traditional medical systems) that incorporate a healthy food philosophy. Newly emerging evidence suggests that CAM use may be associated with greater degrees of health-seeking behavior. While causal relationships between CAM use and healthy behavior have not been established, the claims and preliminary data deserve investigation given the formidable public health challenges in motivating behavior change. Research is needed to explore, clarify, and examine the hypothesis that certain CAM approaches or practices can, in fact, be useful in encouraging better self-care, an improved personal sense of well-being, and a greater commitment to a healthy lifestyle.

CAM RESEARCH CHALLENGES

Given the scope and self-care nature of CAM use by Americans, NCCAM remains committed to supporting rigorous research that will address the need for scientific evidence to help the public and their healthcare providers make better-informed decisions about CAM use. For example, herbal medicines, dietary supplements, and other CAM natural products are readily available to and purchased by consumers, but evidence regarding usefulness of many does not exist. In addition, some people believe that herbal medicines, dietary supplements, and other CAM natural products are inherently healthier or safer than drugs. In fact, there are ongoing concerns about safety, including the presence of contaminants or adulterants (e.g., conventional drugs) in some CAM natural products, and the potential of toxic interactions with drugs or other natural products.

Clinical research to address these needs will remain a cornerstone of the CAM research enterprise, but these studies are complex, expensive, and time-consuming. NCCAM's strategic approach is to ensure that clinical trials of CAM natural products are based on a scientifically sound hypotheses and methods that are grounded in basic mechanistic and translational research. This foundation facilitates design of maximally informative clinical trials that include measures of biological effect relevant to the hypothesis (e.g., biomarkers or surrogate markers), as well as measures of clinical outcomes.

Investigators studying mind and body interventions face other scientific challenges in designing rigorous research that will address the questions of greatest importance to consumers, providers, and healthcare policymakers. These include identifying relevant study endpoints and defining appropriate experimental designs to test interventions. To address such challenges, NCCAM recently collaborated with several NIH ICs to sponsor a workshop on control and comparison groups for studies of non-pharmacological interventions.[3]

CONCLUSION

As established in its third strategic plan, NCCAM is focusing the Center's efforts and resources on two compelling areas of public health need: better strategies for managing symptoms such as chronic pain, and better strategies for promoting health and well-being. In both areas there exist promising scientific opportunities for research on CAM interventions to contribute to real and meaningful progress in addressing common and vexing individual and social problems, and in developing more integrative approaches to healthcare and the support of healthy behaviors and lifestyles.

Finally, NCCAM's plan looks to a vision in which scientific evidence informs decisionmaking by the public, by healthcare professionals, and by health policymakers regarding CAM use. NCCAM will continue its multi-pronged efforts to provide world-class information about the safety and usefulness of CAM interventions to consumers, and to foster dialogue about CAM use between patients and their healthcare providers. In addition, a new online resource, tailored to the needs of healthcare professionals, is being launched on the NCCAM website. It includes information on the safety and efficacy of a range of CAM practices, and was developed in response to providers' needs for an evidence-based, one-stop resource to help answer their patients' questions on CAM.

[3] NCCAM Workshop on Control/Comparison Groups for Trials of Non-Pharmacologic Interventions, April 26, 2010.

## PREPARED STATEMENT OF BARBARA M. ALVING, M.D., DIRECTOR, NATIONAL CENTER FOR RESEARCH RESOURCES

Mr. Chairman and Members of the Committee: It is a privilege to present to you the President's budget request for the National Center for Research Resources (NCRR) programs for fiscal year 2012. The fiscal year 2012 budget of $1,297,900,000 includes an increase of $41,225,000 over the comparable fiscal year 2011 level of $1,256,675,000. Funding priorities for fiscal year 2012 include the continued support and refinement of the Clinical and Translational Science Award program, which will reach its targeted number of 60 consortium members later this year. Funds will also sustain the range of activities supported by the Center's other major programs, including the Research Centers in Minority Institutions, the Institutional Development Awards, the National Primate Research Centers, and the Biomedical Technology Research Centers.

By uniting innovative research teams with the power of shared resources across the Nation, NCRR programs provide laboratory scientists and clinical researchers with the tools and training they need to understand, detect, treat, and prevent a wide range of diseases through clinical and translational research. NCRR's diverse yet interconnected NCRR programs enable the research of more than 30,000 NIH-funded investigators nationwide by providing the resources, tools, and networking connections.

This statement is submitted with the recognition of a publically announced proposal for reorganization that would result in dissolution of NCRR and the transfer of programs to other NIH ICs and Offices.

### BUILDING CLINICAL AND TRANSLATIONAL RESEARCH CAPABILITIES

NCRR's Clinical and Translational Science Award (CTSA) program is transforming biomedical research by building national clinical and translational research capacity to speed the translation of laboratory discoveries into better treatments for patients. Launched in 2006, the CTSA program is a national clinical and translational research consortium which now includes 55 medical research institutions in 28 States and the District of Columbia. The consortium supports research by disseminating clinical research informatics tools, forging new partnerships with healthcare organizations, and expanding outreach to minority and medically underserved communities. The first cohort of CTSAs, now re-competing for their next 5 years of funding, have pushed scientific discoveries toward novel and promising treatments that enable healthcare reform and more cost-effective treatments. For instance, research conducted at the University of California, San Francisco's CTSA found that reducing salt intake by just a half teaspoon per day could help Americans significantly improve their heart health, reduce a number of heart-related deaths and potentially save millions in healthcare costs. The findings influenced the Food and Drug Administration's decision to limit the amount of salt in prepared foods and helped support the CDC's salt reduction campaign.

Importantly, the CTSA consortium serves as a communications hub that ensures sharing among sites and accelerates adoption of best practices for clinical and translational research. The CTSAs are building biomedical research capability by generating new tools and resources, such as ResearchMatch.org, a Web-based national recruitment registry which matches volunteers with clinical studies seeking participants, and the CTSA Pharmaceutical Assets Portal, a public-private collaboration enabling scientists to learn more about existing compounds that are not being actively developed and might be repurposed to treat other types of diseases.

### ENERGIZING RESEARCH COMMUNITIES

NCRR programs support new investigators and promote new ideas through innovative networking collaborations, partnerships, training, and career development for clinical and translational scientists. Members of the Institutional Development Award (IDeA) program, which supports rural and underserved communities, developed the Network of IDeA-funded Core Laboratories (NICL) to address common challenges of NCRR-funded core laboratories. NICL addresses, develops and disseminates sustainable business models for efficient core operations and expands access to advanced core resources and expertise. Now extended to other NCRR programs, NICL supports, encourages, and facilitates resource sharing and collaboration among NCRR-funded cores and shared-resource facilities. NCRR programs are also energizing the research community with the world's first physician-scholar training program on wireless healthcare research, launched through a partnership between The Scripps Translational Science Institute (STSI) CTSA and the wireless

telecommunications company Qualcomm. STSI is positioned to become an invaluable resource for this emerging, high-impact field of research.

ADVANCING INNOVATIVE BIOMEDICAL TECHNOLOGIES

The Biomedical Technology Research Centers (BTRCs) program is producing leading edge technologies to accelerate discoveries that help researchers who are studying virtually every human disease. At the Resource for Magnetic Resonance and Optical Imaging at the University of Pennsylvania, researchers are working closely with clinicians to improve patient care by developing and promoting ready access to imaging tools with the goal of translating novel approaches for imaging blood flow through brain tissue and other organs.

NEW AND BETTER TREATMENTS THROUGH ANIMAL MODELS

The National Primate Research Center (NPRC) program advances research and knowledge in HIV and AIDS, as well as in numerous other diseases. The NPRCs have a close relationship with the CTSAs; one example is the collaboration between the New England NPRC and the Harvard CTSA. The two are jointly examining the observation that insulin resistance appears to be a predictor of dementia utilizing a monkey model of insulin resistance and an analysis of high-field MRI scans in the monkey model conducted by the Harvard CTSA investigators who have expertise with MRI in humans. NCRR continues to supply the research community with animal models and resources. Through the Link Animal Models to Human Disease Initiative (LAMHDI), a Web-based resource, investigators can identify and locate useful animal models that are essential to their research in treatments for human disease.

EXPANDING RESEARCH CAPABILITIES TO ADDRESS HUMAN HEALTH

Through the IDeA and Research Centers in Minority Institutions (RCMI) programs, biomedical research capacities across the Nation are expanding into States with historically low NIH funding and are having a direct impact on human health. One example is from the National Center for Genome Resources in New Mexico, home of the DNA sequencing and bioinformatics core for the New Mexico IDeA Networks of Biomedical Research Excellence (INBRE). Scientists used innovative whole-genome sequencing and expression analyses to study Multiple Sclerosis (MS) in identical twins resulting in the first published genome sequences of female twins or individuals with autoimmune disease. It is also the first systematic comparison of genomes in identical twins, including epigenetic markers and expression profiles. Another study from the New Mexico INBRE used next-generation sequencing methods to develop a pre-conception genetic test for 500+ mutations known to increase the risk of numerous rare diseases in children of carriers.

Another illustrative example is a pilot study, initiated by the RCMI Translational Research Network, to study the effect of Vitamin D on cardiovascular disease risk factors in African Americans. This study is important because racial/ethnic minorities, especially African Americans, continue to suffer a disproportionate burden of cardiovascular disease. African Americans also tend to have low levels of Vitamin D and these low levels have been associated with cardiovascular disease risk. Supplementation with Vitamin D may be an accessible and affordable intervention.

PROVIDING A CATALYST FOR RESEARCH COLLABORATION

Grantee institutions are adopting research networking tools as a step toward national networking of people, resources, and data on the web. The VIVO project, which is an initiative to enable national networking of scientists and resource discovery, is driving the network with availability of linked open data about scientists and their work. The potential will be realized through their commitment to publish data on the web so the information is more easily discoverable and connections with other open linked data can be made. VIVO is an open source semantic web application linking information automatically from institutional and public systems of record to provide detailed profiles of scholars and researchers. The power of this semantic web approach is the ability for creative visualization of connections not previously possible between diverse types of information and data.

This brief overview of NCRR's programs demonstrates our continuing commitment to accelerating clinical and translational research. NCRR will continue to advance research through partnerships among its programs, other Institutes and Centers at the NIH, and with other Federal and non-Federal agencies to advance training and translational research opportunities.

## PREPARED STATEMENT OF PAUL A. SIEVING, M.D., PH.D., DIRECTOR, NATIONAL EYE INSTITUTE

Mr. Chairman and Members of the Committee:I am pleased to present the President's budget request for the National Eye Institute (NEI). The fiscal year 2012 budget of $719,059,000 includes an increase of $18,832,000 over the fiscal year 2011 appropriation level of $700,227,000. As the director of the NEI, it is my privilege to report on the many research opportunities that exist to reduce the burden of eye disease.

### TECHNOLOGIES TO ACCELERATE DISCOVERY

The causes of common diseases are complex in that there are potentially many different environmental factors and genetic variants that can contribute to disease. New technologies such as genome-wide association studies (GWAS) allow investigators to scan the genomes of patients to identify genetic risk variants for common diseases. Individually, each of these variants may only contribute to a small percentage of cases, so GWAS require many subjects to identify low frequency risk variants. In the largest GWAS study in vision research to date, NEI investigators recently sequenced DNA from over 18,000 patients and control subjects and identified three new genes associated with age-related macular degeneration (AMD), the most common cause of vision loss in older Americans. Two of these genes are involved with high-density lipoprotein cholesterol metabolism, implicating a new biochemical pathway involved in the pathogenesis of AMD. These findings will allow researchers to better understand the disease mechanisms underlying AMD and develop therapies that address the root cause of vision loss. Glaucoma is another heritable blinding disease where the genetic underpinnings are poorly understood. The NEI Glaucoma Human Genetics Collaboration, a consortium of clinicians and geneticists at 12 institutions throughout the United States dedicated to identifying the genetic factors associated with glaucoma is conducting a large-scale GWAS that involves scanning 5,000 DNA samples. The consortium is using state-of-the-science technology to sequence the exome, the full complement of protein coding regions in the human genome, in a subset of patients. The data from these DNA samples are expected to be available to the vision research community in 2011.

### TRANSLATIONAL SCIENCES AND THERAPEUTICS DEVELOPMENT

Positive results of ongoing, pioneering clinical trials of gene therapy for Leber congenital amaurosis, a severe, early onset retinal disease, have encouraged applications of this approach to many other eye diseases. In the past year, NEI investigators demonstrated proof-of-concept of gene therapy using animal models of AMD, achromatopsia, Leber's hereditary optic neuropathy, retinitis pigmentosa, and red-green color blindness. Previous work with animal models established the utility of gene therapy in juvenile retinoschisis, optic neuritis, and Stargardt disease. These studies now allow investigators to conduct the pre-clinical work necessary to pursue regulatory approval for clinical trials. In addition, novel gene delivery systems, such as the use of nanoparticles, have shown promise in animal models. Such vectors will be helpful in expanding the reach of gene therapy to target a variety of ocular tissues such as retinal ganglion cells and the light-sensitive photoreceptor cells.

### ENHANCEMENT OF EVIDENCE-BASE FOR HEALTH CARE DECISIONS

For treating the blinding ("wet") form of advanced AMD, monthly ocular injections of a drug, Lucentis, was approved in 2007 by the FDA. This was the first effective treatment that not only stopped progression of the disease, but also improved vision for many patients. Lucentis blocks formation of new, but abnormal blood vessels that leak fluid into the central part of the retina that is responsible for keen vision. It was developed from another inhibitor of blood vessels, Avastin, which since its approval in 2004, has been used to block new vessels that form to nourish growth of some cancers. Even before final FDA approval of Lucentis, ophthalmologists began using Avastin "off-label" for treating AMD, and today, most AMD patients receive Avastin. Given the lack of data regarding the effectiveness of Avastin for AMD treatment, in 2007, the NEI had an obligation to patients and clinicians to compare the two drugs and to evaluate whether the drugs could be used less frequently as needed—called PRN—rather than monthly as originally approved for Lucentis. Visual acuity improvement was virtually identical (within one letter difference on an eye chart) for either drug when given monthly. When each drug was given PRN, there also was no difference between drugs. For PRN dosing, patients required four to five fewer injections per year compared to monthly treatment and still had substantial gains in vision.

Lucentis was also studied in a comparative effectiveness trial for diabetic macular edema (DME), a common sight-threatening complication of diabetes in which fluid from leaky blood vessels causes the retina to swell. For the past 25 years, DME has been treated with a laser to destroy abnormal blood vessels. Although laser therapy slows disease progression, the effects are temporary, and repeated treatments can damage healthy retinal tissue and impair vision. In recent years, ophthalmologists have been supplementing laser treatment with ocular injections of either Lucentis, a drug that prevents blood vessel growth, or triamcinolone, a corticosteroid to reduce inflammatory complications. An ongoing clinical trial comparing the safety and efficacy of these two drugs is being conducted by the Diabetic Retinopathy Clinical Research Network (DRCR.net), a public-private partnership funded by NEI, the Type 1 Diabetes Funding Program, and industry collaborators. After 1 year, Lucentis plus laser treatment was superior in both safety and efficacy compared to triamcinolone plus laser or to laser alone. This landmark clinical trial identified the first new safe and effective treatment regimen for DME in more than two decades. In addition, the study demonstrated that intravitreal triamcinolone, which had been used in 60 percent of patients with DME, had significant side effects (cataract and glaucoma) and was not better than laser alone. These results are already being used by community ophthalmologists to greatly improve the vision and quality of life for people living with diabetes.

Treatment of cataracts in infants is challenging for pediatric ophthalmologists and parents. Replacing the opaque lens with an artificial lens is critical to prevent permanent loss of vision in the eye. After removing the cataract, contact lenses have been the preferred method to overcome the loss of the natural lens. However, it is difficult and stressful for parents to insert a contact lens into an infant's eye. Removing the cataract and surgically implanting a transparent intraocular lens (IOL) in adults is common but had not been fully characterized in infants. An NEI-supported clinical trial found no difference in visual acuity with contact lenses compared to IOLs 1 year after cataract removal. However, IOLs caused significant numbers of surgical complications. Based on these results, the use of contact lenses is considered the safest effective treatment for infants with cataract.

### NEW INVESTIGATORS, NEW IDEAS

The increasingly quantitative nature of the biomedical sciences and the explosive growth of genomic, transcriptomic, proteomic, metabolomic, neurophysiological and clinical data require that investigators work at the interface of biology and computational sciences. The NEI is committed to developing the next generation of vision researchers and has expanded its institutional training grant program with a program in ocular statistical genetics at several universities. This program will partner researchers with expertise in mathematics, modeling, and computation, fields that are not usually affiliated with ocular research, with researchers in all areas of vision science to provide state-of-the-art training for a new breed of researchers.

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## PREPARED STATEMENT OF ERIC D. GREEN, M.D., PH.D., DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2012 President's budget request for the National Human Genome Research Institute (NHGRI). The proposed fiscal year 2012 budget is $524,807,000, an increase of $13,749,000 from the comparable fiscal year 2011 level of $511,058,000.

This is an exciting time for biomedical research in general and for genomics research in particular. NHGRI investments in the development of genomic technologies and their application are generating innovative and powerful approaches to address a diverse array of biological and biomedical questions. In early 2011, after 2-plus years of rigorous consultation and planning, NHGRI published a new strategic plan for the field of genomics in the premiere scientific journal Nature. This comprehensive strategic vision describes the next key steps in the herculean journey to decipher the secrets within our genetic code and to use those discoveries to empower health practitioners and patients in a fashion that leads to improved human health. The strategic plan also challenges the broader biomedical community to anticipate the scientific and non-scientific achievements that will be necessary to implement cost-effective and accessible genomics-based medical care (i.e., genomic medicine).

ENABLING RESEARCH

Basic research lays the foundation for understanding the functional features within our genome and how disruptions in them can lead to disease. In fact, the knowledge gained from basic genomic investigations enables scientists and clinical investigators from other disciplines to pursue translational research programs to understand particular biological pathways or address disease-specific questions. The ENCyclopedia of DNA Elements (ENCODE) project and the related model organism ENCODE (modENCODE) project are moving forward effectively toward their goals of finding all the functional elements in the human genome, as well as in the genomes of organisms that serve as important models for human biology.

To stimulate and accelerate multi-disciplinary research, NHGRI has funded several Centers of Excellence in Genomic Science (CEGS). In addition to pursuing cutting-edge genomics research questions, these centers are associated with rigorous training programs that focus on groups under-represented in biomedical research. Such efforts aim to reinvigorate the biomedical research community by engaging diverse expertise and fostering the development of versatile young scientists.

The unprecedented decreases in the cost of DNA sequencing resulting from the NHGRI-stimulated technology development efforts are moving us steadily closer to the reality of using genome sequencing as a routine part of clinical care. However, even with the three-to-four orders-of-magnitude drop in DNA sequencing costs that has occurred, sequencing an entire human genome remains too expensive for the kind of human research studies needed to dissect the small genetic differences between individuals that contribute to increased risk for common diseases, such as cancer, heart disease, and asthma, because such work often requires the study of thousands or tens of thousands of individuals. To this end, NHGRI continues to push forward technology-development initiatives, such as the $1,000 Genome program, to develop novel and even more cost-effective DNA sequencing methods. Concurrently, the NHGRI-funded large-scale sequencing centers continue to use innovative approaches for improving available DNA sequencing technologies. These efforts are projected to result in a substantial drop in the cost of generating a human genome sequence—to less than $25,000 by the end of fiscal year 2011 and less than or equal to $15,000 by the end of fiscal year 2012.

To develop an appropriately broad catalog of information about the variation within the genomes of different individuals across the world, NHGRI continues to contribute substantially to the international 1000 Genomes Project. In addition, on behalf of NIH, NHGRI led the effort to launch a research partnership with the Wellcome Trust, called the Human Heredity and Health in Africa ($H^3$Africa) Initiative. This new effort seeks to stimulate research within African laboratories to enable leading-edge genomic studies to be conducted across the continent. The knowledge gained through a deeper understanding of genomic variation in African populations will not only lead to improved abilities to study genetic diseases in those populations, but will enhance our understanding of the complex interplay between environmental and genetic factors that influence disease susceptibility and drug responses in many diverse populations.

BUILDING A FRAMEWORK FOR TRANSLATION

Building on the tools and knowledge created by these and other basic research programs, the joint NHGRI-National Cancer Institute (NCI) project, The Cancer Genome Atlas (TCGA), is providing important new insights into some of the most vexing forms of malignancy, including brain cancer and, more recently, acute myeloid leukemia and ovarian cancer. Results from TCGA and associated cancer genomics studies by NHGRI-funded investigators point to new therapeutic targets and, as recently reported in the Journal of the American Medical Association, demonstrate the potential for more precise modes of cancer diagnosis and treatment. As a flagship program for NIH translational research activities, TCGA is expanding its efforts and will focus on an additional 20 major cancers over the next 5 years.

Beginning in fiscal year 2012, NHGRI will expand its large-scale genome sequencing and analysis portfolio to include centers that target the study of rare, single-gene (Mendelian) disorders using cutting-edge genomic technologies. Rare disease research already is benefiting from the new genomic technologies. For example, the causative genes for a pair of developmental disorders were discovered recently: Miller syndrome, which affects the development of the face and limbs, and Kabuki syndrome, which affects facial and cognitive development. These two discoveries represent the "tip of the iceberg" with respect to the identification of altered genes that result in rare diseases, as reports of such discoveries are published in the scientific literature almost weekly. Another new NHGRI initiative in fiscal year 2012 will

pilot the use of genome sequencing in clinical care settings, an important step towards implementing genomic medicine.

Complementing the genome sequencing initiatives, the NIH Therapeutics for Rare and Neglected Diseases (TRND) program, which is currently administered by NHGRI, aims to innovate and accelerate the drug development pathway for rare and neglected diseases. As the TRND pilot projects move toward their initial milestones, the first full-scale project portfolio will be launched in collaboration with external and internal partners. Likewise, the NIH Chemical Genomics Center (NCGC) continues to serve as a national resource for the generation of novel chemical "leads" to spur inventive directions in candidate drug and biological assay identification. This statement is submitted with the recognition of the Department's notification to the Congress of an NIH reorganization that would establish a new National Center for Advancing Translational Sciences (NCATS).

EARLY OPPORTUNITIES FOR GENOMIC MEDICINE

The clinical promise of genomics requires strong foundational knowledge about the structure and biology of genomes as well as the biology of disease. Increasingly, genomics will be used to advance medical science and to improve the practice of medicine.

Cancer genomics (as previously discussed) and pharmacogenomics (or genomically guided medication prescription) are anticipated to be leading-edge examples of genomic medicine. Successes of the latter include the use of genomic information for making decisions about administering the antiretroviral drug abacavir, now the standard of care for HIV-infected patients. Other promising examples of pharmacogenomics involve the use of patient genomic information to target the application and dose of tamoxifen to treat breast cancer, clopidogrel to treat cardiovascular disease, and the blood-thinner warfarin. For cancer genomics, it is expected that genomic profiling of tumors will become increasingly routine for making decisions about treatment strategies.

Major advances in the study of common, genetically complex diseases also have been seen recently. Over the past 5 years, more than 4,000 validated associations have been made between a genomic region and a common disease (or another specific trait). Studies that identify and provide evidence to support the value-added connections between genetic factors and observed phenotype (physical traits, clinical symptoms, etc.) require substantial investments in time, funding, and resources, but are fundamental to translating genomics investments into clinical applications. One such initiative, the Electronic Medical Records and Genomics (eMERGE) Network, aims to advance the efficiency of this scientific approach. This program will enter its second phase in late fiscal year 2011, during which it will not only link patients' DNA to their electronic medical record information, but also will explore the challenges of using the information to inform clinical care in a respectful, responsible manner.

The new NHGRI strategic plan identified several critical cross-cutting elements that are integral to navigating successfully the path to genomic medicine: bioinformatics and computational biology, education and training, and the continued study of the societal implications of genomics. The major bottleneck in genome science is no longer data generation; rather, it is the computational analysis of data. Beyond the research setting, the public, and especially healthcare providers, need to become much more conversant in genomics. To help address the needs of healthcare professionals, NHGRI has launched online tools to support genetic and genomic training in health professional education programs, including bilingual case studies.

Moving forward, translating basic genomic knowledge to improve human health will continue to rely on innovative technology development, large-scale collaborative and, increasingly, multi-disciplinary efforts, and robust attention to the societal implications of genomic advances. Demonstrating utility and feasibility will be critical for widespread adoption of genomic medicine; the thresholds for defining benefit and harm will vary across stakeholders and cultural perspectives. However, overcoming the challenges that accompany such a paradigm-changing venture is within reach. The research and related programs that NHGRI will pursue over the next year will continue to lay the groundwork for an era where individualized genomic medicine will become a reality, and the original promise of the Human Genome Project will be fulfilled.

PREPARED STATEMENT OF RICHARD HODES, M.D., DIRECTOR, NATIONAL INSTITUTE ON AGING

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2012 budget request for the National Institute on Aging (NIA) of the National Institutes of Health (NIH). The fiscal year 2012 budget includes $1,129,987,000 which is $30,450,000 more than the comparable fiscal year 2011 appropriation of $1,099,537,000.

The National Institute on Aging leads the national effort to understand aging and to identify and develop interventions that will help older adults enjoy robust health and independence, remain physically active, and continue to make positive contributions to their families and communities. We support a comprehensive portfolio of genetic, biological, clinical, behavioral, and social research related to the aging process, healthy aging, and diseases and conditions that often increase with age. We also carry out the crucial task of training the next generation of researchers who specialize in understanding and addressing the issues of aging and old age.

Approximately 39 million people age 65 and older live in the United States, and data from the Federal Interagency Forum on Aging-Related Statistics indicate that their numbers will double within 25 years. In less than 50 years, the number of "oldest old"—people ages 85 and older—may quadruple. As record numbers of Americans reach retirement age and beyond, profound changes will occur in our economic, healthcare, and social systems.

TRANSLATIONAL SCIENCES AND THERAPEUTICS DEVELOPMENT

NIA supports a comprehensive portfolio of research that builds upon basic discovery to develop new preventive, diagnostic, and therapeutic interventions for age-related diseases and conditions. For example, investigators with the Alzheimer's Disease Neuroimaging Initiative (ADNI) have found that changes in the structure of the hippocampus, a brain area important to learning and memory, may reflect disease progression and effectiveness of potential treatments, and have established biomarker and imaging measures that may predict risk for cognitive decline and conversion to dementia. Clinical, imaging, and biological data from ADNI are available to qualified investigators around the world; over 1,700 researchers have signed up for access to the ADNI database, and global collaborations have resulted in over 170 published scientific papers since 2004.

NIA-supported research to identify Alzheimer's disease (AD) biomarkers and gain a deeper understanding of the disease's pathology and clinical course has made possible the first revision of the clinical diagnostic criteria for AD in 27 years through a joint effort of the NIA and the Alzheimer's Association. Unlike the criteria that doctors and researchers have been using since 1984, the updated guidelines cover the full spectrum of the disease as it gradually changes over many years, from the earliest preclinical stages before symptoms are apparent through mild cognitive impairment (MCI) and advanced dementia. The new guidelines also address the use of imaging and biomarkers to determine whether changes in the brain and body fluids are due to AD.

Even under the new guidelines, however, diagnosis of AD remains complex. NIA intramural investigators are working toward development of an accurate, noninvasive, inexpensive blood test for AD. Last year, they found that the amount of a protein called clusterin in the blood of AD patients reflected the severity of disease, predicted the progression of memory impairment, and may predict brain amyloid burden long before the patient develops memory problems. These findings were recently replicated by independent researchers, and research is ongoing in this promising area.

A continuing translational research success story for NIH is the ongoing development of the compound exendin-4. NIA intramural investigators originally developed exendin-4 as a treatment for type 2 diabetes, but have since found that exendin-4 may act as a neuroprotective agent in animal models, and they are now conducting a phase II/III clinical trial of the compound in patients with MCI and early AD. NIA also supports over 40 drug discovery and development projects through our AD Translational and Drug Discovery Initiative, including a number of AD pilot clinical trials.

Other NIA-supported researchers are pursuing the development of interventions that will delay disease and dysfunction and even extend lifespan. Investigators with the innovative Interventions Testing Program found that the drug rapamycin, used to help prevent rejection of transplanted organs in humans, extended life span in middle-aged mice, and more recently demonstrated that the drug exerts beneficial effects early in life. Rapamycin inhibits the mTOR pathway, which helps regulate cell growth and proliferation. Building upon these findings, in 2010 NIA began solic-

iting research to identify and characterize molecular targets within the mTOR pathway with potential to impact health span and lifespan.

NIA also partners with other agencies and organizations on translational initiatives. For example, with the Administration on Aging, NIA has established an initiative to support development of evidence-based interventions, programs, policies, practices, and tools that can be used by community-based organizations to help elderly individuals remain healthy and independent in their own homes and communities. NIA is also joining "ambassadors" from organizations interested in the health and well-being of older people to promote Go4Life, our new exercise and physical activity website (www.nia.nih.gov/Go4Life.)

TECHNOLOGIES TO ACCELERATE DISCOVERY

New GWAS (genome-wide association study) technologies are transforming our understanding of the origins of disease and disability by facilitating rapid comparisons of the full genomes of thousands of individuals. This research may lead to the identification of novel disease pathways that can be targeted to develop new treatments. In the largest GWAS ever conducted in AD research, scientists with the AD Genetics Consortium found that a previously unconfirmed gene variant, BIN 1, affects development of late-onset AD and identified four additional genetic variants significant for the disease. The genes identified by this study may implicate pathways involved in inflammation and the movement of proteins and lipids both within and between cells as being important in the disease process. In a another large GWAS, NIA intramural researchers joined an international research consortium to confirm six previously identified genes for Parkinson's disease and identify five new genes or loci (an area on the chromosome where a gene is thought to be located).

A new NIA-supported initiative is underway to develop technologies to better understand the life span and fate of cells in various tissues of aged mammals. In these studies, cells are permanently marked at a specific point in the organism's life and those marked cells are followed to determine their fate and traits over time. These studies will provide important insights into aging at the cell and tissue levels.

USING SCIENCE TO INFORM HEALTH CARE REFORM

Research that will lead to the identification of more effective and less expensive clinical interventions is a high priority for NIA, particularly through a broad portfolio of comparative effectiveness research (CER). A major CER effort has been NIA's administration, on behalf of the Agency for Health Care Research and Quality and the Office of the DHHS Secretary, of an initiative identifying ways that principles of behavioral economics could be used to encourage healthcare providers to incorporate findings from CER studies into their practices. Other ongoing CER studies include a randomized trial of behavioral economic interventions to reduce risk of cardiovascular disease; a study comparing various motivators to increase HIV screening; and a study comparing the effects of an intensive exercise program vs. stretching and range of motion exercises on ambulation in hip fracture patients.

Surprisingly little definitive evidence exists on the impact insuring the uninsured has on their health-related behaviors (including healthcare usage) and outcomes. However, NIA-supported investigators are currently taking advantage of a remarkable opportunity to develop such evidence. For a brief period in 2008, Oregon opened a waiting list for enrollment in its previously closed public health insurance program for certain low income adults, and then offered randomly selected people the opportunity to enroll. By comparing individuals who obtained health insurance through this program with otherwise eligible individuals who were not selected in the "insurance lottery," the investigators are assessing the impact of insurance on healthcare usage and health outcomes, including the differing impacts on different groups. Understanding the consequences of health insurance coverage will be central to evaluating proposals to expand or modify health insurance coverage in the United States.

Recently, NIA-supported investigators studying older populations in the United States, England, and 11 European countries found that retirement prior to age 65 was associated with a significant decline in cognitive performance. The investigators suggest that this may be in part because for many people retirement leads to a less stimulating daily environment, and the prospect of retirement reduces the incentive to engage in mentally stimulating activities on the job. It is possible (although not yet proven) that the recent trend of American workers delaying retirement may eventually lead to improved cognitive performance in this group.

NEW INVESTIGATORS, NEW IDEAS

As the American population grows older, the need for healthcare professionals who specialize in the unique needs of older individuals is becoming ever more urgent. To address this increase in demand effectively, we must foster the development of physician-scientists whose research will lead to improved care and more effective treatment options for older patients with complex medical conditions. Recently, NIA established the Grants for Early Medical/Surgical Subspecialists' Transition to Aging Research (GEMSSTAR) program to support physicians who seek to become clinician-scientists in geriatric aspects of their subspecialty. We anticipate supporting 18 to 20 emerging physician-scientists in this program.

Once again, thank you. I welcome your questions.

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PREPARED STATEMENT OF ROGER I. GLASS, M.D., PH.D., DIRECTOR, FOGARTY INTERNATIONAL CENTER

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2012 President's budget for the Fogarty International Center (FIC). The fiscal year 2012 budget of $71,211,000 reflects an increase of $1,835,000 over the comparable fiscal year 2011 appropriation of $69,376,000.

When it comes to global health, there is no "them"—only "us."[1] In an increasingly interdependent world, the United States and nations around the globe share diseases, as well as the burden that these diseases inflict on healthy people. In fact, the interests of the American people are well-served when the United States promotes global health, as healthy nations are more likely to succeed in economic development and enjoy political stability. In addition, Americans have a strong humanitarian tradition and have long supported efforts to improve the health of people around the world. The U.S. Government (USG) has recognized these realities, and has made global health a national priority. For these investments to yield the maximum benefit however, U.S. and foreign scientists must work together to generate the scientific evidence that will inform how best to allocate resources. These researchers will contribute the necessary local expertise and knowledge to thwart pandemics and fight diseases that prevent societies from achieving their full potential. They will also empower nations to more effectively improve the health of their own populations. The Fogarty International Center plays a unique role at the National Institutes of Health (NIH) and in the USG by supporting the development of global health research expertise in the United States and abroad.

NEW INVESTIGATORS, NEW IDEAS

Research advances are more likely occur when investigators study diseases onsite to develop health interventions that are responsive to local and international priorities. Therefore, Fogarty supports long-term research and training partnerships between United States and low- and middle-income country (LMIC) research institutions, which has resulted in the training of more than 5,000 researchers—many of whom contribute to major scientific advances. For example, the first results from a large clinical trial testing candidate microbicides that use anti-retrovirals (ARVs) found that the incorporation of an ARV into a vaginal gel was more than 50 percent protective against HIV infection when used as directed. This advance is a key step toward empowering women with a safe and effective HIV prevention tool. Notably, six of the study's authors are current or former Fogarty-sponsored trainees.

To increase the pool of physicians who have the necessary skills to conduct robust and critical health research, and to support country-driven efforts that enhance the sustainability of gains made under PEPFAR, Fogarty is also administering a major new program called the Medical Education Partnership Initiative (MEPI)—a joint effort of the Office of the Global AIDS Coordinator, HRSA, DOD, USAID, CDC, and NIH. MEPI supports institutions in Sub-Saharan African countries and their U.S. partners to develop new models of medical education, and to strengthen the ability of medical students and faculty to conduct research that responds to the health needs of their countries.

Non-communicable diseases—such as heart disease, stroke, cancer, and diabetes—are in fact the leading causes of worldwide mortality, accounting for 60 percent of all deaths. According to the World Health Organization, 80 percent of this burden is in LMICs, where these diseases affect people disproportionately during their most economically productive years. Fogarty is addressing this challenge through its expanded program on Chronic, Non-Communicable Diseases and Disorders across the

[1] Global Health Council, Washington, DC.

Lifespan, which will support training of in-country scientists to conduct research on these diseases. Given the high burden of non-communicable diseases in the United States, knowledge gained from these research activities can inform domestic efforts to prevent and treat these diseases—particularly in low-resource settings.

Fogarty also supports the training of U.S. investigators to conduct global health research and actively engage in international scientific collaborations. These investments directly respond to the overwhelming demand for global health opportunities on university campuses across the United States, and are helping early career scientists to build long-term relationships and acquire skills that will help to ensure that the United States continues to be a global leader in health innovation.

ENHANCEMENT OF EVIDENCE BASE FOR HEALTH CARE DECISIONS

There is a tremendous gap between scientific advances and health outcomes in the developing world. Therefore, there is an urgent need to bridge the gap between what we know and what we do. Fogarty has expanded support for research training in implementation science, which generates knowledge and methods to better integrate research findings and proven health interventions into health policy and practice.

For example without a significant shift in global prevalence patterns, smoking is projected to cause roughly 8 million deaths annually by 2030; notably, more than 80 percent of these deaths will occur in LMICs. Fogarty's International Tobacco and Health Research and Capacity Building Program addresses the critical role of research and local research capacity in reducing the global burden of tobacco consumption and the need to generate a solid evidence base that can inform effective local tobacco control strategies and health policies. The program supports epidemiological and behavioral research, as well as prevention, treatment, communications, implementation, health services and policy research. In Delhi, India, researchers are testing the efficacy and cost-effectiveness of a community-based behavioral intervention for tobacco cessation among youth living in low-income communities. Such studies can inform efforts to curb adolescent smoking in the United States—particularly in resource-poor settings.

Another example is Fogarty's International Implementation, Clinical, Operational, and Health Services Research Training Award for AIDS and Tuberculosis program, which supports training of scientists and health professionals in developing countries to conduct research-related to implementation of prevention, care and treatment interventions for HIV and/or TB. Researchers supported by this program recently made a significant discovery regarding the treatment of patients with both HIV/AIDS and TB. In these resource-limited settings, a high proportion of patients begin antiretroviral therapy (ART) while on TB treatment, and paradoxical tuberculosis-associated immune reconstitution inflammatory syndrome (TB–IRIS) is a frequent complication of the ART. To address this disease management challenge, investigators in South Africa found that a 4-week course of prednisone reduced the need for hospitalization and therapeutic procedures, and hastened improvements in symptoms, performance, and quality of life—all without excess adverse events.

Fogarty has also partnered with the Bill and Melinda Gates Foundation and the Foundation for NIH on a study that examines the relationship between malnutrition and intestinal infections, and also the consequences of these conditions on various aspects of child health and development. Investigators across multiple international research sites seek to facilitate the design of more targeted, cost-effective interventions that will reduce the burden of child morbidity and mortality from diarrheal diseases. One area of focus is the impact of malnutrition, along with damage to the gut (from repeated and persistent episodes of diarrheal disease), on the effectiveness of childhood vaccines. In many low-resource settings, the immunity conferred by various vaccines is significantly lower than in high-income countries. A better understanding of the links between nutrients and the health and function of the intestinal immune system will likely lead to the development of targeted and modified vaccine formulations and delivery strategies (e.g., dosing, schedules) for improved control of intestinal infections.

TECHNOLOGIES TO ACCELERATE DISCOVERY

With increasing globalization, the need to monitor, diagnose and respond to epidemics has risen dramatically. Since 1998, Fogarty has supported partnerships between the United States and LMIC research institutions to increase the capacity of biomedical scientists to design, access and use modern information technology in support of health sciences research. These partnerships are training biomedical and behavioral scientists, engineers, clinicians, librarians, and other health professionals to access, manage, analyze, and share biomedical information electronically. They

are also training individuals who will be capable of developing new informatics applications. This will increase the ability of local scientists and institutions to conduct multi-site clinical trials and perform international disease surveillance and prevention programs. Several Fogarty-supported informatics projects have now reached new levels of maturity, expanding to form regional networks and leveraging tools and lessons learned to benefit more researchers. For example, a program in Brazil is sharing its materials with Mozambique, where Portuguese is also the national language. Researchers in Peru are building a Latin American training network, and a university in South Africa is forming a consortium to strengthen biomedical informatics throughout Africa.

TRANSLATIONAL SCIENCES AND THERAPEUTICS DEVELOPMENT

Fogarty's International Cooperative Biodiversity Groups program supports natural products drug discovery and ethnomedical and botanicals research. Investigators supported by this program are generating new and exciting leads from natural products that may result in new therapeutics for a range of diseases. For example, a promising new weapon in the war against malaria may come from seaweed found in Fiji, as discovered by Fogarty grantee Dr. Julia Kubanek, a chemical ecologist at the Georgia Institute of Technology. She and her team discovered that a type of red algae in Fiji has strong anti-malarial properties. Animal studies have begun to further explore the compound's potential as a new therapeutic.

In conclusion, to effectively confront complex health issues that transcend national boundaries, more scientific collaborations must be developed and strengthened. Deep regional expertise enables Fogarty to facilitate these scientific collaborations. In the context of advancing science and health, Fogarty seeks opportunities to bridge differences between countries that might otherwise not engage and to build trust by encouraging scientists from around the world to work together to address shared health challenges. These partnerships promote goodwill, stability and peace, and effectively harness science for diplomacy. As the world continues to become more interdependent, international scientific partnerships will play a critical role in building bridges and in improving health for people worldwide. Working in partnership with rest of the NIH, Fogarty's unique programs will continue to enable scientists in the United States and abroad to work together to tackle the most pressing and complex health challenges of our time.

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PREPARED STATEMENT OF DR. KENNETH WARREN, PH.D., DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2012 budget request for the National Institute on Alcohol Abuse and Alcoholism (NIAAA), of the National Institutes of Health (NIH). The fiscal year 2012 budget includes $469,197,000 for the NIAAA, which reflects an increase of $11,304,000 over the fiscal year 2011 level of $457,893,000, comparable for transfers proposed in the President's request.

ALCOHOL AND HEALTHCARE—TRANSFORMING THE LANDSCAPE

NIAAA-supported research is leading to dramatic changes in the understanding of alcohol-related problems and their prevention and treatment across the lifespan. By translating this research into new and better prevention and treatment approaches we have the ability to reduce the heathcare burden due to alcohol and enhance the well-being of individuals, their families, and society-at-large.

SCOPE OF THE PROBLEM

According to the World Health Organization, alcohol is among the ten leading causes of death and disability worldwide; and according to the Centers for Disease Control and Prevention (CDC), alcohol is also a major cause of preventable death and disability in the United States. As the United States. implements healthcare reform, it is important to recognize that alcohol misuse costs our Nation an estimated $235 billion annually.[1]

The consequences of alcohol misuse can affect both drinkers and those around them at all stages of life. NIAAA's National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) estimates that almost 18 million people in the United States. ages 18 and older suffer from alcohol abuse or dependence (collectively known as alcohol use disorders, AUDs). The highest prevalence of alcohol depend-

[1] Rehm J, et al. The Lancet 373(9682): 2223–2233, June 27, 2009–July 3, 2009.

ence, which encompasses a broad spectrum of disease ranging from a single episode of a few years duration to a chronic relapsing disorder, occurs among 18–24 year olds. Of note, more than 85 percent of individuals with an AUD do not have another drug use disorder. Returning war veterans represent a particularly vulnerable population for developing AUDs that co-occur with Post Traumatic Stress Disorder (PTSD) and other mental health problems. Chronic, heavy alcohol use can damage tissues and organs, most notably in the brain, liver, heart, pancreas, and esophagus. According to the CDC, in 2007, alcoholic liver disease accounted for over 14,000 deaths and in 2008 was responsible for nearly 20 percent of U.S. liver transplants.

Alcohol misuse can also have second hand effects, both direct effects of alcohol exposure such as damage to the developing embryo due to drinking by the pregnant mother, as well as indirect effects experienced by individuals other than the drinker such as car crashes, sexual assault, and violence. According to an analysis of NIAAA's NESARC, one in four children grow up in a household where alcohol is a problem, putting them at risk for short and long-term adverse physical and psychological health outcomes.

*Research to Practice*

NIAAA-supported research is increasing our understanding of how to identify and address alcohol-related problems across the lifespan. Research shows that early identification and intervention are key to reducing future health problems and can dramatically reduce healthcare and other costs for individuals who misuse alcohol and those around them.

*The Value of Screening and Brief Intervention*

The medical and economic value of screening and brief intervention (SBI) to identify and address high risk drinking behavior early has been well documented. In fact, according to an analysis in the American Journal of Preventive Medicine, SBI for alcohol misuse was ranked similarly in cost-effectiveness to screening for colorectal cancer and hypertension, and to influenza immunization. Using NIAAA's A Clinician's Guide: Helping Patients Who Drink Too Much, SBI can be performed efficiently and effectively by primary care clinicians. By intervening early, providers are able to offer their patients more appealing, accessible options to address their alcohol problems, options that are less resource intensive and less expensive than those needed to treat more severe forms of dependence. For individuals who want to assess and address their drinking behavior on their own, NIAAA has developed an interactive Web site and booklet, Rethinking Drinking, http://rethinkingdrinking.niaaa.nih.gov. These tools offer evidence-based information about risky drinking patterns, the alcohol content of drinks, and the signs of an alcohol problem, along with other resources to help people who choose to cut back or stop drinking. Tools such as Rethinking Drinking may benefit those who could ultimately recover from dependence without treatment by decreasing the severity and duration of dependence. For others it may provide the motivation to seek professional help.

*Underage and College Drinking*

According to the Substance Abuse and Mental Health Services Administration, more than one-fourth of 16–17 year olds drank in the past 30 days, and 17 percent engaged in binge drinking, i.e. drinking more than five drinks on an occasion. For 18–20 year olds, over one-third engaged in binge drinking in the past 30 days. According to The Surgeon General's Call to Action to Prevent and Reduce Underage Drinking, each year underage drinking results in the death of about 5,000 people under the age of 21 from alcohol-related injuries. This number is equivalent to the incoming freshman class at Virginia Tech, and greater than the total student body at the United States Naval Academy. Given the widespread use of alcohol and high prevalence of binge drinking by children and adolescents, and the link between early alcohol use and later problems including alcohol dependence, it is important to identify children and adolescents who are at high risk for alcohol use and/or alcohol use disorders. NIAAA will soon release an easy to use two question screener and guide for pediatricians and other clinicians who provide medical care to children and adolescents. This empirically based screening instrument is devised to identify children at elevated risk for using alcohol as well as those who have already begun to experiment or are more heavily involved with alcohol. In addition to identifying individuals who need any level of intervention, health practitioners can also use the screening process to provide information to patients and their parents about alcohol's effects on the developing body and brain. In collaboration with other Federal and non-Federal partners NIAAA will implement and evaluate the new guide.

Alcohol use is also a serious public health and safety problem among college students with adverse consequences that range from poor academic performance to al-

cohol poisoning. NIAAA has an ongoing research focus on reducing college drinking and its consequences. Research encompasses both individual approaches, such as screening and brief intervention in college health centers, and environmental approaches including studies on college and community policies. NIAAA has also established a College Presidents Working Group to advise the Institute.

*Exploiting Technology to Improve Treatment*

For those who need treatment, NIAAA seeks to provide more and improved options. Individuals experience alcohol differently, for some it provides almost immediate euphoria, others can drink much higher quantities yet feel relatively little effect. Both types may be at risk for developing alcohol dependence. Clinical trials with alcohol dependent patients testing a variety of medications suggest that, just as their physiological response to alcohol differs, so too does their response to a specific treatment; and genes appear to be responsible, at least in part, for these differences. Given that alcohol dependence is a complex disorder influenced by multiple genes, along with the evidence that specific treatments only work for subsets of individuals, NIAAA continues to seek additional medications that target different molecules and pathways in the brain. A number of medications currently prescribed for other indications are being evaluated as pharmacotherapies to reduce heavy drinking including: the mood stabilizing drug quetiapine, the antiepileptic drug levetiracetum, the smoking cessation drug varenicline and the anti-nausea drug ondansetron. Recently, clinical trials with ondansetron revealed that individuals with specific variations in a gene which encodes the serotonin transporter respond better to treatment than individuals without these variants. Similarly, individuals with a specific variant in the mu opioid gene respond better to the FDA-approved alcohol dependence treatment naltrexone than those lacking the variant. The identification of additional medications, along with the knowledge of what works for whom, will soon make personalized treatment for alcohol dependence a reality. NIAAA's efforts to make testing of compounds more efficient, its active role in engaging the pharmaceutical industry in concert with its willingness to test novel compounds, and its work with the FDA to improve guidelines and methodology for alcohol clinical trials have greatly accelerated the pace of medications development for alcohol dependence.

In parallel, NIAAA is exploiting technological advances in genomics to determine the multiple underlying genetic signatures that contribute to the range and severity of alcohol use disorders. As part of the next NIAAA NESARC, DNA samples will be collected from an estimated 46,000 people for use in genome-wide association analyses. The level and complexity of information derived from new, large-scale, comprehensive genomic studies will facilitate our ability to correlate genetic make-up with subtypes of alcohol dependence improving our ability to match patients with treatments.

Treating the medical consequences of heavy chronic drinking is also a priority. For example, currently liver transplantation is often the only viable option for treating advanced liver disease but it is a prolonged, expensive and risky process only available to patients who maintain abstinence. To expand treatment options, NIAAA is supporting studies to test a number of compounds that target progressive stages of liver disease including fatty liver and liver fibrosis. In addition, seminal research is providing a better understanding of why some individuals develop liver cirrhosis whereas others who consume similar amounts of alcohol do not. Over-activation of the body's natural repair mechanisms may actually promote liver disease, suggesting new targets for prevention and treatment of alcoholic and non-alcoholic liver disease.

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## PREPARED STATEMENT OF STEPHEN I. KATZ, M.D., PH.D., DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2012 budget for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) of the National Institutes of Health (NIH). The fiscal year 2012 budget includes $547,891,000 which is $14,002,000 more than the comparable fiscal year 2011 appropriation of $533,889,000.

### INTRODUCTION

NIAMS addresses diseases that affect individuals of all ages, of all racial and ethnic backgrounds, and across all economic strata; many disproportionately affect women and minorities. Some are rare disorders, but many are very common, and all have a major impact on the quality of people's lives. Twenty-five years of

NIAMS-funded research has contributed greatly to a variety of new treatment and prevention strategies that are reducing the burden the diseases place on individuals, their families, and society.

### LEVERAGING BASIC SCIENCE TO IMPROVE PATIENT CARE

NIAMS research has been the basis for the development and testing of many new medications, including biologic therapies for autoimmune diseases. The newly approved drug belimumab, the first lupus treatment to receive U.S. Food and Drug Administration approval in over 50 years, interferes with a molecule that NIAMS-funded researchers showed to be involved in the immune dysfunction that characterizes this disorder. Other, more recent basic research results suggest another existing drug, omalizumab, may prevent lupus-associated kidney damage. NIAMS investigators in Bethesda, Maryland, are planning to start testing the drug's safety for lupus patients soon.

Basic research into disease mechanisms also is explaining why some therapies do not work as well as expected. In 2003, investigators were baffled when two NIAMS-funded clinical trials showed that combining two medications (a bisphosphonate and parathyroid hormone) that each improve bone mass and prevent fractures did not help people any more than either drug did individually. Eight years later, research into the mechanisms by which bisphosphonates preserve bone revealed that they interfere with parathyroid hormone's bone-forming activity. This discovery can help physicians choose drug regimens that are best for their patients.

### DEVELOPING TOOLS TO DIAGNOSE AND MONITOR DISEASE

Improvements in bone health have underscored the importance of identifying which of the 40 million Americans[1] who have low bone mass are most likely to break a bone. Several large, NIAMS-funded studies have indicated that spine fractures predict both future spine fractures and debilitating hip fractures. Researchers recently published evidence that women who have mild spine defects may also be at risk of hip fractures and could benefit from lifestyle changes or drugs that prevent bone deterioration. However, the ability to distinguish between deformities related to fragile bones and those from other causes is critical. If imaging tools that are under development can make this distinction, clinicians will be better able to predict patients' risk and monitor responses to therapies. Also, the new tools potentially could reduce the cost of clinical trials by allowing investigators to assess a medication's effects relatively quickly.

Other researchers are testing whether a specific type of magnetic resonance imaging can predict worsening of knee arthritis. Preliminary work—using images that are available to the research community through a public-private partnership supported by the NIH and various companies—is promising. If confirmed, clinicians could use the technology to identify patients whose knee cartilage is likely to rapidly deteriorate due to osteoarthritis. Moreover, like the imaging tools mentioned above, the discovery and validation of structural changes that researchers can visualize could lead to shorter, more efficient trials of promising disease-modifying agents that may help the more than 27 million Americans[2] who have osteoarthritis pain in their knees or other joints.

Many diseases within the NIAMS mission involve pain, fatigue, and other difficult-to-measure symptoms. A test to quantify changes in these parameters could enhance clinical outcomes research and, ultimately, clinical practice. NIAMS is one of several NIH components engaged in the Patient-Reported Outcomes Measurement Information System (PROMIS) initiative to develop such a tool. In addition to managing PROMIS on behalf of the NIH, NIAMS encourages researchers to use the resource. For example, NIAMS is funding a study to test questions for fibromyalgia patients, along with information collected through PROMIS, for development of disease-specific measures that allow investigators and healthcare providers to monitor patients more effectively.

### APPLYING GENETICS, GENOMICS, AND OTHER CUTTING-EDGE RESEARCH TO NEW TREATMENTS

Researchers have been trying to determine for decades if pain and itch send different signals to the brain. Difficulties distinguishing the two symptoms at molecular and cellular levels had hindered this effort, but a group of NIAMS investigators finally identified an itch-specific molecule. Their work also illuminated a previously

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[1] Looker AC, et al. J Bone Miner Res. 2010 Jan;25(1):64–71. PMID: 19580459.

[1*] Lawrence RC, et al. Arthritis Rheum. 2008 Jan;58(1):26–35. PMID: 18163497.

elusive mechanism by which the itch message travels through the spinal cord to be perceived by the brain. Such a discovery should pave the way for studies into how chronic itch develops, and make it possible, for the first time, to design better treatments.

Research is providing hope to patients with epidermolysis bullosa (EB), a group of rare, inherited blistering skin conditions. When investigators repaired the genetic defect in an EB patient, NIAMS-funded scientists wondered if gene therapy might also work for another form of the disease. The strategy seemed promising in a mouse model of recessive dystrophic EB (characterized by large, painful blisters, open wounds, and early death due to cancer). A first-in-human clinical trial will begin this year.

NIAMS also is funding a Phase I clinical trial that suggests that a different gene transfer approach may correct the molecular defect underlying type-2 limb-girdle muscular dystrophy (LGMD–2D). The study, supported through one of the Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers, demonstrated that the procedure could safely produce the corrected protein for at least 6 months. The data provide a framework that investigators can use when designing subsequent LGMD–2D clinical trials. Furthermore, researchers can leverage the study's findings about immune responses as they develop gene-based therapies for other diseases.

In the past 12 months, muscular dystrophy researchers also have made considerable progress toward understanding the genetic underpinnings of facioscapulohumeral muscular dystrophy (FSHD). Prior findings from an NIH-funded FSHD patient registry showed that the disease is associated with a shorter-than-normal series of repeated genetic sequences. Recent technologic advances enabled researchers to identify a genetic pattern within these sequences in FSHD patients. This discovery, combined with findings that the defects cause FSHD by activating a gene and allowing its product to accumulate in muscle, are enabling new directions that will accelerate progress. For example, researchers can now engineer animal models of the disease, something that they could not do without a basic understanding of the genes involved.

Like FSHD, many health problems are influenced by complex genetic factors. Over the last few years, the ability of genome-wide association (GWAS) approaches to identify gene variants related to disease risk has matured from an intriguing concept to a widely used scientific tool. These analyses can require thousands of patients, and often entail data sharing among NIAMS-funded researchers and scientists around the globe.

An international GWAS team including researchers at the NIH Clinical Center showed that a gene involved in the body's immune response underlies a person's susceptibility to a painful, inflammatory condition called Behcet's disease, which primarily affects people of Asian, Middle Eastern, Turkish, or European descent. The gene linked to Behcet's disease is associated with other conditions for which treatments exist or are being developed. Because of this connection, therapies might be available sooner than if the investigators had found a completely new disease mechanism.

In the past year, other genetic studies uncovered additional, shared links among diseases. Investigators discovered that rare variants of a gene encoding the enzyme sialic acid acetylesterase are associated with rheumatoid arthritis and type 1 diabetes, and may play a role in other autoimmune diseases. Likewise, researchers leveraging the NIAMS-sponsored National Alopecia Areata Registry found that genes associated with rheumatoid arthritis and type 1 diabetes are linked to the development of alopecia areata, a disease in which the body's immune system attacks the hair follicles and causes hair loss. As with Behcet's disease, the possibility of a common mechanism is particularly exciting because drugs under development for other diseases might also be effective against alopecia areata.

GWAS also holds promise for understanding the genetic differences that give rise to more common diseases, such as osteoporosis. The NIAMS dedicated funds from the American Recovery and Reinvestment Act of 2009 toward developing a resource that investigators can use to identify molecular changes that influence bone health. The discovery of gene variants that protect against osteoporosis or increase a person's risk of having low bone mass is likely to suggest targets that researchers can pursue when exploring new ways to prevent fragility fractures. Moreover, investigators could use genetic markers to identify appropriate participants for clinical trials. Data from this effort is likely to be available to the wider research community at the end of this year.

CONCLUSION

Twenty-five years ago, a few months after Congress passed the Health Research Extension Act of 1985 (Public Law 99–158), the NIH established the NIAMS. Over the past two and one-half decades, the increased emphasis on research on arthritis and musculoskeletal and skin disorders has benefited nearly every household in our Nation. We are proud of the scientific advances that our researchers have made toward helping people who have diseases of the bones, joints, muscles, and skin, and are excitedly looking forward to the discoveries they will make in the future.

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PREPARED STATEMENT OF RODERIC I. PETTIGREW, PH.D., M.D., DIRECTOR, NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2012 budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH). The fiscal year 2012 budget is $322,106,000, which is $8,573,000 more than the fiscal year 2011 appropriation of $313,533,000. This statement is submitted with the recognition of the Department's notification to the Congress of an NIH reorganization that would establish a new National Center for Advancing Translational Sciences and reallocate the remaining portions of the National Center for Research Resources to other parts of NIH, including NIBIB.

The mission of NIBIB is to improve human health by leading the development and accelerating the application of biomedical technologies. NIBIB invests resources in scientific and technological research opportunities at the convergence of the quantitative and life sciences, and in training the next generation of researchers. The Institute is at the forefront of translating scientific advances into engineered medical solutions. Ultimately, NIBIB seeks to realize innovations that address healthcare challenges, reduce disease mortality and morbidity, and enhance quality of life. To accomplish this goal, NIBIB continues to fund bold and far-reaching projects that facilitate discovery and translate basic science into new and better healthcare.

TRANSLATIONAL SCIENCE AND THERAPEUTICS DEVELOPMENT

*Biodegradable Home-Based Vaccination System*.—Influenza is a major cause of morbidity and mortality worldwide. Despite vaccination campaigns, the CDC attributes 36,000 deaths and 226,000 hospitalizations per year in the United States to influenza, with an associated cost of approximately $100 billion per year. The number of cases could be greatly reduced if more people were vaccinated and if the vaccine was more effective. Researchers at the Georgia Institute of Technology are addressing both issues by developing a bio-dissolvable micro-patch that will allow people to vaccinate themselves. The patch is painless, has an application time of just seconds, has no biohazardous waste, does not require refrigeration for storage, and develops an enhanced immune response to flu. The patch combines cutting edge technology and user-friendly simplicity to address this significant public health problem.

*Noninvasive Image-Guided Therapy: Focused Ultrasound*.—NIBIB supports research to develop and promote innovative image-guided therapies. One of these technologies is High-Intensity Focused Ultrasound (HIFU). HIFU is a non-invasive, image-guided and controlled new therapy delivery system which consists of a highly focused beam of high-intensity ultrasound that is capable of ablating tissue in a targeted region of the body, without harming surrounding tissues. Researchers are combining magnetic resonance imaging and HIFU to form an image-guided therapy delivery system for non-invasive tumor ablation, which can either replace or complement surgery or radiation therapy. In addition, transcranial transmission of HIFU can also induce the opening of the blood-brain barrier, which allows delivery of drugs directly to specific locations in the brain. HIFU for treatment of uterine fibroids is now an FDA-approved clinical procedure. These developments could revolutionize surgery, cancer therapy and the delivery of therapeutic agents in new targeted approaches.

*Regenerative Medicine for Wounded Warriors*.—The NIBIB is the lead NIH institute for participation in the U.S. Military's signature Armed Forces Institute for Regenerative Medicine (AFIRM), now in its third year. AFIRM is a multi-institutional, interdisciplinary network to develop advanced treatment options for our wounded servicemen and women. Researchers are addressing many severe medical conditions including burns, compartment syndrome, complex craniofacial injuries, limb/digit salvage, and wound healing.

TECHNOLOGIES TO ACCELERATE DISCOVERIES

*Monitoring Tumor Cells and Cancer Biology*.—NIBIB Quantum Grant investigators have successfully developed a test capable of detecting a single cancer cell among the billions of normal cells in a blood sample. The microchip device, known as the HB-Chip (after the micro herringbone pattern on the chip surface), enables the isolation of rare circulating tumor cells that may be the source of cancer metastasis. Subsequent molecular characterizations of these cells have led to the discovery of several subtypes of prostate, breast, and lung cancer. These subtypes serve as the basis for customized cancer treatments that are tailored to specific patients. The isolation and characterization of circulating tumor cells has the potential to revolutionize the management of care in cancer patients. Recently, Johnson & Johnson announced a partnership with the researchers at Massachusetts General Hospital to further develop and market this blood test. "Stand Up to Cancer," an organization focused on translational cancer research, is supporting four leading cancer centers to launch clinical trials using the HB-Chip to determine the sensitivity and specificity of the device for various cancers.

*Global Technologies for Disease at the Point of Care*.—NIBIB has partnered with the Department of Biotechnology and the Ministry of Science and Technology in India to support the development of low-cost diagnostic and therapeutic technologies that will be used in underserved communities worldwide. As the prevalence of chronic diseases in low-resource settings increases, PATH (Program for Appropriate Technology in Health, a nonprofit organization that improves the health of people around the world) is working on new initiatives to tackle diabetes. NIBIB-supported researchers are evaluating cost-effective technologies to monitor and screen for gestational and type 2 diabetes in India. These technologies are also applicable to rural and low resource settings in the United States and can lead to more effective interventions and therapies.

In the United States, about 500 mothers die every year during childbirth, and in Africa, childbirth-related deaths are nearly 300,000 annually. Many of these deaths could be prevented if these populations had ready access to ultrasound exams, which identify mothers at high risk for birth complications. In addition, cardiovascular disease and abdominal illnesses could be broadly monitored and managed with wide access to ultrasound exams. NIBIB has supported the successful development by GE of a hand-held battery powered portable ultrasound system (VSCAN™) that costs approximately $8,000 but has the features of a conventional hospital or office based system costing approximately $200,000. The broad goal is to make ultrasound imaging as available as stethoscopes, to facilitate earlier detection and monitoring response to therapies.

TECHNOLOGIES TO IMPROVE EVIDENCE-BASED CLINICAL DECISIONS

Patients routinely receive their healthcare at multiple locations ranging from physician's offices to major medical centers. For optimal care, medical records and medical imaging studies must be readily available at different sites. To address the need for sharing of images and to enhance the adoption of evidence and comparative effectiveness in clinical decisions, NIBIB has funded several coordinated projects.

*Patient Controlled Web-Based Access and Sharing of Medical Images*.—A contract with the Radiological Society of North America (RSNA) includes five academic institutions: UCSF, University of Maryland, Mayo Clinic, University of Chicago, and Mount Sinai. Two additional grants provide support to Wake Forest University and the University of Alabama at Birmingham. Each of these projects is developing an approach to patient-controlled medical image sharing systems for secured image sharing among radiologists and clinicians across organizational boundaries. The project at Wake Forest University has a special focus on image sharing in rural and under-served areas. Validation testing of patient health records that can accept images with the appropriate controls and privacy safeguards has begun and will start enrolling patients in the near future.

*On Line Decision Support Systems*.—NIBIB is providing resources to the Brigham and Women's Hospital and the Massachusetts General Hospital to implement information technology systems that include clinical decision support capability. These systems enable the care providers to make clinical decisions that are based on the best available evidence and the patient's comprehensive medical data set, including clinical images.

NEW INVESTIGATORS, NEW IDEAS

*Nanoparticles for Improved Drug Delivery: Overcoming the Mucus Barrier*.—The delivery of bioactive molecules to target tissues can significantly improve drug effec-

tiveness while reducing side effects by concentrating medicine at selected sites in the body. While the barrier properties of mucus provide protection against infection and other potentially toxic particles, they also have thwarted efforts to achieve uniform and sustained drug delivery to mucosal surfaces, and have likely prevented successful delivery of genes that could potentially treat fatal diseases, such as cystic fibrosis. The work of NIBIB grantee Dr. Justin Hanes at Johns Hopkins University seeks to understand the properties of mucosal barriers and use this knowledge to guide the development of polymeric nanoparticulate carriers capable of more efficient drug and gene delivery to the respiratory tract, female reproductive tract, gastrointestinal tract, surface of the eye, and other mucosal tissues for improved therapies. The delivery of bioactive molecules to target tissues can significantly improve drug effectiveness while reducing side effects by concentrating medicine at selected sites in the body.

*Robotic Prostheses for Amputees*.—Despite significant technological advances over the past decade, state-of-the-art transfemoral prostheses are unable to provide power for joint motion. The absence of joint power significantly impairs the ability of these prostheses to restore many locomotive functions, including walking upstairs and up slopes, running, and jumping, all of which require significant net positive power at the knee joint, ankle joint, or both. Dr. Michael Goldfarb, an NIBIB Edward C. Nagy Young Investigator, recently reported the development of the first robotic transfemoral prosthesis with fully powered knee and ankle joints. The device allows above-the-knee amputees to walk 25 percent faster with less energy than is expended with conventional prosthetics and provides increased balance, agility, and recovery reflexes to prevent falls. In April, Freedom Innovations announced a worldwide licensing agreement for exclusive rights to commercialize this device.

The Institute's emphasis on interdisciplinary approaches to biomedical research has provided unprecedented opportunities for collaborations among the life and physical scientists leading to advances in biology and medicine through the quantitative, physical sciences, and engineering perspective, as well as the development of technologies that reflect the translation of biological mechanisms. These advances will produce remarkable improvements in the health of individuals around the world.

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## PREPARED STATEMENT OF ALAN E. GUTTMACHER, M.D., DIRECTOR, EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2012 President's budget request for the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of $1,352,189,000. This reflects an increase of $35,466,000 over the fiscal year 2011 level of $1,316,723,000.

In my short time as NICHD Director, the breadth and importance of the Institute's mission have already impressed me. Our research changes clinical practice and improves health for many people, particularly those who may be under-represented in medical research—pregnant women and their offspring; adolescents; and people with intellectual, developmental, and physical disabilities. Our research shows that even simple approaches can have significant impact. For example, a recent study found that an inexpensive program teaching newborn care to Zambian midwives reduced deaths in the first week of life by 40 percent. Today, I would like to highlight a few other examples of NICHD's recent progress toward improving health, and describe a new effort to position our research to continue to contribute to a healthier Nation and world.

### IMPROVING HEALTHCARE FOR WOMEN AND CHILDREN

Thanks partly to NICHD research, Centers for Disease Control and Prevention (CDC) data show that the preterm birth rate in the United States declined for the second year in a row in 2008. Still, 12 percent of all pregnancies end in preterm birth, a leading cause of infant death in our country. Preterm infants have greater risk for breathing problems, life-threatening infections, cerebral palsy, and developmental disabilities. In recent years, NICHD research showed that treating pregnant women with a prior history of preterm birth with a type of progesterone reduced their risk of another preterm delivery. Now, a new study shows that a vaginal gel containing another type of progesterone substantially reduces the risk of premature delivery in women with a short cervix. With adoption of such treatments, the preterm birth rate should drop further.

Spina bifida, which occurs when the fetal spinal column does not close properly, affects nearly 1,500 U.S. infants a year, according to the CDC. The most common and severe form of spina bifida, myelomeningocele, can cause paralysis, problems

with nerve function, and brain damage. Recently, the NICHD reported an important trial, the Management of Myelomeningocele Study (MOMS). MOMS researchers compared standard surgical repair of the spinal cord after birth to repair while the fetus is in utero. They found that repairing the spinal cord in the womb greatly reduced risk of death and the need to divert fluid from the brain. It also doubled the chance of walking and improved later motor and cognitive development. Infants undergoing prenatal surgery, however, were also more likely to be born preterm, and their mothers more likely to experience a uterine tear in childbirth. While researchers continue to study this specialized surgery, the initial findings promise to improve the quality of life for thousands of children.

New findings also can improve healthcare for women: NICHD researchers recently showed that women's cholesterol levels correspond with monthly changes in estrogen levels. On average, the total cholesterol level of the women studied varied 19 percent over the course of the menstrual cycle. Although previous data showed that estrogen-containing oral contraceptives or menopausal hormone therapy could affect cholesterol levels, this was the first study to show conclusively that the cyclical levels of naturally occurring hormones have similar effects. This natural variation suggests that clinicians should consider the phases of a woman's monthly cycle when evaluating her cholesterol levels and before prescribing treatment to help protect women against heart disease.

### NEW TECHNOLIGES ADVANCE HOPE FOR AUTISM AND PARKINSON'S

Autism spectrum disorder (ASD) encompasses a range of conditions involving impaired social interactions and communication, atypical behaviors, and health problems. While ASD is known to have genetic components, researchers have not identified a consistent pattern of variant genes. In fact, dozens of gene variants, along with other factors, are now linked with ASD, complicating, but also advancing, our understanding of the condition and ability to develop new treatments. Using advanced imaging technology, NICHD-supported researchers identified a gene that impairs communication between parts of the brain. Additional genetic studies may reveal ASD subtypes and how certain genes function and interact with each other. This research could help individualize treatments based on a child's genetic profile. New technologies also hold promise for other neurologic conditions, such as Parkinson's disease, which results from a loss of brain cells that help coordinate movement. NICHD-supported researchers injected stem cells from the endometrium (lining of the uterus) into the brains of mice with a laboratory-induced form of the disease. These new cells took over the function of the brain cells eradicated by Parkinson's. This is the first time that scientists showed endometrial stem cells could assume the properties of the tissue into which they were transplanted. Since endometrial stem cells are widely available, this suggests that women with Parkinson's disease might serve as their own stem cell donors, or healthy endometrial stem cells might be stored and later matched to individuals with the disease.

### TRANSLATING SCIENCE TO ADVANCE REHABILATION

Applying basic scientific findings to clinical problems can help scientists develop new diagnostics or therapeutics for many conditions. For instance, NICHD researchers seeking to understand how the vitamin folate is metabolized found that the vitamin appears to promote healing in rats with damaged spinal cord tissue. Up to 20,000 people yearly suffer a spinal cord injury, and about 200,000 people currently live with such injuries, according to the National Center for Injury Prevention and Control. Folate, a B vitamin that naturally occurs in leafy green vegetables and other foods, plays an important role in early embryonic brain and spinal cord development. Further translational studies on folate could lead to new techniques to help regenerate nerve fibers and heal damaged nervous system tissue.

### THE NATIONAL CHILDREN'S STUDY (NCS)

The NCS is designed to examine the effects of genetic factors and a broad range of environmental factors such as physical environment and family, community, and cultural influences on the development and health of children in the United States over time. The NCS will yield a rich repository of environmental and genetic/genomic data and biospecimens that can be mined by scientists for years to come and help answer questions concerning the earliest origins of health and disease. Over the past year, the NCS has been in a pilot phase, known as the "Vanguard Study," enrolling about 650 children in 37 sites as of February 2011. Three separate recruitment strategies are being tested to optimize participation and cost management. During the coming year, a range of experts will review ongoing findings, al-

lowing staff to develop, by late summer 2011, evidence-based cost-estimates and recommendations for the initial phase of the Main Study.

VISION FOR THE FUTURE

The NICHD has embarked on crafting a vision for the future that inspires the institute and its partners to achieve critical scientific goals and meet pressing public health needs. In early 2011, in a series of workshops, we asked leading scientific and health experts to identify what the scientific future should look like in 10 years and what knowledge must be obtained to reach these new frontiers. We focused on such areas as plasticity, development, cognition, behavior, reproduction, pregnancy and pregnancy outcomes, developmental origins of health and disease, environment, and diagnostics and therapeutics. Resultant white papers are posted on our website for additional public comment. In June, we will assemble another diverse group of experts to refine these concepts and identify those that are most promising. We will publish the final vision document by early 2012, helping to ensure that NICHD addresses the most important science for the Nation's women, children, families, and individuals with special needs.

Mr. Chairman and members of the Committee, thank you for your continued support of NICHD's important work. I would be pleased to respond to any questions.

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PREPARED STATEMENT OF NORA VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2012 budget request for the National Institute on Drug Abuse (NIDA). The fiscal year 2012 budget of $1,080,018,000 includes an increase of $30,377,000 over the comparable fiscal year 2011 level. The following statement updates NIDA's scientific progress in addressing drug abuse and addiction. These public health problems cost our society more than $600 billion annually in health- and crime-related costs and losses in productivity, not to mention incalculable personal and social devastation (ONDCP 2004; Rehm et al. 2009; CDC 2007). NIDA has crossed a threshold into a new research era, unprecedented in its scope, and transformative in its prevention, treatment, and policy implications for substance use disorders (SUDs).

RETURN ON INVESTMENT: TECHNOLOGIES TO SPEED DISCOVERY

New technologies and scientific breakthroughs continue to generate actionable information about the genetics, chemistry, and circuitry of the human brain. This knowledge has dramatically enhanced our understanding of the underlying vulnerabilities and the long-term effects of addiction on neurophysiology and behavior. Continuing advances in DNA sequencing and analytical tools have transformed the landscape of genomic exploration. For example, we can now engage in high resolution and accurate sequencing of vast genomic tracts, from many different individuals, to systematically search for and identify addiction risk variants, which may open up new targets for medications. Also, we are dissecting the epigenetic processes that can affect gene expression through persistent but reversible changes. Epigenetics research has started to help explain the deleterious impact of known environmental risk factors, like poverty or chronic stress, on vulnerability for SUDs. The burgeoning availability of genetic, epigenetic, and environmental data heralds new opportunities for translational applications. NIDA is committed to optimizing this potential through harmonization efforts that help ensure the comparability of pooled data.

Harmonized databases are crucial for individualized medicine. This is clear in the genomics field, but also in the emerging field of globally connected biomarkers, or the "human connectome," and for brain imaging. NIDA is supporting research to develop biomarkers to screen for drug exposure and addiction vulnerability that would be more accurate, reliable, and sensitive than current tests (i.e. bodily fluids, hair, questionnaires) and would help transform the way SUDs are identified and treated.

Other innovations, such as wireless remote sensing and virtual technologies, offer opportunities for transforming how prevention messages, real-time monitoring, and even some treatment modalities are delivered to the public. Having real-time, objective measures of drug use could have a huge impact on SUD treatments. One example is remote physiological monitoring (RPM), a rapidly evolving form of telemedicine that can track patients' health status (e.g., heart rate, blood pressure, skin temperature, and glucose levels) remotely, using devices that can store and transmit the results in real-time. NIDA is supplementing studies on the use of RPM for moni-

toring drug use to evaluate the effects of treatment interventions and their relationship to clinical outcomes. Such data could support the establishment of non-abstinence endpoints, which in turn could inform the Food and Drug Administration (FDA) addiction medications approval process.

EMERGING PSYCHOACTIVE THREATS TO PUBLIC HEALTH

The past few years have witnessed several alarming trends, particularly prescription drug abuse. Although opioid analgesics are among the most effective medications for pain management, they are also associated with serious and growing public health problems, including drug abuse, addiction, and overdose deaths. The Substance Abuse and Mental Health Services Administration reports a six-fold increase in treatment admissions for opioid analgesics, from nearly 20,000 in 1998 to about 120,000 in 2008, while the Centers for Disease Control and Prevention acknowledge that unintentional poisonings involving opioid analgesics have more than tripled from 1999 through 2007, exceeding the total number of deaths involving heroin and cocaine. These trends illustrate the challenge of balancing access to critical medications for those who need them and preventing their abuse, particularly when the public does not perceive their dangers and has much greater access to them from a decade-long surge in availability. In 2009, 202 million opioid prescriptions were dispensed in the United States making opioids the most prescribed class of medications. NIDA is committed to helping reverse this trend by providing information on the patterns and motivations behind their abuse, sponsoring research on developing pain medications with less abuse potential, and creating curricula to minimize diversion through better prescribing practices.

Lingering public misperceptions, particularly among youth, continue to hinder our marijuana prevention efforts. The latest Monitoring the Future survey of 8th, 10th, and 12th graders reveals that daily marijuana use is up for all grades. These teens are not only at higher risk of becoming addicted, but they are functioning below optimal level at a time when their future depends on peak cognitive performance. Why is this happening now? We do not know for sure, but it is reasonable to infer that the public debates surrounding medical marijuana have increased confusion and lowered the perception of risk, an important factor in curtailing use.

Meanwhile, new drugs routinely emerge and gain rapid notoriety thanks to the Internet. Recent examples include "bath salts" and "spice," which are synthetic stimulants and cannabinoids, respectively.

IMPROVING PUBLIC HEALTHCARE—DELIVERY AND PERFORMANCE

NIDA will continue to leverage our knowledge base into better strategies for battling addiction. To further this goal, NIDA takes advantage of collaborative research infrastructures designed to deploy proven strategies rapidly and effectively. For example, NIDA's Drug Abuse Treatment Clinical Trials Network (CTN) tests evidence-based treatments in community settings with diverse patient populations, optimizing the utility and cost-effectiveness of treatments and fostering their adoption. Similarly, NIDA's Criminal Justice-Drug Abuse Treatment Studies (CJ–DATS) network promotes multilevel collaborations to bring proven treatment models into the criminal justice system, disproportionately affected by both drug abuse and HIV. These infrastructures allow for the broad testing of promising new strategies. One example, called "Seek, Test, and Treat," has great potential to improve the public health by expanding access to HIV testing and treatment, and ultimately reducing HIV spread.

Another cornerstone of our strategy is to engage physicians as "frontline" responders to patient substance abuse, providing the science-based tools they need to identify potential substance abuse in their patients and offering better options for treatment. Recent research shows, for example, that compared with methadone, buprenorphine results in fewer neonatal abstinence symptoms among babies born to opioid-addicted mothers, and is associated with decreased hospital stays and thus, costs. To bolster education in the treatment of pain, NIDA is leading a multi-Institute effort to create Centers of Excellence (CoEs) to develop curricula for medical students, nurses, resident physicians, and others. Part of our NIDAMED physician outreach initiative, CoEs have also developed and are helping to disseminate substance abuse training curricula, woefully neglected in most medical training. NIDA continues to encourage physician screening of drug abuse with the help of a Web-based interactive screening tool that generates clinical recommendations. The broad availability of these resources is an important step toward integrating substance abuse screening, brief intervention, and referral to treatment (SBIRT) into medical care, which will enable better healthcare decisions and outcomes.

TRANSLATION—THERAPEUTICS DEVELOPMENT

To help those affected by the disease of addiction, we need to expand the pharmacological and behavioral tools available to treat SUDs. Thus, medications development is one of the main areas that benefits from new discoveries. For example, the century-old practice of vaccination has recently been found to be a viable approach for treating addiction. In this case, the body itself is coaxed to produce antibodies that bind a drug while still in the bloodstream, blocking its psychoactive effects in the brain. Already, a nicotine vaccine that reduces craving and withdrawal symptoms is in advanced stages of development and will be market-ready following approval by the FDA. Another strategy has been the development of long-acting, or depot, formulations of medications that serve to overcome poor compliance. One example is Vivitrol, an extended-release opioid antagonist (naltrexone), recently FDA-approved for treating opioid addiction. NIDA is now testing the use of depot medications in high-risk groups, such as criminal justice offenders, and in regions of the world that have high rates of HIV infection and are resistant to treatment with opioid agonist medications.

In parallel, NIDA is supporting research on drug combinations, an effective strategy for treating many diseases (e.g., HIV/AIDS, cancer) and one starting to show success with addiction. For example, the combination of lofexidine (a hypertension medication) and marinol (a synthetic form of marijuana's THC) shows promise in treating withdrawal symptoms among marijuana-addicted individuals. Early results also suggest that a buprenorphine-naltrexone combination could be effective in treating cocaine addiction.

NEW INVESTIGATORS, NEW IDEAS

To help sustain our commitment to the next generation of biomedical research scientists, NIDA supports multiple training initiatives at various career levels and areas of need (e.g., physician scientists, computational neuroscience, and medicinal chemists). Examples include efforts aimed at mentoring minority investigators and international HIV/AIDS researchers, as well as multi-Institute training programs. To identify and encourage the next generation of addiction scientists, NIDA also awards special prizes at the annual Intel International Science and Engineering Fair to high school students whose projects exemplify excellent achievement in addiction science.

In closing, NIDA pledges to continue to tackle the emerging and significant public health needs related to drug abuse and addiction, taking advantage of unprecedented scientific opportunities to close the gaps in our knowledge base and develop and disseminate more effective strategies to prevent and treat drug abuse and addiction.

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PREPARED STATEMENT OF JAMES F. BATTEY, JR., M.D., PH.D., DIRECTOR, NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Mr. Chairman and Members of the Subcommittee: I am pleased to present the President's budget request for the National Institute on Deafness and Other Communication Disorders (NIDCD) of the National Institutes of Health (NIH). The fiscal year 2012 NIDCD budget of $426,043,000 includes an increase of $11,244,000 over the comparable fiscal year 2011 appropriation of $414,799,000. This statement is submitted with the recognition of the Department's notification to the Congress of an NIH reorganization that would establish a new National Center for Advancing Translational Sciences (NCATS).

The NIDCD conducts and supports research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech, and language. Our Institute focuses on disorders that affect the quality of life of millions of Americans in their homes, workplaces, and communities. The physical, emotional, and economic impact for individuals living with these disorders is tremendous. NIDCD continues to make investments to improve our understanding of the underlying causes of communication disorders, as well as their treatment and prevention. It is a time of extraordinary promise, and I am excited to be able to share with you some of NIDCD's ongoing research and planned activities on communication disorders.

AFFORDABLE HEARING HEALTHCARE

Hearing loss is a serious public health issue and has significant social and economic impacts. Approximately 17 percent of American adults, or 36 million individuals, report a hearing loss, and only about one in five of those individuals who could

benefit from a hearing aid wears one. Additionally, hearing healthcare and hearing aids are only rarely covered by health insurance, and are not covered by Medicare. A recent industry survey found that the average cost per hearing aid to an individual is $1,600, and for many, the cost is much higher. Hearing aids are also consumable devices, often requiring replacement every 4–6 years, and frequent battery replacement. This makes hearing aids potentially the third highest cost item for an individual, following just behind the purchase of a home and car. In 2009, NIDCD sponsored a workshop, Accessible and Affordable Hearing Health Care for Adults with Mild to Moderate Hearing Loss, to examine the factors that contribute to hearing healthcare access, affordability, and usage; and to develop a set of research objectives which could be explored in the future. Based on the recommendations, NIDCD published several targeted research initiatives for hearing healthcare: to explore new approaches that could lead to improved access, assessment, and intervention; to develop methods to determine the success of new or improved approaches; and to create small business technologies to improve access for underserved patients. The research supported through these and other NIDCD-sponsored efforts will enhance the evidence-base for hearing healthcare decisions, and provide a strong research base for future policy decisions related to affordable hearing healthcare.

TINNITUS

Tinnitus—a perceived ringing, buzzing or roaring in the ears—is a major public health concern, affecting more than 25 million American adults. It can range in severity from a mild condition, requiring no medical intervention, to a severe debilitating disease with significant physical, emotional, and economic impacts. The Department of Veterans Affairs reports tinnitus as the most prevalent service-connected disability for veterans receiving disability compensation. More than 744,000 veterans received service-connected disability compensation for tinnitus in fiscal year 2010, presenting a significant cost burden for the Nation. Past research has shown that tinnitus is often associated with hearing loss; however, little is known about the specific neural dysfunctions that lead to the disorder. There are also limited treatment options available, and their effectiveness varies widely. In response to this need, NIDCD is supporting a strong research portfolio on tinnitus. In 2009, NIDCD sponsored a research symposium, Brain Stimulation for the Treatment of Tinnitus, to explore the potential translation of existing brain stimulation technologies for the treatment of tinnitus. Recently, NIDCD supported scientists have demonstrated that stimulation of the vagus nerve (a large nerve that runs from the head to the abdomen) with an implantable electrode, in combination with the playing of tones, is able to "reset" the brain, eliminating tinnitus in a rat model of the disease. (Vagus nerve stimulation is already in use for the treatment of epilepsy and depression in more than 50,000 individuals). By varying the tones played and the co-stimulation of the vagus nerve, scientists were able to abolish the tinnitus sensation and restore the normal function of the brain. These exciting findings are the first demonstration of a treatment that specifically erases the tinnitus, rather than simply masking the sound or providing coping mechanisms for the individual. Scientists are now working to translate these findings from the animal model into a novel therapeutic strategy for people with severe tinnitus.

VESTIBULAR PROSTHESIS

Based on the recent 2008 National Health Inventory Survey, Balance and Dizziness Supplement, about 15.5 percent of U.S. adults, or about 33.6 million individuals, reported they had a problem with dizziness or balance in the past 12 months. Balance disorders are one of the reasons older people fall, and falls and fall-related injuries, such as hip fracture, can have a serious impact on an older person's life. One balance disorder which has been particularly difficult to treat is Ménière's disease. This disorder causes severe dizziness (vertigo), tinnitus, hearing loss, and a feeling of fullness or congestion in the ear. NIDCD estimates that approximately 615,000 individuals in the United States are currently diagnosed with Ménière's disease and that 45,500 cases are newly diagnosed each year. While many individuals are able to manage the symptoms associated with Ménière's disease through diet, drugs, or surgery, up to 2 in 10 do not find adequate relief from their symptoms after exhausting all treatment options. NIDCD-supported scientists are working to adopt cochlear implant technologies to produce a vestibular implant that could counteract vertigo attacks that persist despite other treatments. Scientists have already demonstrated the ability of a vestibular implant to induce, and provide recovery from, vertigo attacks in animal models of Ménière's. Most recently, scientists have translated this technology to humans and performed their first implantation into an

individual. While clinical trials are still several years away, this recent breakthrough provides hope to many for whom traditional treatments have failed.

STUTTERING

The popularity of the recent Academy Award winning movie, "The King's Speech," has brought to light the communication challenges faced by approximately 3 million Americans each day. Stuttering can affect individuals of all ages, but occurs most frequently in young children between the ages of 2 and 6, with boys 3 times more likely than girls to stutter. Most children, however, outgrow their stuttering, and it is estimated that less than 1 percent of adults stutter. For those individuals who continue to stutter into adolescence and adulthood, there are limited treatment options. NIDCD supports a research portfolio on stuttering to understand the underlying genetic, neurologic, and physiologic causes of stuttering, to predict which children will continue to stutter, and to develop novel and effective therapies for treatment of stuttering. Recently, NIDCD intramural scientists pinpointed the first specific genes that underlie stuttering. Building on previous studies which identified a genetic region linked to stuttering, and harnessing new technologies in genetic sequencing, the researchers found mutations in three genes important in the recycling of cellular breakdown products inside cells. Different mutations in two of these genes are related to severe metabolic disorders, called mucolipidosis II and III, which cause joint, skeletal, heart, liver, and other health problems, including speech problems. The findings may result in the development of new drug therapies for individuals who stutter.

OLFACTORY DEFICITS EARLY WARNING OF ALZHEIMER'S DISEASE

For several years, it has been know that individuals with Alzheimer's disease (AD) often exhibit an impaired sense of smell (olfaction), making a smell screening test an attractive opportunity for development as a biomarker of disease. However, it was not known why AD impacts olfaction. Recently, NIDCD-supported scientists used a mouse model of AD to identify pathological changes in the olfactory system very early in the animals' lives, indicating a sensitivity of the olfactory system to this type of damage. These changes manifested well in advance of the onset of changes in other areas of the brain involved in memory, and were predicted by the animals' performance on a smell discrimination task. In addition, NIDCD-supported scientists have used brain imaging of humans to examine changes in brain activity during smell discrimination tasks. These imaging studies have identified a significant blunting of response in individuals with AD. Both of these discoveries could lead to new, non-invasive tools to enhance the early diagnosis of AD, and better inform healthcare decisions for affected individuals.

NEW STRATEGIC PLAN FOR NIDCD

NIDCD has initiated the development process for a new Strategic Plan. In March 2011, NIDCD convened a series of working groups of scientific experts in the smell and taste; voice, speech, and language; and hearing and balance fields to advise us on emerging scientific opportunities in four priority areas: understanding normal function of communication systems; understanding diseases and disorders of communication systems; improving diagnosis, treatment, and prevention of communication disorders; and accelerating translation of research findings into practice. In addition, we remain committed to continuing our leadership in fostering the development of new investigators in the communication sciences. Our staff is currently working to compile these priority areas into a document that will guide our research investments from fiscal year 2012 through 2016. A draft will be made available for public comment later this year and we anticipate publication of our new Strategic Plan in January 2012.

Mr. Chairman, I would like to thank you and Members of this Subcommittee for giving me the opportunity to present examples of recent research progress and to highlight some programs made possible through your support of the NIDCD.

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PREPARED STATEMENT OF DR. A. ISABEL GARCIA, D.D.S., M.P.H., DIRECTOR, NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Dental and Craniofacial Research (NIDCR) of the National Institutes of Health (NIH). The fiscal year 2012 budget request for NIDCR is $420,369,000, which reflects an increase of $11,113,000 over the

fiscal year 2011 enacted level of $409,256,000 comparable for transfers proposed in the President's request.

The NIDCR goal of improving the Nation's dental, oral, and craniofacial health is an ambitious one. It demands that we address the wide array of diseases and conditions that affect the oral cavity and craniofacial structures, including diseases such as dental caries (tooth decay) and periodontal diseases that are endemic in the United States, as well as birth defects such as cleft lip and palate, chronic oral-facial pain conditions, oral and pharyngeal cancers, and oral manifestations of systemic diseases, such as Sjögren's syndrome, diabetes, and HIV infection. NIDCR is committed to identifying effective preventive, diagnostic, and treatment approaches for these diseases and conditions. Today, I will describe how we are investing in basic discovery and preclinical studies across these myriad areas and applying new knowledge to the development of clinical trials and studies in humans.

ACCELERATING BASIC DISCOVERY

Joshua Lederberg, who shared the 1958 Nobel prize for discovering that bacteria can mate and exchange genes, once quipped about microbes that "you know one when you see it." The problem, he explained, is that microbes were largely "invisible" and noticed only after their damage had been wrought. NIDCR-supported researchers and others recently identified—made "visible"—more than 600 distinct microbial species as residents of the human mouth. NICDR scientists are also systematically exploring how the individual bacterial species assemble into biofilms. Biofilms are the living, mat-like microbial communities found on many parts of the human body, including our teeth and gums, and play a major role in the development of dental and oral disease.

Microbial biofilms can form on any surface, including on medical devices, and are implicated in more than 80 percent of human infections. The oral cavity offers tremendous potential both as a diagnostic window and an easily accessible model for research aimed at understanding the host of bacteria associated with biofilm-mediated disease throughout the body. Researchers now possess the tools to extract a biofilm sample and determine the identities of most of its microbial inhabitants.

Recently, NIDCR grantees devised a new fluorescent imaging system that successfully distinguished among 28 oral microbes within a single field of view and that soon will be able to distinguish among at least 100, providing spatial analysis in three dimensions. Enhanced imaging of the oral biofilm will accelerate discovery in studies of biofilm formation, organization, and composition and thus the keys to their control. This structural understanding will form the basis for research aimed at development of tools to combat oral and other infectious diseases and improve health.

An NIDCR grantee and colleagues recently performed a novel type of systematic genetic analysis to better elucidate microbial behavior. The researchers collected over 4,000 mutant bacterial strains and tested them in 324 different environmental conditions. Pulling all the data together, the scientists gained a fuller understanding of the functional molecular networks governing bacterial response. They also gleaned new information about a gene involved in antibiotic resistance and the synergy of three common antibiotic drugs.

Both of the exciting advances described above were spearheaded by young investigators on NIDCR training grants, offering prime examples of the vital importance of continuing to support new investigators and new ideas. NIDCR is committed to developing and strengthening the workforce of researchers that can leverage the latest tools of discovery and are dedicated to solving urgent problems in oral, dental and craniofacial health. To enhance this critical pipeline further, NIDCR continues to create innovative new training and career programs, such as a new transition path for clinical researchers, as well as an initiative to catalyze the formation of multidisciplinary teams led by new investigators researching temporomandibular disorders and orofacial pain.

TRANSLATING BASIC SCIENCE INTO IMPROVED PUBLIC HEALTH

Advances in studying oral microbial communities have the potential for rapid impact on research for new, more personally targeted, clinical treatment. A team of NIDCR-supported scientists recently reported that a microbe called Scardovia wiggsiae appears to be linked with severe forms of early childhood caries (ECC), the most prevalent chronic childhood disease in the United States. For decades, the oral bacterium Streptococcus mutans has been singled out as the primary pathogen involved in ECC. The scientists found that S. wiggsiae often was present in children with decayed teeth in the absence of S. mutans. The discovery of this bacterium's

role in ECC offers a future target in efforts to identify children at risk and to prevent or stop progression of this disease before it leads to destruction of the teeth.

The burden of craniofacial, oral, and dental disease, particularly untreated disease, falls heaviest on lower socioeconomic status (SES) groups, which include disproportionately large numbers of racial and ethnic minorities. Researchers, including those at the five NIDCR-supported Centers for Research to Reduce Disparities in Oral Health, continue working to identify creative, practical approaches to deal with pressing oral health issues, including ECC and oral and pharyngeal cancer. These approaches must be inexpensive, easily applied, and readily tailored to meet individual and community needs. Three of these Centers recently initiated clinical trials to test new interventions to prevent ECC among American Indian and Hispanic children and in residents of public housing. Children in low SES families are particularly vulnerable to ECC's painful and costly impact. Three additional trials will launch in fiscal year 2012.

ENHANCING THE EVIDENCE BASE FOR ORAL HEALTH CARE

Tackling real-world clinical issues and generating evidence that will be of immediate value to practitioners and patients is the central goal of the NIDCR-supported dental Practice-based Research Networks (PBRNs). Conducting research in dental practices draws on the experience and insight of practicing clinicians to help identify and frame research questions. Because PBRN studies address practice-based problems, their results tend to be more quickly translated into daily clinical care.

Leveraging the infrastructure of established dental practices for conducting PBRN studies also can be a powerful and cost-effective means to conduct clinical research. For example, the past decade brought reports that people who take bisphosphonates, a class of drug prescribed for osteoporosis or to treat the bone-wasting effects of cancer, can develop osteonecrosis (bone death) of the jaw, or ONJ. To address the problem, the three regional PBRNs, taking advantage of their presence in practices spanning multiple States, teamed up to carry out a collaborative study on ONJ. The study results, published in 2010, confirmed that bisphosphonate use is a risk factor for ONJ, and provided additional important evidence to guide clinicians in their treatment of this challenging condition.

In fiscal year 2012, NIDCR will launch a new National Dental PBRN. This single network, more national in scope and more representative of a greater variety of practice settings, will provide a framework to study and improve the delivery of oral care and will build upon the collaboration among the regional networks that was crucial to the successes to date. Critical to this effort is an improved capacity to collect data electronically. Using an adaptable electronic platform for enhanced connectivity, data sharing, and communication within and between networks will help providers conduct research effectively and efficiently and strengthen the PBRN enterprise.

DEVELOPING NEW CLINICAL TREATMENTS

Each year, about 400,000 people worldwide are diagnosed with cancer in the head and neck region. In an effort to identify new treatments and improve the stagnant 5-year survival rate that hovers only slightly above 50 percent, NIDCR scientists focused their research on the immunosuppressive drug rapamycin. This research is now moving from the basic and preclinical phases, which included studies in an NIDCR-developed mouse model, to clinical studies. By fiscal year 2012, scientists will be recruiting subjects for a clinical trial to assess rapamycin's safety and efficacy in humans.

Research is also needed to combat harmful treatment side effects for head and neck cancers. Many patients with head and neck cancers will receive radiation therapy, which has the significant long-term side effect of xerostomia (dry mouth). The salivary glands, damaged by the radiation used to kill nearby tumor cells, can become less permeable to the fluid that naturally flows through them and yield less saliva, or stop working altogether. Many functional and quality-of-life problems occur when oral tissues are deprived of saliva's protective properties, including difficulty chewing and swallowing, burning mouth, and greater risk of dental caries and oral fungal infections. Despite continuing efforts to eliminate this problem, many patients continue to suffer.

Moving from bench to bedside, NIDCR scientists began the first gene-transfer study in people with radiation-induced xerostomia. The transferred gene, Aquaporin-1, encodes a protein that conveys fluid by forming pores, or water channels, in the cell membrane. The study assesses whether the transferred gene will open water channels in the duct cells, allowing the rapid movement of water through the duct. In fiscal year 2012, NIDCR will issue an initiative to stimulate

additional research on restoring damaged salivary gland structure and function to complement this important clinical advance.

As these highlights illustrate, NIDCR has made a strong commitment to advancing oral health science through efforts in the laboratory, in training sites, in dental practices, and in the community. This investment is providing new tools and scientific approaches that may greatly accelerate the next breakthroughs in oral health research. NIDCR will continue to support research that provides new and exciting leads that can translate into better ways to prevent, diagnose, and manage oral, dental, and craniofacial diseases and disorders. In so doing, NIDCR seeks to improve the oral health of the Nation.

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PREPARED STATEMENT OF LINDA S. BIRNBAUM PH.D., D.A.B.T., A.T.S., DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES AND HEALTH SERVICES

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2012 budget request for the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH). The fiscal year 2012 budget includes $700,537,000; an increase of $17,400,000 over the comparable fiscal year 2011 enacted level of $683,137,000, comparable for transfers proposed in the President's request.

INTRODUCTION

Good health is vitally important for all Americans, and it depends on a clean and safe environment. Currently, our healthcare system expends huge resources controlling a variety of diseases and dysfunctions that are known to be at least partially connected with environmental exposures: asthma, cancer, developmental disabilities, neurological/cognitive deficits, heart attack, and many others. Preventing these diseases through prevention of adverse environmental exposures could make an enormous difference in reducing healthcare costs. At NIEHS, and through NIEHS-funded projects in research institutions across the United States, we are bringing all the tools of biomedical science to bear on the fundamental questions of the effects of environmental exposures to toxic substances on biological systems. Environmental health science is advancing at a tremendous rate and new tools—genetics, genomics, proteomics, metabolomics, informatics, and computational biology, just to name some of these new disciplines—give us new insights on how environmental effects happen in our bodies. They also point the way toward technologies and testing procedures to provide better and more timely information for the use of our agency partners who are responsible for policy decisions and regulations.

ADVANCES IN TOXICOLOGY AND EXPOSURE ASSESSMENT

With our rapidly increasing understanding of the subtleties of biological effects of environmental exposures, we are moving toward a new kind of toxicological testing that is less expensive and time-consuming than our current methods, and also gives us an improved understanding of the actual effects on humans. Toxicology is becoming a more powerful predictive science focused on making target-specific, mechanism-based, biological observations. Alternative assays are targeting the key pathways, molecular events, and processes linked to disease or injury and incorporating them into a research and testing framework. Our National Toxicology Program (NTP) at NIEHS is laying the foundation for this new testing paradigm in partnership with the National Human Genome Research Institute, the Environmental Protection Agency, and the Food and Drug Administration. We are using quantitative high-throughput screening assays to test a large number of chemicals. The resulting data are being deposited into publicly accessible relational databases. Analyses of these results will set the stage for a new framework for toxicity testing.

The NIEHS-led Exposure Biology Program (EBP), part of the NIH Genes, Environment and Health Initiative, has resulted in the development of dozens of new technological advances for personalized measurement of environmental exposures. At a recent workshop, EBP investigators presented their prototypes: miniaturized personal monitors for black carbon and other air pollutants; a wearable nanosensor array for real-time monitoring of exposure to diesel and gasoline exhaust; a personal aerosol sensor platform to link children's exposures to asthma severity; personal exposure assessment systems for chemical toxicants; gene expression biomarkers of airway response to tobacco exposure; and biomarkers of organophosphate-linked proteins. One prototype of a continuously operating wearable badge that provides real-time measurements of chemical toxicants has attracted subsequent R&D funding from the Department of Defense to develop this model for use by military personnel.

Others are being moved into validation studies as a next step toward their deployment in environmental health research.

EPIGENETICS, ENDOCRINE DISRUPTERS, AND ENVIRONMENTAL HEALTH

Our understanding of chemical toxicity has been challenged by the new science of epigenetics, which is the study of changes to the packaging of the DNA molecules that influence the expression of genes, and hence the risks of diseases and altered development. Studies indicate that exposures that cause epigenetic changes can affect several generations.[1] This new understanding heightens the need to protect people at critical times in their development when they are most vulnerable. NIEHS is making key investments in understanding basic epigenetic processes and how they are influenced by environmental factors. Recently, some of this work has provided a critical resource for understanding and characterizing properties of human induced pluripotent stem cells.[2] The development of pluripotent stem cells shows promise for research and clinical applications in lieu of embryonic stem cells, but many questions remain to be answered about their structure, utility, and safety. NIEHS-funded investigators have established genome-wide reference maps of DNA methylation (an epigenetic marker) and gene expression in previously derived human embryonic cell lines and human iPS cell lines, to assess their epigenetic and transcriptional similarity and predict their differentiation efficiency. A separate report by another NIEHS-funded group reported "hotspots" of aberrant epigenomic reprogramming in human iPS cells.[3] There are still many questions about the role of these important epigenetic processes which will need to be answered before iPS cells can be confidently used in research and therapy.

Related to the field of epigenetics is the key concept of "windows of susceptibility." Research shows that the developmental processes that occur at fetal and early life stages are especially vulnerable to disruption from relatively low doses of certain chemicals.[4] [5] [6] We first saw this in the case of lead and other metals, such as mercury and arsenic, which we learned decades ago could harm neurological development as a result of fetal and childhood exposures. This concept also applies to hormonally active agents which disrupt the endocrine system. This is an active area of our research program. For example, NIEHS and NTP are funding important studies to fill the gaps in our knowledge about bisphenol A (BPA), a widely distributed compound used in plastics, can linings, thermal paper, and more. NTP's Center for Evaluation of Risks to Human Reproduction determined that there was "some concern" about effects to the brain, behavior, and prostate gland in fetuses, infants, and children exposed to BPA.[7] NIEHS is now supporting an aggressive research effort to fill the research gaps in this area, especially concerning BPA effects on behavior, obesity, diabetes, reproductive disorders, development of prostate, breast and uterine cancer, asthma, cardiovascular diseases and transgenerational or epigenetic effects.

Any consideration of important public health issues in the United States. has to include obesity. Environmental exposures are beginning to be implicated in the obesity epidemic.[8] [9] NIEHS is supporting research on the developmental origins of obesity and the theory that environmental exposures during development play an important role in the current epidemic of obesity, diabetes, and metabolic syndrome. There are data showing weight gain in adult rats and mice following developmental exposure to a number of different chemicals, such as tributyltin compounds,[10] which

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[1] Anway MD, Cupp AS, Uzumcu M, Skinner MK (2005) Epigenetic transgenerational actions of endocrine disruptors and male fertility. Science 308:1466–1469.

[2] Bock C, Kiskinis E, Verstappen G, et al. (2011) Reference maps of human ES and iPS cell variation enable high-throughpu characterization of pluripotent cell lines. Cell 144(3):439–52.

[3] Lister R, Pelizzola M, Kida YS, et al. (2011) Hotspots of aberrant epigenomic reprogramming in human induced pluripotent stem cells. Nature 471(7336):68–73.

[4] Rogan WR, Ragan NB (2003) Evidence of effects of environmental chemicals on the endocrine system in children. Pediatrics 112:247–252.

[5] Dolinoy DC, Weidman JR, Jirtle RL (2007) Epigenetic gene regulation: Linking early developmental environment to adult disease. Reproductive Toxicology 23:297–307.

[6] Committee on Environmental Health, American Academy of Pediatrics (1999) Pediatric environmental health, 2nd edition, pp 9–23.

[7] http://www.niehs.nih.gov/news/media/questions/sya-bpa.cfm See "What does some concern mean?".

[8] Grun F, Blumberg B (2009) Endocrine disrupters as obesogens. Mol Cell Endocrinol 304:19–29.

[9] Verhulst SL, Nelen V, Hond ED, Koppen G, Beunckens C, Vael C, Schoeters G, Desager K (2009) Intrauterine exposure to environmental pollutants and body mass index during the first 3 years of life. Environ Health Perspect 117:122–126.

[10] Iguchi T, Watanabe H, Ohta Y, Blumberg B (2008) Developmental effects: oestrogen-induced vaginal changes and organotin-induced adipogenesis. Int J Androl 31:263–268.

have been termed "obesogens" by some researchers. A groundbreaking workshop on environmental factors in obesity and diabetes was sponsored by NIEHS in January 2011. Many research gaps still need to be filled, but if these early research results are confirmed, we may find it more useful to expand our approach to fighting obesity to include not just educating about diet and lifestyle but also reducing early life exposure to these "obesogenic" chemicals that might be setting the stage for us to gain weight later in life.

### PLANNING FOR THE FUTURE

NIEHS recently began work on the development of a new Strategic Plan to set goals for guiding our research investments over the next 5 years. Our process is designed to bring in information and perspectives from a wide variety of sources: community members, advocacy groups, agency partners, and scientists from all disciplines.

In summary, understanding the connection between our health and our environment, with its mixture of chemicals, diet and lifestyle stressors, is a complex and intricate scientific endeavor. At NIEHS, we remain committed to leading the evolution of the field of environmental health sciences to meet emerging public health challenges.

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## PREPARED STATEMENT OF THOMAS R. INSEL, M.D., DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Mental Health (NIMH) of the National Institutes of Health (NIH). The fiscal year 2012 NIMH request of $1,517,006,000 includes an increase of $40,981,000 over the fiscal year 2011 appropriated level of $1,476,025,000. In my statement, I will underscore the impact that mental disorders have on public health in the United States; outline examples of NIMH's strategies for reducing the burden associated with mental disorders; and, highlight examples of research activities that are advancing us toward this goal. I submit this statement with the recognition of the Department's notification to the Congress of an NIH reorganization that would establish a new National Center for Advancing Translational Sciences.

### PUBLIC HEALTH BURDEN OF MENTAL ILLNESS

NIMH's mission is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. The burden of mental illness is enormous. In 2009, an estimated 11 million American adults (approximately 1 in 20) suffer from serious mental illness.[1] According to the World Health Organization, mental disorders are the leading cause of medical disability in the United States and Canada.[2] In contrast to many other chronic medical conditions, mental disorders typically begin at an early age, usually before the age of 30. Mental disorders, such as schizophrenia, depression, and bipolar disorder, are increasingly recognized as the chronic medical illnesses of young people.

The annual economic costs of mental illness in the United States are enormous. The direct costs of mental health treatment represent an estimated 6.2 percent of all healthcare spending,[3] which, according to the Centers for Medicare and Medicaid Services, totals 15.8 percent of the gross domestic product. Indirect costs, which include all non-treatment-related costs such as Social Security disability payments, lost earnings, and incarceration, account for an even greater expense than the direct costs associated with mental healthcare. A conservative estimate places the total direct and indirect costs of mental illness at well over $300 billion annually.[4]

NIMH's mission is not merely to reduce the symptoms and disability associated with mental disorders, but to promote recovery, to extend healthy life, and ulti-

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[1] SAMHSA. *Results from the 2009 National Survey on Drug Use and Health: Mental Health Findings* (Office of Applied Studies, NSDUH Series H–39, HHS Publication No. SMA 10–4609). Rockville, MD; 2010.

[2] The World Health Organization. The global burden of disease: 2004 update, Table A2: Burden of disease in DALYs by cause, sex and income group in WHO regions, estimates for 2004. Geneva, Switzerland: WHO, 2008.

[3] Mark TL, et al. *National Expenditures for Mental Health Services and Substance Abuse Treatment*, 1993–2003. SAMHSA Publication No. SMA 07–4227. Rockville, MD: SAMHSA, 2007.

[4] Insel TR. Assessing the economic cost of serious mental illness. Am J Psychiatry. 2008 Jun;165(6):663–5.

mately, to discover preventive interventions. In the year ahead, NIMH will work toward this mission by fostering and facilitating a collaborative approach across the spectrum of mental health research approaches—from discovery to dissemination—to make a positive change in the lives of people with mental disorders and their families.

TECHNOLOGIES TO ACCELERATE DISCOVERY

Funding from the American Recovery and Reinvestment Act of 2009 has enabled NIMH to support infrastructure development that will provide a framework for future discoveries. One large, collaborative project that promises to provide researchers with an invaluable reference tool is the Transcriptional Atlas of Human Brain Development. This atlas is mapping when and where genes are switched on and off during normal brain development, because to understand disorders, scientists must first understand what the normal patterns of gene expression are during development. The atlas will contain data from 16 brain regions at 11 developmental stages—ranging from embryonic development to mid-adulthood. These maps will highlight differences between prenatal and postnatal brains, changes across adolescence, and unique patterns of gene expression that only occur during development. The first maps from the atlas were released this year and will form the foundation for future maps and releases.

TRANSLATIONAL SCIENCES AND THERAPEUTICS DEVELOPMENT

NIMH-funded researchers are working to translate discoveries from basic science into targeted, rapidly acting therapeutics. Current antidepressant medications and cognitive behavioral therapies often require 6 to 8 weeks to have an effect. Previous NIMH research has shown that the drug ketamine can reduce depression, including thoughts of suicide, within 6 hours. However, long-term use is associated with side effects, and the mechanism by which ketamine works remained unclear, until NIMH-funded researchers made a significant discovery in 2010. They identified how the brain responds to ketamine, as well as the molecular mechanism for this rapid response—the rapid activation of an enzyme, mTOR, which regulates cell growth, proliferation, and survival. The discovery of this cellular mechanism today helps point the way to developing practical, rapid-acting treatments for depression tomorrow.

In tandem with this cutting-edge discovery-to-treatment research, NIMH is looking into ways to personalize and optimize current treatments for depression. While effective interventions do exist, there is considerable variation in individual treatment outcomes. The Establishing Moderators/Mediators for a Biosignature of Antidepressant Response in Clinical Care (EMBARC) study is working to develop a collaborative approach among researchers who are focusing on biological indicators (biomarkers) of depression. EMBARC researchers hope to identify a standard set of biomarkers and other measures that can be used to predict which interventions will produce the best treatment outcomes for an individual. Taken together with our advancing knowledge of ketamine, we can say with confidence that rapid, personalized, and effective treatments for depression are close at hand.

ENHANCEMENT OF EVIDENCE-BASE FOR HEALTHCARE DECISIONS

NIMH's basic and translational research will improve U.S. public health only when they lead to improved mental healthcare. To improve the outcomes for people suffering from schizophrenia, NIMH is funding the Recovery After an Initial Schizophrenia Episode (RAISE) project—a large-scale clinical trial designed to alleviate the long-term disability associated with schizophrenia by intervening as early as possible after the first onset of symptoms, so that people with the disorder can lead more productive, independent lives. RAISE addresses the effectiveness of providing early, sustained, and integrated care to improve health and life functioning outcomes, and develops strategies to facilitate implementation of successful, cost-effective early interventions in the U.S. healthcare system. RAISE incorporates features necessary for rapid dissemination into community settings, thus accelerating the transition from research to practice.

NIMH has also launched the Mental Health Research Network to encourage scientific collaboration among nine established research centers that are based in integrated, not-for-profit healthcare systems. These systems provide care coverage to a diverse population of 10 million people in 11 States, and they share rich and compatible data resources to support a range of effectiveness research. Researchers have begun to use this network to address vital issues, including the development of a geographically and ethnically diverse autism research registry; a pilot study for a

new type of therapy for postpartum depression; and, a longitudinal analysis of how suicide warning labels on antidepressants affect later suicidality among youth.

NEW INVESTIGATORS, NEW IDEAS

The future of discovery and translational research lies in the next generation of mental health researchers. NIMH's Biobehavioral Research Awards for Innovative New Scientists (BRAINS) program provides support to early stage investigators to foster innovative research aimed at critical gaps identified by the NIMH Strategic Plan. NIMH also recognizes the importance of ensuring that our workforce reflects the diversity of backgrounds and perspectives that has made the United States a source of innovation. NIMH is leading an NIH Blueprint for Neuroscience initiative to enhance diversity in neuroscience through undergraduate research education experiences, and has established a supplemental funding program to provide underrepresented minority scholars with mentored research training in strong institutional training programs.

WORKING COLLABORATIVELY TO COMBAT SUICIDE

NIMH is committed to collaborating with other Federal agencies and private partners to hasten the development of interventions and to facilitate their widespread use by those most in need. As an example, NIMH has been concerned by the high rate of suicide among our Nation's military personnel, and has partnered with the Army to conduct the Study to Assess Risk and Resilience of Service Members (Army STARRS)—the largest mental health study of military personnel ever conducted. Early examination of Army STARRS data has begun to reveal potential predictors of risk for suicide among soldiers. Researchers plan to analyze additional historical data and new survey data collected by Army STARRS to confirm and expand upon these findings.

Suicide among civilians is also of significant concern. Approximately 34,500 American lives are lost to suicide each year, nearly twice the number lost due to homicide, making it the 10th leading cause of death in the United States.[5] [6] To combat this issue, under the leadership of the Substance Abuse and Mental Health Services Administration, NIMH joined the Army, the Centers for Disease Control and Prevention, other NIH Institutes, and private partners to form the National Action Alliance for Suicide Prevention. NIMH is spearheading a Research Prioritization Taskforce on behalf of the Action Alliance to develop a strategic research agenda that could reduce suicide-related mortality by 20 percent in 5 years, or 50 percent in 10 years, if fully implemented.

Successfully combating mental disorders requires collaboration across multiple levels of society; Federal agencies, the research community, private industry, and the individuals and families affected each day. Despite the tremendous burden of mental disorders, NIMH is up to the challenge of bringing all stakeholders to the table, harnessing scientific advances, and directing the next generation of research to improve the lives of people affected by mental disorders.

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PREPARED STATEMENT OF JOHN RUFFIN, PH.D., DIRECTOR, NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute on Minority Health and Health Disparities (NIMHD) of the National Institutes of Health (NIH). The fiscal year 2012 budget of $214,608,000 includes an increase of $5,073,000 over the fiscal year 2011 comparable appropriation level of $209,535,000.

This statement is submitted with the recognition of the Department's notification to the Congress of an NIH reorganization that would establish a new National Center for Advancing Translational Sciences and reallocate the remaining portions of the National Center for Research Resources to other parts of NIH, including NIMHD.

INTRODUCTION

Health disparity is an issue of immense proportions with health, economic, social and environmental impact for the Nation. Disparities in the burden of illness and

[5] CDC, National Center for Injury Prevention and Control. Web-based Injury Statistics Query and Reporting System.

[6] U.S. Department of Justice, Federal Bureau of Investigation. (September 2009). Crime in the United States, 2008.

premature death experienced by racial and ethnic minorities, low-income, and rural populations, apply to a broad spectrum of disease types. Evidence-based research reveals that health disparities are the result of interacting factors that may be genetic, biological, environmental, social, economic, or psychological in nature. The causes of and solutions to health disparities are multidimensional and require multidimensional approaches to improve health and eliminate the disparities.

Health disparities have had a longstanding economic burden on the healthcare system. The Affordable Care Act (ACA) included several provisions aimed at mobilizing the Nation around actions to confront health disparities in order to overcome the multiple barriers faced by underserved communities in obtaining quality healthcare. One provision in the ACA re-designated the National Center on Minority Health and Health Disparities (NCMHD) at the NIH to an Institute—named the National Institute on Minority Health and Health Disparities. The NIMHD was created to strengthen the base for the acceleration of scientific discovery already initiated by the predecessor organization, the NCMHD, to understand health disparities and to identify and implement strategies to eradicate them across the Nation. In accordance with the Affordable Care Act, NIMHD is charged to plan, review, coordinate, and evaluate minority health and health disparities research activities conducted by the NIH Institutes and Centers (ICs). As health disparities transcend many diverse areas of biomedical science and public health, this work must involve all of the NIH ICs, and numerous Federal Government and non-Federal Government partners.

BUILDING ON A DECADE OF PROGRESS

During the past decade, under the aegis of the NCMHD, the NIMHD launched its congressional mandates, and established new programmatic initiatives and partnerships, allowing it to create the infrastructure required to be at the cutting edge of scientific discovery through its independent programs and support for collaborative research, research infrastructure development, and outreach projects with partners within the NIH, HHS, and beyond.

The foundation of the NIMHD's research portfolio is the NIMHD Exploratory and Comprehensive Centers of Excellence (COE) programs. Research in the COEs spans the wide array of diseases, health conditions, and complex non-biological factors contributing to health disparities. Translational research and the development of appropriate health interventions is a particular strength of the NIMHD COEs. The NIMHD University of Puerto Rico-Cambridge Health Alliance Research Center of Excellence has focused its research on Latino health and healthcare disparities, specifically mental disorders, substance abuse and asthma. This COE has generated and tested models aimed to improve health service delivery to eliminate these disparities. This includes multi-level interventions at the provider, individual/family and policy levels to reduce health services disparities and has provided invaluable data to understand the magnitude of substance abuse treatment disparities and the social and economic burden of these disparities.

In addition, NIMHD COEs have assisted in emergency response to disasters with health disparities implications such as Hurricane Katrina in 2005, and the Haiti earthquake in 2010. NIMHD COEs responded to the Haitian earthquake crisis with assistance to Haitian communities in south Florida and beyond the borders of the country. These efforts have improved the understanding of the global nature of health disparities.

To effectively conduct research, individuals, institutions and organizations must have the capacity and access to the resources that are necessary to conduct research. NIMHD is a leader in advancing the NIH efforts to increase the number of underserved populations represented in science and medicine. The NIMHD Health Disparities Research and the Clinical Research for Individuals from Disadvantaged Backgrounds Loan Repayment Programs (LRP) have supported more than 2,300 individuals representing multiple disciplines through loan repayment of educational loans. More than 60 percent of the LRP scholars represent racial/ethnic minority populations. The program has incentivized the pursuit of a scientific or health disparities research career and many former LRP recipients have been successful in competing for other NIH grants. Also, NIMHD offers the opportunity for LRP recipients to transition into becoming independent investigators through its Disparities Research and Education Advancing our Mission (DREAM) program in its Intramural Research Program (IRP). During their 2-year appointment at the NIH conducting research on health disparities, the DREAM fellows work with mentors within the NIH Intramural Research Program across different NIH Institutes and Centers. After the 2-year period, the DREAM fellows have the option of returning to

their originating academic institution or to a health disparity community to further hone their research skills and complete the final 3 years of the program.

In addition, programs such as the Research Centers in Minority Institutions and the new NIMHD Science Education Initiative which focuses on promoting science education and increasing the pool of individuals from health disparity populations in the science field starting from kindergarten through the post-doctoral level, will play a key role in advancing the NIMHD's activities in this area.

There is growing interest in scientific research including health disparities research at academic institutions throughout the Nation. However, many institutions have limited or no current capacity to conduct scientific research. Recognizing the variance in capacity among institutions of higher education, the NIMHD has invested considerable resources in the enhancement of research infrastructure and capacity of less research-intensive institutions through programs such as the NIMHD Building Research Infrastructure and Capacity (BRIC) program. Over time, the BRIC awards have been instrumental in transforming the abilities of some institutions to conduct health disparity research. For example, San Francisco State University (SFSU) through the development of shared research facilities has resulted in the publication of approximately 70 research articles on a variety of scientific topics, 76 SFSU students have entered highly competitive Ph.D. programs, and BRIC-supported faculty have received more than $13 million in support to conduct health disparity research. Importantly, BRIC support has provided a strong base for institutions to expand their graduate level educational programs to include new doctorate opportunities to advance health disparities research, as well as the development of NIMHD Centers of Excellence.

### A NEW ERA IN THE FIGHT AGAINST HEALTH DISPARITIES

The next decade will focus on bridging persistent gaps in health disparities, sustaining effective investments, and developing and adapting innovative approaches to health disparities. NIMHD will lead the development, implementation and evaluation of the agency's health disparities research agenda in collaboration with the other NIH Institutes and Centers. Research on minority health and health disparities, research capacity-building and outreach/information dissemination priorities across the NIH will emphasize areas such as: translational research, genetics and biological factors, global health, social determinants of health, behavioral and social sciences, innovative health technologies, developing a diverse scientific workforce, health informatics capacity, public-private partnerships, social networking, and diverse participation in clinical trials.

NIMHD will advance this health disparities research agenda through translational research and dissemination of research findings for the benefit of clinical practice and health disparity communities. Community and population health intervention studies that map social, economic and environmental determinants will provide greater insight into the underlying causes of health disparities. In addition, primary care and prevention research to inform healthcare reform, improve healthcare quality, reduce costs and ultimately improve health outcomes for health disparity populations will be examined.

In today's culturally diverse and technologically advanced society, the construction of health messages that do not consider culture, history, environments, or literacy levels of certain health disparity communities can result in the inability of those communities to receive health information. NIMHD is committed to supporting and developing vehicles to translate and deliver research findings and health information to health disparity communities in a culturally and linguistically appropriate manner.

### CONCLUSION

While many health disparities concerns of the past decade remain pervasive, the NIMHD sees opportunities to accelerate the pace of scientific discovery and translation. Within the context of the NIH and HHS priorities for eliminating health disparities, the NIMHD will intensify and diversify its research focus to elucidate the Nation's understanding of health disparities. Research strategies must continue to be innovative and the results of this research must reach the community at a faster pace. The NIMHD is committed to strengthening its research efforts to realize these goals.

PREPARED STATEMENT OF STORY C. LANDIS, PH.D., DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2012 President's budget request for NINDS. The fiscal year 2012 budget is $1,664,253,000. Our mission is to reduce the burden of neurological disorders through research. NINDS research has improved diagnosis, prevention, and treatment, but the best of medical science is still far from optimal for most nervous system disorders. Fortunately, advances in understanding the brain and its disorders are providing extraordinary opportunities for progress.

ENHANCING THE EVIDENCE BASE FOR MEDICAL DECISIONS

U.S. Centers for Disease Control and Prevention statistics show that from 1997 to 2007 the stroke death rate in the United States decreased 34.3 percent, and the number of stroke deaths declined 18.8 percent, which translates to thousands of lives saved and thousands with reduced disability every year. For decades, NINDS clinical trials have contributed to this trend by providing evidence that enables physicians to choose the best stroke prevention interventions according to each person's risk factors. In April, NINDS stopped a stroke prevention clinical trial early because the results were already clear[1]. The trial included patients at high risk because of a prior non-disabling stroke and severe narrowing of arteries to the brain. Angioplasty combined with stenting, which opens clogged arteries with a tiny balloon and inserts a device to prop them open, plus aggressive medical therapy led to a higher risk of stroke than the medical therapy alone. Another recent NINDS clinical trial showed that a procedure using stents is as safe and effective in preventing stroke as carotid endartarectomy, a more invasive surgical procedure to clear arteries, in people with certain risk factors.[2] Follow up to monitor longer term results is continuing for both trials. NINDS clinical trials are similarly guiding treatment for other diseases. A recent clinical trial showed that an older drug, ethosuximide, may be the best first drug to test to prevent seizures with minimum side effects in children with absence epilepsy, providing much needed guidance for treating this common disorder[3]. An NINDS-Department of Veterans' Affairs trial showed that surgical implantation of deep brain stimulators (DBS) can yield better movement and quality of life than drug treatment for people with advanced Parkinson's disease, and more recent results of this trial provided information about choosing the best site in the brain to implant electrodes for each patient[4]. NINDS currently supports 32 multi-site clinical trials to test the safety and effectiveness of interventions in stroke, epilepsy, traumatic brain injury, multiple sclerosis, muscular dystrophy, and other diseases, and more than 120 earlier phase trials that are essential steps toward large efficacy trials.

ADVANCING TRANSLATIONAL SCIENCE

Since long before the term "translational" became common, NINDS has pushed development of basic science advances into drug, biologic, and device therapies. The first enzyme therapy for inherited metabolic diseases, several drugs for epilepsy, the first emergency treatment for stroke, and pioneering technology for devices that replace lost nervous system function are among advances that NINDS translational research made possible. Often, industry capitalizes on NIH basic science findings to develop a new therapy. However, rare diseases, bold new therapeutic strategies, and new uses for existing drugs are all challenges that NINDS is more likely than industry to take on. This is especially so now because drug companies, citing the extraordinary challenges of brain research, are reducing programs to develop nervous system drugs[5].

NINDS launched the Cooperative Program in Translational Research in 2003 to exploit increasing opportunities from neuroscience research. This program supports teams of academic and small business investigators to carry out milestone-driven, preclinical therapy development for a broad range of neurological disorders. The

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[1] http://www.nlm.nih.gov/databases/alerts/intracranial_arterial_stenosis.html.

[2] Brott TG et al. Stenting Compared to Endarterectomy for Treatment of Carotid Artery Stenosis, New England Journal of Medicine 363:11–23 2010.

[3] Glauser et al. Ethosuximide, Valproic Acid, and Lamotrigine in Childhood Absence Epilepsy. New England Journal of Medicine. 362:790–799 2010.

[4] Weaver F. et al. Best Medical Therapy versus Bilateral Deep Brain Stimulation for Patients with Advanced Parkinson's Disease: A Randomized Controlled Trial. JAMA 301:63–73 2009; Follett et al. Pallidal versus Subthalamic Deep Brain Stimulation for Parkinson's Disease. New England Journal of Medicine 362:2077–91 2010.

[5] "R&D Cuts Curb Brain-Drug Pipeline," The Wall Street Jounal, March 27, 2011.

first candidate therapies from this program have moved into clinical testing for disorders including stroke, Batten disease, and muscular dystrophy.

Several NINDS programs meet special translational needs for particular diseases. Among these are the Anticonvulsant Screening Program, the Specialized Centers of Translational Research in Stroke (SPOTRIAS), the Udall Centers of Excellence in Parkinson's Disease, and the Wellstone Centers for Muscular Dystrophy Research. NINDS chose spinal muscular atrophy (SMA) as the disease to pilot another innovative approach to drug development. With experts from academia, industry, and FDA, the SMA Project designed a drug development plan and is implementing the plan through a "virtual pharma" organization that engages resources via contracts. Promising drug candidates are now in advanced pre-clinical testing, and the Project is working toward certification for a clinical trial in 2012. Building on the SMA Project strategy, NINDS is leading the NIH Blueprint for Neuroscience in a larger scale Grand Challenge on Neurotherapeutics. The challenge goal is to develop truly novel drugs that will transform the treatment of nervous system diseases. The NINDS Intramural Research Program, which has a long record of therapy development, is also accelerating translational research under a new Clinical Director. NINDS translational programs work closely with all of the NIH-wide programs and resources that will become part of the National Center for Advancing Translational Sciences (NCATS), and will certainly benefit from NCATS programs to catalyze translational research.

Because novel therapies for several neurological diseases are moving toward readiness for clinical testing, NINDS is developing a multi-site clinical network to improve the speed and effectiveness of the early steps in clinical testing of novel therapies for neurological disorders. Better early phase testing will increase the likelihood of success in larger and more expensive phase III clinical trials of effectiveness. This network will test promising interventions, whether they arise from academia, foundations, or industry, and will engage expertise much greater than the Institute could dedicate to separate networks for each of the many neurological diseases. This is especially important for rare disorders, including pediatric diseases. A project to validate biomarkers for SMA will be among the network's first studies.

Another major clinical initiative will develop and validate biomarkers for Parkinson's disease, that is, measurable indicators of the disease process. Biomarkers research, which NINDS supports for many disorders, exemplifies another way that NINDS programs can catalyze both NIH and industry therapy development efforts. With biomarkers for neurodegenerative disorders, clinical trials can determine in months, rather than years, whether drugs are slowing the progression of disease and understand why a new treatment worked or did not. Better biomarkers can reduce the cost of research and speed the development of better treatments in NIH and industry.

### ACCELERATING PROGRESS THROUGH TECHNOLOGY

An extraordinary array of technologies has accelerated progress in neuroscience. These range in scale from imaging activity of the thinking human brain as people carry out complex tasks, to understanding atom by atom how molecules control electrical activity in brain cells. This year research demonstrated the power of whole genome sequencing to understand Charcot-Marie-Tooth disorder, a peripheral nerve disease[6]. This is a harbinger of personalized genomics for many diseases. Next generation genomics research is underway for several neurological disorders. A "Center without Walls" will bring together the best possible team, regardless of geography, to apply advanced genomics to epilepsy. On another technological frontier, ARRA enabled NINDS to accelerate research on induced pluripotent stem cells (iPSC's) that can be derived from patients with Parkinson's, Huntington's, ALS, epilepsy, and other disorders. A spate of new technologies, from methods that label nerve cells with more than a hundred different colors, to computerized three-dimensional reconstruction of intricate nerve cell circuits, to techniques that control the activity of individual nerve cells with light, are arming neuroscientists to meet the long-standing challenge of understanding how circuits of nerve cells underlie memory, perception, complex movement, and other higher brain functions. This has implications for understanding autism, epilepsy, Parkinson's, Alzheimer's, and many other diseases.

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[6] Lupski JR et al. Whole-genome sequencing in a patient with Charcot-Marie-Tooth neuropathy. New England Journal of Medicine 362:1181–91 2010.

ENCOURAGING NEW INVESTIGATORS AND NEW IDEAS

When progress against disease is not forthcoming, a gap in basic understanding of the normal brain or the disease process is often the cause. Physicians and scientists across academia and industry agree that basic research propels long-term progress against disease. The insight and ingenuity of the research community is the key. Supporting a vigorous scientific community and investigator-initiated research are thus high priorities throughout NINDS programs and policies. To encourage innovative research, for example, the EUREKA (Exceptional Unconventional Research Enabling Knowledge Acceleration) program complements the NIH Pioneer Awards, New Innovator Awards, and Transformative R01's, all of which support neuroscientists. To prepare the next generation of neuroscientists, NINDS training and career development programs are tailored to the needs of basic and clinical researchers, and funding policies favor early stage investigators. NINDS encourages cooperative research and promotes sharing through several programs. Examples include the Common Data Elements program, Human Genetics Resource Center, consortia on induced pluripotent stem cells, disease centers programs, and other grants to multi-investigator teams. NINDS is improving programs on workforce diversity and health disparities based on guidance from an external review and planning process that was completed in 2011.

CONCLUDING REMARKS

Neurological disorders present formidable challenges. Nonetheless, prospects for progress have never been more encouraging because of progress in understanding the nervous system and its diseases at every level from molecules through the working human brain. NINDS is aggressively pursuing better prevention and treatment with a balance of basic, translational, and clinical research, supported through investigator-initiated and priority-targeted programs.

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PREPARED STATEMENT OF PATRICIA A. GRADY, PH.D., RN, FAAN, DIRECTOR, NATIONAL INSTITUTE OF NURSING RESEARCH

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2012 budget request for the National Institute of Nursing Research (NINR) of the National Institutes of Health (NIH). The fiscal year 2012 budget includes $148,114,000 which is $3,857,000 more than the comparable fiscal year 2011 appropriation of $144,257,000.

INTRODUCTION

I appreciate the opportunity to share with you some of the exciting areas of research that we support at the National Institute of Nursing Research (NINR). As you know, a unique combination of societal trends challenges our Nation's health, including an aging population, increased chronic illness and obesity rates, and shortages in the healthcare workforce. At NINR, we address these issues by supporting research across the life span that: builds the scientific foundation for clinical practice; improves quality of life through managing and easing symptoms of illness; promotes health and prevents disease through biological and behavioral interventions; and enhances end-of-life and palliative care. We also seek to ensure future discoveries by training the next generation of nurse scientists. NINR's emphasis on clinical research and training places NINR in a position to make major contributions to trans-NIH initiatives to enhance the evidence-base for healthcare decisions, promote translational research, and support new investigators and new ideas. NINR was established 25 years ago, in 1986, as the National Center for Nursing Research. This year, we are commemorating our 25th anniversary through a series of scientific outreach events to celebrate our longstanding emphasis on translating science to improve health and clinical practice. In our first event, a scientific symposium entitled "Bringing Science to Life," some of our distinguished scientists presented cutting edge research on topics as varied as: the role of sleep in health and safety; managing chronic illness in racially/ethnically diverse groups; testing interventions to educate and support parents with premature infants; and understanding the biological underpinnings of muscular dystrophy. This Anniversary is an opportunity to review what NINR science has accomplished, and more importantly, to envision and plan the next phase of evidence-based research to meet future health and healthcare needs, challenges, and priorities. As we look forward to the next 25 years, we are confident that NINR-supported science will play an ever-increasing role in addressing the most pressing issues facing our Nation's health. I would, next, like to share

with you some examples of the research that we support and how it improves quality of life.

CHILDHOOD AND ADOLESCENCE: RISK AND RESILIENCE

From birth through young adulthood, children and adolescents face many health challenges and also demonstrate incredible resilience. NINR supports research to promote positive outcomes for children and families facing a myriad of challenges. For example, chronic health conditions in children, such as diabetes, arthritis, and obesity, pose challenges for the entire family and require sustained attention to treatment adherence and health assessment. NINR-funded scientists have made advances both in understanding the family's role in children's health and in improving assessment strategies. One study found that although parents detected significant pain in their child following the child's surgery, they tended to under-treat it, suggesting that educating parents about pain management may be beneficial. Another study found that screening children's waist circumference, which can be easily implemented in schools, identifies more cases of high blood pressure than the usual measure of body mass index alone. A current initiative led by NINR aims to improve self-management of chronic illness in children. An increasing challenge later in childhood comes from HIV, with adolescents and young adults comprising one-third to one-half of new infections in the United States,[1] despite numerous prevention campaigns. Moreover, adolescents from racial/ethnic minority groups are disproportionately affected.[2] A new NINR initiative supports projects to examine psychosocial, cognitive, and neurological predictors of HIV/AIDS risk decisionmaking in adolescents. This research will provide an evidence-base to guide future culturally and developmentally relevant interventions to prevent HIV/AIDS.

CHALLENGES AND CHANGES IN AN AGING POPULATION

The population of our Nation is aging rapidly, due in large part to increased longevity and the aging of the baby boomers. These changes are giving rise to significant challenges, resulting in a need for: improved strategies to manage co-occurring chronic illnesses; better interventions to support family caregivers; and new ways to address health disparities and meet the needs of an elderly population that is more racially and ethnically diverse than ever before. One pressing challenge is the increase in the number of older adults with multiple chronic illnesses, such as heart disease, diabetes, and arthritis. Such older adults have complex care needs, face long-term self-management of illness, and may experience poor coordination of care in the community. In a recent NINR-supported Nurse Coordinated Care Intervention, advanced practice nurses developed individualized care plans for older adults, which included family members and ongoing follow-up care. The intervention improved health outcomes and reduced costs of care for Medicare patients. A new NINR initiative, that benefits not only older adults but individuals across the life span, supports research that translates basic genomic science to clinical practice with the goal of preventing and alleviating symptoms of chronic illness. Such efforts have the potential to improve quality of life for older adults and families. Another challenge is Alzheimer's disease (AD), which is incurable, affects up to 5.1 million Americans, and is expected to dramatically increase in incidence by the year 2030.[3] NINR is addressing the quality of care for AD patients, and the quality of life of, and burden on, family caregivers. For example, researchers funded by NINR and the National Institute on Aging (NIA) developed an intervention to teach caregivers about AD, stress management, and maintaining their own health. The intervention showed promising improvements in emotional, mental, and physical health in racially diverse groups.

END OF LIFE: SUPPORTING INDIVIDUALS AND FAMILIES

As a society we are living longer lives than ever before; however, we are also more likely to die from chronic and sometimes painful illnesses[4] that require families to make complex decisions about life and death issues, often without adequate support and information. As the lead NIH Institute on issues related to end-of-life research, NINR supports research leading to evidence-based end-of-life and palliative care

[1] National Institute for Child Health and Human Development. AIDS/HIV. 2008.
[2] Centers for Disease Control and Prevention. 2008. HIV/AIDS among youth.
[3] National Institute on Aging. 2009 Progress report on Alzheimer's disease: Translating new knowledge.
[4] Centers for Disease Control and Prevention and The Merck Company Foundation. The state of aging and health in America 2007. Whitehouse Station, NJ: The Merck Company Foundation; 2007.

that ultimately assists individuals, families, and healthcare professionals in alleviating symptoms, planning for end-of-life decisions, and promoting psychological, social, spiritual, and physical well-being. NINR's Office of Research on End-of-Life Science and Palliative Care, Investigator Training, and Education coordinates research, training, and educational efforts in end-of-life and palliative care science. One NINR-supported study recently examined the effectiveness of a program to communicate patient preferences for end-of-life decisions to clinicians. Compared to traditional practices such as Do-Not-Resuscitate orders, the program led to fewer unwanted life-sustaining treatments without affecting quality of remaining life. In addition, a new NINR initiative begun in 2011 will support research to address issues related to end-of-life and palliative care for individuals with chronic illness who also experience life-threatening acute illness. Finally, on August 10–12, 2011, NINR, with support from partners across the NIH, will convene a forum entitled "The Science of Compassion: Future Directions in End-of-Life and Palliative Care." This forum is intended to energize and mobilize end-of-life and palliative care research and to draw attention to the end-of-life and palliative care processes, the care options available to patients and their families, and the obligations of health service communities to address these complex needs.

### TRAINING THE NEXT GENERATION OF SCIENTISTS

NINR places strong emphasis on equipping the next generation of scientists with the necessary skills to conduct research that improves the Nation's health. In light of the societal trends that will characterize the coming decades, NINR recognizes that tomorrow's nurse scientists need to be trained in rigorous, innovative, and interdisciplinary research that reaches diverse individuals, families, and communities. NINR supports young scientists and junior and senior scholars through grant funding, fellowships, and career development awards. NINR also offers an intensive summer training program, the Summer Genetics Institute, to improve research and clinical practice among graduate students and faculty by providing a foundation in molecular genetics. Additionally, our Pain Boot Camp, held for the first time in 2010, is a 1-week research intensive program where participants learn innovative pain research methodology from nationally and internationally known scientists. NINR's efforts to invest in new investigators and new ideas are critical investments in preparing a nursing workforce to address the healthcare challenges of the coming years.

### FUTURE DIRECTIONS IN NURSING SCIENCE

Nursing science is at the forefront of efforts to improve health and healthcare practice. NINR is currently formulating its new strategic plan and will continue its focus on the unique social, cultural, societal, genetic, and biological factors that contribute to disease prevention, health promotion, and self-management of illness. We look forward to the next 25 years in which nursing science, focused on individuals, patients and families, will make critical contributions to improving healthcare practice and quality of life across the disease spectrum and across the lifespan. Thank you, Mr. Chairman. I will be happy to answer any questions that the Committee might have.

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## PREPARED STATEMENT OF DONALD A.B. LINDBERG, M.D., DIRECTOR, NATIONAL LIBRARY OF MEDICINE

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2012 budget request for the National Library of Medicine (NLM) of the National Institutes of Health (NIH). The fiscal year 2012 NIH request includes $387,153,000 for NLM, which is $24,420,000 more than the comparable fiscal year 2011 NLM appropriation of $362,733,000.

As the world's largest biomedical library and the producer of internationally trusted electronic information services, NLM delivers trillions of bytes of data to millions of users every day. Many who begin a search in Google, another search engine, or a mobile "app" actually receive health information from an NLM website. Now in its 175th year, NLM is a key link in the chain that makes the results of biomedical research—DNA sequences, clinical trials data, toxicology and environmental health data, published scientific articles, and consumer health information—readily available to scientists, health professionals, and the public worldwide. A leader in biomedical informatics and information technology, NLM also conducts and supports leading-edge informatics research and development in electronic health records, clin-

ical decision support, information retrieval, advanced imaging, computational biology, telecommunications, and disaster response.

NLM's programs and services directly support NIH's four key initiatives. The Library organizes and provides access to massive amounts of scientific data from high throughput sequencing; assembles data about small molecules to support research and therapeutic discovery; provides the world's largest clinical trials registry and results database; and is the definitive source of published evidence for healthcare decisions. Research supported or conducted by NLM underpins today's electronic health record systems. The Library has been the principal funder of university-based informatics research training for 40 years, supporting the development of today's leaders in informatics research and health information technology. NLM's databases and its partnership with the Nation's health sciences libraries deliver research results wherever they can fuel discovery and support health decisionmaking.

RESEARCH INFORMATION RESOURCES

NLM's PubMed/MEDLINE database is the world's gateway to research results published in the biomedical literature, linking to full-text articles in PubMed Central, including those deposited under the NIH Public Access Policy, and on publishers' websites, as well as connecting to vast collections of scientific data. Through its National Center for Biotechnology Information (NCBI), NLM is a hub for the international exchange and use of molecular biology and genomic information, with databases accessed by more than 2 million users daily. NCBI meets the challenge of organizing, analyzing, and disseminating scientific research data with more than 40 integrated databases and analysis tools that enable genomic discoveries in the 21st century. These databases are fundamental to the identification of important associations between genes and disease and to the translation of new knowledge into better diagnoses and treatments. Resources such as dbGAP and the upcoming Genetic Testing Registry (GTR) create a bridge between basic research and clinical applications. dbGaP links genotype and phenotype information from clinical studies to identify genetic factors that influence health and serves as the public repository for data from genome wide association studies (GWAS) supported by NIH and other research funders. The GTR will be a central source for healthcare providers and patients to find detailed information about genetic tests and the laboratories that offer them.

NLM also stands at the center of international exchange of data about clinical research studies. NLM's Lister Hill National Center for Biomedical Communications builds ClinicalTrials.gov, the world's largest clinical trials database, including registration data for more than 106,000 clinical studies with sites in 174 countries. ClinicalTrials.gov has novel and flexible mechanisms that enable submission of summary results data for clinical trials subject to the Food and Drug Administration Amendments Act of 2007. To date, summary results are available for about 3,400 completed trials of FDA-approved drugs, biological products, and devices—providing a new and growing source of evidence on efficacy and comparative effectiveness.

HEALTH DATA STANDARDS AND ELECTRONIC HEALTH RECORDS

Electronic health records with advanced decision-support capabilities and connections to relevant health information will be essential to achieving personalized medicine and will help Americans to manage their own health. For 40 years, NLM has supported seminal research on electronic health records, clinical decision support, and health information exchange, including concepts and methods now used by MicroSoft Health Vault and Google Health. As the central coordinating body for clinical terminology standards within HHS, NLM works closely with the Office of the National Coordinator for Health Information Technology (ONC) to facilitate adoption and "meaningful use" of electronic health records (EHRs). NLM supports, develops, and disseminates key data standards for U.S. health information exchange in ONC's criteria for certification of electronic health records. NLM is actively engaged in research on Next Generation EHRs, while also developing tools and frequently used subsets of large terminologies to help EHR developers and users implement health data standards right now. Most recently, NLM released MedlinePlus Connect, which allows application developers to establish direct links from a patient's view of his or her EHR to high quality health information relevant to that person's specific health conditions, medications, and (coming soon) recent tests.

INFORMATION SERVICES FOR THE PUBLIC

This new EHR connection builds upon NLM's extensive information services for patients, families and the public. The Library's MedlinePlus website provides integrated access to high quality consumer health information produced by all NIH com-

ponents and HHS agencies, other Federal departments, and authoritative private organizations and serves as a gateway to specialized NLM information sources for consumers, such as the Genetic Home Reference and the Household Products database. Available in English and Spanish, with selected information in 40 other languages, MedlinePlus averages well over 600,000 visits per day. Covering nearly 900 health topics, MedlinePlus has interactive tutorials for persons with low literacy, an illustrated medical encyclopedia, surgical videos and links to the scientific literature in PubMed. Mobile MedlinePlus, also in both English and Spanish, reaches the large and rapidly growing mobile Internet audience.

The NIH MedlinePlus quarterly magazine is an outreach effort made possible with support from many parts of NIH and the Friends of the NLM. Like MedlinePlus itself, the magazine is free and contains no advertising. It is distributed to the public via physician offices, community health centers, libraries and other locations and has a readership of up to 5 million nationwide. Each issue focuses on the latest research results, clinical trials and new or updated guidelines from the 27 NIH Institutes and Centers. A Spanish/English version, NIH MedlinePlus Salud, launched with support from the National Alliance for Hispanic Health and the National Hispanic Medical Association, addresses the specific health needs of the growing Hispanic population and showcases the many Hispanic outreach efforts and relevant research results funded by the NIH.

To be of greatest use to the widest audience, NLM's information services must be known and readily accessible. The Library's outreach program, with a special emphasis on reaching underserved populations, relies heavily on the more than 6,300-member National Network of Libraries of Medicine (NN/LM). The NN/LM is a network of academic health sciences libraries, hospital libraries, public libraries and community-based organizations working to bring the message about NLM's free, high-quality health information resources to communities across the Nation.

### DISASTER INFORMATION MANAGEMENT

Events of the past year, such as the *Deepwater Horizon* oil spill and the earthquake, tsunami, and radiation event in Japan, demonstrated yet again the importance of rapid, organized response to natural disasters and other emergencies. NLM has a long history of providing health information to prepare for, respond to, and recover from disasters and has tools and advanced information services designed for use by emergency planners, responders and managers. Through its Disaster Information Management Resource Center, NLM builds on proven emergency backup and response mechanisms within the National Network of Libraries of Medicine to promote effective use of libraries and disaster information specialists in disaster preparedness and response. NLM also conducts research on new methods for sharing health information in emergencies as its contribution to the Bethesda Hospital Emergency Preparedness Partnership, a model of private-public hospital collaboration for coordinated disaster planning. NLM partners with the Pan American Health Organization (PAHO) and other bodies in the Latin American Network for Disaster and Health Information to promote capacity-building in the area of disaster information management.

Within 2 days of the gulf oil spill, NLM launched a web page focused on the potential effects of oil on human health, which quickly became a highly regarded resource for evidence-based information by Federal, State, and local agencies and communities. NLM continued to support information needs in Haiti, including onsite assistance to PAHO in setting up a system for collecting information from cholera treatment centers. The Radiation Emergency Medical Management (REMM) tool, previously developed by NLM, the HHS Office of the Assistant Secretary for Preparedness and Response, CDC and NCI, was deployed in Japan, via the web and on mobile devices, to assist with assessing and managing the health effects of radiation. NLM also activated the Emergency Access Initiative, a partnership with publishers and medical libraries which provides free temporary access to key electronic medical journals and books when disasters interrupt regular health information services, and provided practical advice to Japanese libraries and archives on rescuing water-damaged books and documents.

In summary, NLM's information services and research programs serve the Nation and the world by supporting scientific discovery, clinical research, education, healthcare delivery, public health response, and the empowerment of people to improve personal health. The Library is committed to the innovative use of computing and communications to enhance public access to the results of biomedical research.

PREPARED STATEMENT OF JACK WHITESCARVER, PH.D., DIRECTOR, OFFICE OF AIDS RESEARCH

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2012 President's budget request for the trans-NIH AIDS research program, which is $3,159,531,000. This amount is an increase of $100,254,000 over the fiscal year 2011 enacted level. It includes the total NIH funding for research on HIV/AIDS and the wide spectrum of AIDS-associated malignancies, opportunistic infections, co-infections, and clinical complications; intramural and extramural research; research management support; research centers; and training. It also includes a transfer of approximately $27 million to the HHS Office of the Assistant Secretary of Health to foster collaborations across HHS agencies and finance high priority initiatives in support of the President's National HIV/AIDS Strategy.

THE AIDS PANDEMIC

Nearly 30 years since the recognition of AIDS and the identification of HIV as its causative agent, the HIV/AIDS pandemic remains a global scourge. UNAIDS reports that in 2009, more than 33 million people were estimated to be living with HIV/AIDS; 2.6 million were newly infected; and 1.8 million people died of AIDS-related illnesses. The majority of cases worldwide are the result of heterosexual transmission, and women represent more than 50 percent of HIV infections worldwide. More than 1,000 children become infected each day, most of them as newborns. More than 25 million men, women, and children worldwide have already died.

In the United States, CDC reports that more than 1.1 million people are estimated to be HIV-infected; approximately 56,300 new infections occur each year; and someone is infected with HIV every 9½ minutes. HIV/AIDS continues to be an unrelenting public health crisis, disproportionately affecting racial and ethnic populations, women of color, young adults, and men who have sex with men. The number of individuals aged 50 years and older living with HIV/AIDS is increasing, due in part to antiretroviral therapy, which has made it possible for many HIV-infected persons to live longer, but also due to new infections in individuals over the age of 50.

NIH AIDS RESEARCH PROGRAM

To address this pandemic, NIH has established the most significant AIDS research program in the world, a comprehensive program of basic, clinical, translational, and behavioral research in domestic and international settings—a multi-disciplinary, global research program carried out by every NIH institute and center in accordance with their mission. This diverse research portfolio requires an unprecedented level of trans-NIH planning, scientific priority-setting, and resource management. The Office of AIDS Research (OAR) was authorized to plan, coordinate, evaluate, and budget all NIH AIDS research, functioning as an "institute without walls," to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently.

NEW SCIENTIFIC ADVANCES AND OPPORTUNITIES

The past year has been a significant one for AIDS research. The NIH investment in the priority areas of HIV prevention research and in basic science over the past several years has resulted in important progress in critical areas of the NIH AIDS research program. Recent research advances by NIH intramural and extramural investigators have opened doors for new and exciting research opportunities in the search for strategies to prevent, treat, and ultimately cure HIV infection. These advances include:

*Technologies to accelerate discovery—*

—*Vaccines*.—A team of scientists led by researchers at the NIAID Vaccine Research Center discovered two potent human antibodies that can stop more than 90 percent of known global HIV strains from infecting human cells in the laboratory and determined the structural analysis of how they work. The novel techniques used in this research may accelerate HIV vaccine research as well as the development of vaccines for other infectious diseases. An HIV vaccine clinical trial conducted in Thailand by NIH and the Department of Defense demonstrated the first indication of a modest but positive effect in preventing HIV infection. The trial marked the first step in proving the concept that a vaccine to prevent HIV infection is feasible.

—*Microbicides*.—For the first time in nearly 15 years of research, scientists discovered a vaginal microbicide gel that gives women a level of protection against

HIV infection. The study, sponsored by USAID and conducted by the Centre for the AIDS Programme of Research in South Africa (CAPRISA), found that the use of a microbicide gel containing the antiretroviral drug tenofovir resulted in 39 percent fewer HIV infections compared with a placebo gel. NIH provided substantial support and resources to establish the infrastructure and training for CAPRISA. Ongoing and future NIH clinical trials will build on these study results with the goal of bringing a safe and effective microbicide to licensure.

—*Basic Science*.—This past year, using genome-wide association studies, NIH-sponsored researchers made an important discovery related to the genetics of an individual's immune system. These genes appear to be involved in the control of HIV disease progression among a group of individuals considered "elite controllers," who have been exposed to HIV over an extended period, but whose immune systems have controlled the infection without therapy and without symptoms. These findings will contribute to the development of potential HIV prevention strategies.

*Translational sciences and therapeutic development*.—New lymphoma regimens have been developed that can be tailored to specific tumor types. This development has markedly improved the therapeutic outcome and survival of patients with AIDS-related lymphoma. In addition, progress in both basic science and treatment research aimed at eliminating viral reservoirs has been significant enough that scientists are now, for the first time, planning to conduct research aimed at a cure. NIH has announced several initiatives to generate new ideas for curing HIV infection through domestic and international partnerships among government, industry, and academia.

*Enhancement of evidence-base for healthcare decisions*.—In the critical area of treatment as prevention, two recent studies have demonstrated the effectiveness of new multi-drug antiretroviral regimens for the prevention of mother-to-child-transmission of HIV during pregnancy and breastfeeding. In addition, a large international NIH clinical trial provided strong evidence that the use of pre-exposure prophylaxis (PrEP), that is, the use of antiretroviral treatment before exposure to prevent infection, can reduce risk of HIV acquisition in men who have sex with men. Additional and continued research is needed to determine whether PrEP will be similarly effective at preventing HIV infection in other at-risk populations and assist healthcare workers in providing these potential options.

### TRANS-NIH PLAN AND BUDGET

These advances, while preliminary and incremental, provide the groundwork for further scientific investigation and the building blocks for the development of the trans-NIH AIDS strategic Plan, developed by OAR in collaboration with both government and non-government experts. The priorities of the strategic Plan guide the development of the trans-NIH AIDS research budget. OAR develops each IC's AIDS research allocation based on the Plan, scientific opportunities, and the IC's capacity to absorb and expend resources for the most meritorious science—not on a formula. This process reduces redundancy, promotes harmonization, and assures cross-Institute collaboration. The priorities of the Plan will establish the biomedical and behavioral research foundation necessary to implement the major goals of the President's National HIV/AIDS Strategy and to implement the NIH Director's themes.

### FISCAL YEAR 2012 SCIENTIFIC PRIORITIES

A growing proportion of patients receiving long-term antiretroviral therapy (ART) are demonstrating treatment failure, experiencing serious drug toxicities and side effects, and developing drug resistance. Recent studies have shown an increased incidence of malignancies, as well as cardiovascular and metabolic complications, and premature aging associated with long-term HIV disease and ART. NIH research will address the need to develop better, less toxic treatments and to investigate how genetic determinants, sex, gender, race, age, pregnancy status, nutritional status, and other factors interact to affect treatment success or failure and/or disease progression.

NIH-funded research is needed to address the causes of HIV-related health disparities, their role in disease transmission and acquisition, and their impact on treatment access and effectiveness. These include disparities among racial and ethnic populations in the United States; between developed and resource-constrained nations; between men and women; between youth and older individuals; and disparities based on sexual identity. In addition, specific fiscal year 2012 research priorities include: biomedical and behavioral research focused on the domestic AIDS epidemic, particularly in racial and ethnic populations of the United States; research to build on important research advances in prevention research in the past

year in the areas of microbicides, vaccines, and treatment as prevention; research to prevent and treat HIV-associated co-morbidities, malignancies, and clinical complications; research to address the complex issues around AIDS and aging; research to better understand the issues of adolescents and AIDS; basic and therapeutic research focused on elimination of viral reservoirs leading toward a cure; genetic studies to delineate the genetic basis for immune responses to HIV and to sequence HIV-associated tumors; and research on feasibility, effectiveness, and sustainability required for the scale-up and implementation of interventions in communities at risk.

SUMMARY

The OAR has utilized its authorities to shift AIDS research program priorities and resources to meet the changing epidemic and scientific opportunities. This investment in AIDS research has produced groundbreaking scientific advances. AIDS research also is helping to unravel the mysteries surrounding many other cardiovascular, malignant, neurologic, autoimmune, metabolic, and infectious diseases as well as the complex issues of aging and dementia. Despite these advances, however, AIDS has not been conquered, and serious challenges lie ahead. The HIV/AIDS pandemic will remain the most serious public health crisis of our time until better, more effective, and affordable prevention and treatment regimens are developed and universally available. NIH will continue its efforts to prevent, treat, and eventually cure AIDS.

Thank you for your continuing support for our efforts.

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PREPARED STATEMENT OF LAWRENCE A. TABAK, D.D.S., PH.D., PRINCIPAL DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2012 President's budget request for the Office of the Director (OD). The fiscal year 2012 budget includes $1,298,412,000; an increase of $132,451,000 over the comparable fiscal year 2011 enacted level of $1,165,961,000, comparable for transfers proposed in the President's request.

The OD promotes and fosters NIH research and research training efforts in the prevention and treatment of disease through the oversight of the Intramural Research program and through coordination of program offices responsible for stimulating specific areas of research throughout NIH to complement the ongoing efforts of the Institutes and Centers. The OD also develops policies in response to emerging scientific opportunities employing ethical and legal considerations; maintains peer review policies; provides oversight of grant and contract award functions; coordinates information technology across the Agency; and coordinates the communication of health information to the public and scientific community. Moreover, the OD provides the core management and administrative services, such as budget and financial management, personnel, property, and procurement services, ethics oversight, and the administration of equal employment policies and practices.

The principal OD offices providing these activities include the Offices of Extramural Research, Intramural Research, Science Policy, Communications and Public Liaison, Legislative Policy and Analysis, Equal Opportunity and Diversity Management, Financial Management, Budget, Management, Human Resources, Chief Information Office, and the Executive Office. This request contains funds to support the functions of these offices as will be outlined in the Program, Project and Activities Table which follows.

The statement is submitted with the recognition of the Department's notification to the Congress of an NIH reorganization that would establish a new National Center for Advancing Translational Sciences and reallocate the remaining portions of the National Center for Research Resources to other parts of NIH, including the OD.

DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES (DPCPSI)

The DPCPSI mission includes identifying the most compelling scientific opportunities, emerging public health challenges, and scientific knowledge gaps that merit further research or would otherwise benefit from strategic coordination and planning across the Agency. DPCPSI provides key support of research that is consistent with the NIH Director's Themes. The Division is comprised of the Office of AIDS Research, Office of Research on Women's Health, Office of Behavioral and Social Sciences Research, Office of Disease Prevention, Office of Medical Applications of Research, Office of Dietary Supplements, Office of Rare Diseases Research, and the

Office of Strategic Coordination (OSC). The OSC is responsible for the oversight and management of the NIH Common Fund. The Division is responsible for agency-wide effort in portfolio analysis and also manages NIH-wide evaluation and performance activities, including the Evaluation Set-Aside program and the Government Performance and Results Act plans and reports. The fiscal year 2012 budget for DPCPSI/Office of the Director is $8,401,000. Descriptions of the eight programmatic offices within DPCPSI, and their separate budgets, follow.

THE OFFICE OF AIDS RESEARCH

The Office of AIDS Research (OAR) plays a unique role at NIH, establishing a plan for the AIDS research program. OAR coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. OAR's response to the AIDS epidemic requires a unique and complex multi-institute, multi-disciplinary, global research program. This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently, allowing NIH to pursue a united research front against the global AIDS epidemic. The fiscal year 2012 budget for OAR is $65,760,000.

THE OFFICE OF RESEARCH ON WOMEN'S HEALTH

The Office of Research on Women's Health (ORWH) mission is to enhance and expand research supported by the NIH to adequately address women's health. This is done by identifying gaps in knowledge, and collaborating with the ICs to stimulate and support innovative research including interdisciplinary scientific approaches to women's health and studies of sex and gender differences in health and diseases. ORWH continues to lead efforts to ensure adherence to policies for the inclusion of women and minorities in clinical research The fiscal year 2012 budget for ORWH is $43,811,000.

THE OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

The Office of Behavioral and Social Sciences Research (OBSSR) was established by Congress to stimulate behavioral and social science research at NIH and to integrate it more fully into the NIH research enterprise. The Office furthers the NIH mission by emphasizing the critical role that behavioral and social factors play in health, healthcare, and well-being. The Office supports the activities of the NIH Basic Behavioral and Social Science Opportunity Network, a trans-NIH initiative to expand the agency's funding of basic behavioral and social sciences research. The fiscal year 2012 budget for OBSSR is $27,949,000.

THE OFFICE OF DISEASE PREVENTION

The primary mission of the Office of Disease Prevention (ODP) is to stimulate disease prevention research across the NIH and to coordinate and collaborate on related activities with other Federal agencies as well as the private sector. The fiscal year 2012 budget for ODP is $1,400,000. The Office of Medical Applications of Research (OMAR), Office of Dietary Supplements (ODS), and Office of Rare Diseases Research (ORDR) are within the ODP organizational structure.

The Office of Medical Applications of Research (OMAR) mission is to work with NIH Institutes, Centers, and Offices to assess, translate and disseminate the results of biomedical research that can be used in the delivery of important health interventions to the public. The fiscal year 2012 budget for OMAR is $4,877,000.

The Office of Dietary Supplements (ODS) promotes study of the use of dietary supplements by supporting investigator-initiated research, and through other major mechanisms. The fiscal year 2012 budget for ODS is $28,691,000.

The Office of Rare Diseases Research (ORDR) supports activities that stimulate research on rare diseases by collaborating with the research institutes, research investigators, patient advocacy groups, the pharmaceutical industry, and Federal regulatory and research agencies. The fiscal year 2012 budget for ORDR is $18,423,000.

THE OFFICE OF STRATEGIC COORDINATION AND THE COMMON FUND

The Office of Strategic Coordination (OSC) facilitates strategic planning and management of Common Fund-supported programs by working with groups of staff from across the NIH to develop and implement each individual program while providing central management for the Common Fund as a whole. The NIH Common Fund was enacted into law by Congress through the 2006 NIH Reform Act to support cross-cutting, trans-NIH programs that require participation by at least two NIH Insti-

tutes or Centers (ICs) or would otherwise benefit from strategic planning and coordination. The Common Fund provides limited-term funding for new programs that are intended to catalyze research in the ICs through the development of cross-cutting resources, technologies, and data sets. Common Fund programs do not address any particular disease or condition, but rather, are designed to be broadly relevant. The fiscal year 2012 budget for the Common Fund is $556,890,000.

THE OFFICE OF SCIENCE EDUCATION

The Office of Science Education (OSE) develops science education programs, instructional materials, and career resources that serve our Nation's science teachers, their students (kindergarten through college), and the public. OSE's activities are an important component to the overall Agency effort to achieve the NIH Director's goal to reinvigorate and empower the biomedical research community and enhance America's competitiveness in the global economy. The OSE creates programs to improve science education in schools (the NIH Curriculum Supplement Series) that stimulate interest in health and medical science careers (LifeWorks Web site); and advance public understanding of medical science, research, and careers; and advises NIH leadership about science education issues. The OSE website is a central source of information about available education resources and programs. http://science.education.nih.gov. The fiscal year 2012 budget for OSE is $4,120,000.

LOAN REPAYMENT AND SCHOLARSHIP PROGRAMS

The Office of Intramural Training and Education administers the NIH Intramural Loan Repayment and Undergraduate Scholarship Programs (UGSP). The Loan Repayment Programs (LRPs) seek to recruit and retain highly qualified physicians, dentists, and other health professionals with doctoral-level degrees. These programs offer financial incentives and other benefits to attract highly qualified physicians, nurses, and scientists into careers in biomedical, behavioral, and clinical research as employees of the NIH. The NIH UGSP offers competitive scholarships to exceptional college students from disadvantaged backgrounds that are committed to biomedical, behavioral, and social science health-related research careers at the NIH. The fiscal year 2012 budget is $7,653,000 for the Intramural Loan Repayment and Undergraduate Scholarship Programs.

I am happy to answer any questions you may have about the OD's programs and activities as well as our plans for the upcoming year.

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PREPARED STATEMENT OF JEREMY M. BERG, PH.D., DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2012 President's budget request for the National Institute of General Medical Sciences (NIGMS). The fiscal year 2012 budget request includes $2,102,300,000, an increase of $70,263,000 above the fiscal year 2011 appropriation of $2,032,037,000, which has been adjusted comparably to reflect NIH proposed transfers. This statement is submitted with the recognition of the Department's notification to the Congress of an NIH reorganization that would establish a new National Center for Advancing Translational Sciences and reallocate the remaining portions of the National Center for Research Resources to other parts of NIH.

Since the mid-20th century, NIGMS has played a leading role as NIH's "basic research institute." Spanning a broad spectrum, the Institute's mission supports discovery ranging from how cells work to how diseases affect communities across towns, nations, and countries. NIGMS-supported scientists probe the unknown to solve mysteries about fundamental life processes. This effort goes well beyond the need to satisfy innate curiosity; answering basic research questions such as how bacterial and human cells divide, move, and communicate has increased our knowledge about infections, cancer, birth defects, and heart disease in ways that would have been difficult to achieve with more directed studies. Other ongoing NIGMS research investments, such as in chemistry, continue to provide tangible benefits to society and our economy. This past year, an NIGMS-supported scientist shared a Nobel Prize for his discovery of a ground-breaking chemistry method that is used routinely in the pharmaceutical, electronic and agricultural industries.

Continued investment in basic research is vital because many of today's therapies, although effective, nevertheless have significant limitations. Treatments that are applied after the onset of serious illness—kidney transplants and dialysis, bypass surgery for coronary artery disease, surgical removal of tumors—though often lifesaving, are still not optimal. Treating disease before such interventions are needed

would likely improve both outcomes and quality of life. Basic biomedical and behavioral research has the power to move treatments in this direction, and in the coming years, emerging biotechnology and nanotechnology tools will give researchers unprecedented precision to detect and derail disease at its earliest stages.

TECHNOLOGIES TO ACCELERATE DISCOVERY

Basic research on stem cells remains one of the most rapidly advancing areas of biomedicine, in large part because of the knowledge base scientists already have about how cells behave and change. NIGMS-supported research on stem cells continues to provide hope that these multitalented cells will find use in customized therapies for a range of conditions. In the near term, stem cells are providing researchers powerful tools for understanding diseases and developing drugs to treat them. This past year, NIGMS-funded researchers made important progress on several fronts:

—Stem cell research pioneer James Thomson, D.V.M., Ph.D., created a powerful tool to trace the individual steps in a deadly cancer by turning the clock back on blood cells from a person with leukemia.

—Chemist Laura Kiessling, Ph.D., developed an inexpensive and simple synthetic culture system for growing embryonic stem cells in the laboratory.

—NIH Director's New Innovator Awardee Alysson Muotri, Ph.D., used cells from a person with Rett syndrome to create a cellular model of autism.

Another area showing great promise is molecular diagnosis. This past year, NIH Director's Pioneer Awardee Thomas Kodadek, Ph.D., applied a unique and creative strategy that conducts an "immune surveillance" of human blood to look for early signs of disease before symptoms appear. To date, he has obtained exciting evidence that Alzheimer's disease may be detectable by this approach, and he has licensed the technology to further its development and application.

The study of systems—of cells, organs, and diseases—is an important area of basic discovery within the NIGMS mission. In 2010, the Institute grew its support of systems biology by adding two new National Centers for Systems Biology. All 12 centers integrate approaches from engineering, genomics, and systems and synthetic biology to identify principles and architectural features involved in common cellular behaviors, including the response to disease-causing microorganisms, poisons, and metabolic imbalances.

Computer modeling is a key element of all systems biology, and a central aspect of the NIGMS-led Models of Infectious Disease Agent Study (MIDAS). This international effort continues to add new research expertise to increase its capacity to simulate disease spread, evaluate different intervention strategies, and help inform public health officials and policymakers. This past year, two MIDAS findings are worth highlighting:

—One MIDAS study used computer modeling to analyze the spread of H1N1 flu in a Pennsylvania elementary school. The researchers collected extensive data from seating charts, school timetables, bus schedules, nurse logs, attendance records and questionnaires. The findings indicated that transmission occurs mostly through girl-to-girl and boy-to-boy interactions and that sitting directly next to a child with the flu does not raise a child's risk of getting it.

—In another MIDAS study, researchers learned that the Haiti cholera outbreak that followed that Nation's colossal earthquake in 2010 could have been blunted with the use of a mobile stockpile of oral cholera vaccine.

TRANSLATIONAL SCIENCES AND THERAPEUTICS DEVELOPMENT

Since the landmark discovery of the structure of DNA in the 1950s, our increasing knowledge of how all living things share a basic set of working parts has catalyzed progress in biomedicine. Large-scale efforts to scan and compare genomes are teaching scientists about individual differences in DNA scripts that predispose us to disease. However, such sequence information is only useful if it can be properly interpreted. NIGMS has been at the forefront of supporting research that facilitates this interpretation, leading to numerous discoveries that have revealed new, unforeseen mechanisms by which DNA information is made operational.

As one example, the NIGMS Protein Structure Initiative (PSI) has been creating knowledge and providing tools to researchers for more than 10 years. This past year, NIGMS enhanced this signature effort by launching PSI:Biology, a new program that supports research partnerships between groups of biologists and high-throughput structure determination centers to solve medically important problems. Already this investment is bearing fruit, yielding new structures that show how the largest class of drug receptors functions.

Another example is a pilot study by an individual scientist that searched systematically for environmental factors—nutrients, chemicals and toxins—that may be linked to diabetes. Based conceptually on the Genome-Wide Association Studies approach, Atul Butte, M.D., Ph.D., developed a new technique he calls Environment-Wide Association Studies. In this method, he considered many different factors at once, using health survey data from the U.S. Centers for Disease Control and Prevention, which led him to identify 266 environmental factors linked to type 2 diabetes. This example highlights the tremendous potential benefits of integrating existing data sources and asking the right questions.

ENHANCEMENT OF EVIDENCE BASE FOR HEALTHCARE DECISIONS

Although medicines have been revolutionary in humankind's ability to stay healthy, we now know that people having widely varying responses to the drugs they take to heal their various ills. NIGMS has been a long-time supporter of pharmacogenomics, the study of how our DNA influences the way we respond to medications. This area of research is an especially important focus in our country today, as the baby-boom generation gets older and is more likely to take multiple medicines routinely. NIGMS leads the trans-NIH Pharmacogenomics Research Network (PGRN), a nationwide collaborative of scientists looking for clues to inherited variability in the response to medicines used to treat heart disease, asthma, cancer, depression and addiction.

This past year, two new groups joined the network, adding rheumatoid arthritis and bipolar disorder as new focus areas. Over the next 5 years, the PGRN plans to expand to pursue cutting-edge DNA sequencing methods and statistical analysis, as well as to perform pilot studies to learn about medication response from de-identified medical records in healthcare systems. Furthermore, previous PGRN-based discoveries are now moving further into clinical application with evidence accumulating on improved outcomes and lower costs.

NEW INVESTIGATORS, NEW IDEAS

Biomedical and behavioral research is a human endeavor, and NIGMS has a long-standing commitment to supporting and sustaining the people behind the research. Creativity comes from the sparks of individual minds, and thus the Institute has always adhered to the principle that a healthy workforce is an essential ingredient for good science that leads to better health for all.

Science and the conduct of research continue to evolve, though, as do workforce needs. It is our responsibility to stay attuned to these new needs and opportunities. In 2010, NIGMS launched a process to examine its activities and general philosophy of research training—to assure that all of the Institute's activities related to the training of scientists are aligned with our commitment to build an excellent, diverse research workforce to help achieve the NIH mission, now and in the long term.

NIGMS gathered data and input from the scientific community through a series of regional meetings across the country, as well as through other means of electronic communication including a webinar, online postings, and comment submissions via e-mail. The resulting plan, Investing in the Future, the NIGMS Strategic Plan for Biomedical and Behavioral Research Training, was released in early 2011.

A key focus of this plan is the importance of putting the needs of trainees first—by focusing on mentoring, career guidance, and diversity. The plan also affirms the Institute's strong assertion that there are multiple avenues in which a well-trained scientist can make meaningful contributions to society. These include research careers in academia, Government, or the private sector, as well as careers centered on teaching, science policy, patent law, communicating science to the public, and other areas.

In closing, and on the cusp of my departure from Federal service, I want to note how proud I have been to play a role in furthering the basic research that has had such a profound effect on the health and well-being of our Nation. I will treasure the time and effort spent leading the fine institution that is NIGMS.

AVERAGE COST OF RESEARCH PROJECT GRANTS

Senator HARKIN. Well, thank you, Dr. Collins. Very poignant ending for your testimony.

We will now begin a round of 5-minute questions.

Dr. Collins, in addition to drastically cutting NIH funding, the House Appropriations bill would have required NIH to fund a min-

imum number of new competing research grants and put a ceiling on the average cost to them.

I have a letter here from a number of different entities—American Association for Cancer Research, American Medical Colleges, American University—a whole list of different people who've written us a letter saying that this would really hamper the ability of NIH to fund the best, the most innovative, the brightest by putting a cap on it. Now, you have to fund so many and you have to—I think it was 9,000—and then they put a cap on it of, I think, $400,000, if I'm not mistaken.

Again, I'd like you to speak to that. We've been down this road before over the last 25 or 30 years that I've been on this subcommittee, in saying that NIH really ought to do this on a peer-reviewed basis. Some of the projects cost more, some cost less, but to limit it and then to say you have to do so many, takes away the ability to really do a good peer-reviewed systematic approach to this.

I would like you to respond to that and what that would mean to NIH if, in fact, we were to set a limit on how much and to mandate that you have to fund at least so many grants.

Dr. COLLINS. Senator, I appreciate the question. This is a very serious issue and you've set it up quite well in terms of what the risks might he here.

Certainly, that feature of the language that was part of H.R. 1 was deeply troubling to those of us at NIH, because, as you have just said, the goal of all of us who tried to carry out our responsibilities to support the very best biomedical research is to utilize the tools of peer review, to seek advice from the scientific community and our advisory councils about how best to utilize the resources that the taxpayers, through this Congress gives to us.

The idea that we would have to manage that enterprise in an arbitrary way to try to hit a certain number of grants, and particularly to try to hit some average cost of a new and competing grant could potentially seriously interfere with the flexibility that we believe is necessary for the best science to be supported.

For instance, clinical trials tend to be more expensive. Would this kind of a limit on the average costs of a new and competing grant find its way into conversations about, well, maybe we should do fewer clinical trials and more grants that happen to be inexpensive, like conference grants? That would be, I think, a serious intrusion into the ways in which, really, scientific decisions should be made.

So I agree with you that that particular kind of way of tying NIH's hands would be very unfortunate. Given all of the scientific opportunities that we have right now, we should be able to pursue them in a way that represents the best decisions and not managed in this sort of arbitrary way by trying to hit certain numerical grant limits.

## DIABETES

Senator HARKIN. I appreciate that.

Dr. Rodgers, on diabetes, I think we saw that chart there about moderate changes in diet and exercise resulting in a huge decrease in the incidence of the disease. I had 71 percent and the chart said 58 percent, so I have to figure out why there's a difference here.

When you testified a few years ago on this, you said you would be undertaking a follow-up study to see whether these could be sustained over time. What's happened?

Dr. RODGERS. That's correct, Senator, and thanks for the question.

First of all, the 71 percent, even though the average improvement in terms of a reduction with that intensive lifestyle modification was 58 percent for all comers, among the people over 60 years of age, it was 71 percent. So they really enjoyed the best benefit of all of the subsets of the patients studied.

Now, the initial trial, the diabetes prevention trial, was published in 2002, and, at that point, the reduction was 58 percent for intensive lifestyle, 31 percent for a drug, metformin.

But, more recently, the 10-year follow-up, which is what I was referring to at that hearing, was just published in the Lancet in 2009, and that shows, as Dr. Collins mentioned, a durable effect out 10 years. These patients who engaged in the intensive lifestyle still showed a reduction of their going on to develop diabetes, and the patients, in fact, who were on the metformin also continued to show an improvement.

Senator HARKIN. Very good.

Now, my 5 minutes is up, but I have other questions for other people here. I'll do that on my second round.

Senator Shelby.

## NCATS BUDGET AMENDMENT

Senator SHELBY. Thank you, Mr. Chairman.

Dr. Collins, I'm going to get back into NCATS for a minute. I think it's very important, and I think it has great promise.

I think that NCATS proposal requires thoughtful consideration to the effect that it will have on NIH, the extramural research community and the private pharmaceutical market. You've alluded to this a little.

As I stated, I remain concerned that this announcement was made in December, yet we don't have some details before the subcommittee yet.

The reorganization will impact all of NIH's 27 Institutes and Centers and will shift at least $1.3 billion. I believe the subcommittee needs to review such a proposal, especially one that has such a potential impact on the NIH community.

My question is when will we receive some more details that we can renew—for the staff and the subcommittee—or do you have a timeline? I know it's a difficult transition.

Dr. COLLINS. Senator, it's a very fair question, and I had certainly hoped that by the time of this hearing we would have been able to provide the full details about the budgetary consequences of standing up this new and exciting new center.

It is a complicated process. The recommendation to do this came forward from my Scientific Management Review Board last December 7.

Rather than putting this off until fiscal year 2013, which I thought would really have wasted an opportunity, we decided we would try to move as quickly as possible. Although some people said, "Hey, this is the Government. You can't possibly do that by

October", well, they used to say that about the Genome Project. So I decided that we could, and we should, because this is the best way to move the science forward.

But, of course, what this means is taking a number of components that already exist in various institutes and in the common funded NIH and moving them together into this new synergistic entity. That's important to point out.

Actually, what we're talking about is not to create new budgetary implications, with the one exception of the Cures Acceleration Network, which is in the President's fiscal year 2012 budget at $100 million, and which we hope this subcommittee and others will see fit to support, because it'll give us some flexibilities in terms of how we manage the budget that we would dearly love to have.

But the other pieces of NCATS are basically derived from existing programs that are moved together in a way that are going to be highly complementary and synergistic.

We needed, of course, to consult with our communities, with our constituencies, and, as we figured out how to do the shifting right down to every employee to make sure that the programs were encouraged and nurtured, we had to be sure we had that right.

We are at the point now where we believe we have that together. It needs, of course, to be reviewed by the Department of Health and Human Services (HHS) and Office of Management and Budget (OMB) experts. We hope to get that to you, Senator, in the fairly near future, within, certainly, the next few weeks and, hopefully, a very few weeks.

COST OF DE-RISKING PHARMACEUTICALS

Senator SHELBY. Dr. Collins, you've also described the NCATS mission as one of what you call de-risk—that moves basic scientific discoveries beyond the lab to a point where the private pharmaceutical market feels confident enough to jump in.

What is the policy or what would you think the policy would be if a selected project is successfully de-risked, but no companies produce the drug or medical product? I know you've thought about that.

Dr. COLLINS. And, indeed, I should point out that this is an activity which NIH has been engaged in for some long periods of time, and my colleagues, particularly from the National Cancer Institute (NCI) and National Institute of Allergy and Infectious Diseases (NIAID), have been supporting this kind of translational effort in always looking for a commercial partner at the earliest moment in order to be able to carry a project through to completion and limit the amount of dollars that the taxpayers have to cover.

I would say projects that get undertaken at this point need to think about that from the very beginning. There will be instances perhaps where no commercial partner can be found, even all the way through to the end of a phase III trial, but they will be rare indeed, because those are very expensive enterprises.

But for very rare diseases, where the economic incentives are simply going to be very limited, and especially if one is in a circumstance where you could conduct such a clinical trial by repurposing a drug that's already been approved for something

else, then NIH may very well find it worthwhile to undertake that effort.

But you're quite right to point this out. We have to get the balance——

HEALTH PREPAREDNESS AND OBESITY

Senator SHELBY. Absolutely.

Just want to touch on health disparities. You got into it a little. Health disparities most often associated with the ethic population persist in rural United States. Stroke, diabetes, kidney disease and cancer are all more prevalent in both the African-American community as well as the South.

One of the root causes to health disparity is the obesity epidemic that is rampant in our Nation. You pointed it out in your slides. Southern States have the highest rates in the Nation.

My question is should we be looking for a new paradigm that broadly addresses this critical national issue at multiple levels for molecules to behavior to policy? You touched on it with your slide. And how can NIH help the American people meet that challenge?

Dr. COLLINS. So, Senator, I really appreciate the question because this is an enormous public-health challenge for all communities, but particularly so for certain underserved communities.

I'm going to turn to my colleagues, Dr. Rodgers and Dr. Shurin, who lead the Obesity Task Force at NIH, who are just putting forward a new research plan that's quite exciting.

Dr. RODGERS. Thank you, Senator.

Because of the extreme importance of this project, and particularly the recognition that obesity is occurring much more frequently in children in this country, we've also asked Dr. Collins for his permission to have the Director of the Child Health Institute on board as a co-chair of this obesity research task force.

As Dr. Collins indicated, we just put out this last month a strategic plan which highlights a blueprint for research in these critical areas related to prevention and potential treatment of obesity, particularly in health disparities or in certain ethnic and racial groups, in older adults, in young children.

And it recognizes the fact that obesity is a multifaceted problem, and, therefore, you need multifaceted solutions, including behavioral, medical, surgical and others.

Senator SHELBY. How important is behavioral here——

Dr. RODGERS. Behavioral research is extremely important. For example, we know that for childhood obesity just decreasing screen time, the amount of time kids are in front of the television, the computer, video games can greatly reduce the risk. Increasing physical activity is another important component to this.

Let me turn to my colleague, Dr. Shurin, who actually has a very active program involving children.

Dr. SHURIN. Thank you, Senator. We share your very deep concerns about this.

One of the things that Dr. Rodgers and I have done is to convene a group, a collaborative on obesity with the CDC and the Department of Agriculture with the support of the Robert Wood Johnson Foundation, which has a particular interest in childhood obesity.

So we have a multifaceted research program. Much of it is community-based research, but it also ties in to many biologically and behaviorally oriented research programs really looking at the factors that impact obesity.

As Dr. Rodgers has said, we've got several studies now which show a very profound influence of screen time. Physical activity is at least as important as diet, but dietary issues are obviously of major importance. And we have a very rich portfolio of research projects looking at what are the most effective interventional strategies.

Many of these are site-based, worksite-based and school-based programs. I think one of the things that's particularly important is that many of the projects that we get into which look very promising don't actually pan out. It's very helpful for us to know what doesn't work, so we can really be fairly aggressive in pursuing the ones that do.

The impact of policy changes, the engagement of the food industry and of preventive health services we think are particularly important. We initiated a program called We Can, which is ways of enhancing childhood activity and nutrition, which we have now several thousand community partners aimed very heavily at reducing screen time and increasing physical activity and focusing very heavily on dietary activities.

We have several collaborations with the food industry, with several partners in the food industry which have become increasingly responsive, but we think that there are probably going to have to be some policy approaches that will have an impact on this, that simply relying on individual choices is not going to be sufficient.

Senator SHELBY. Thank you. Thank you, Mr. Chairman.

Senator HARKIN. Thank you. In keeping with the subcommittee's policy in order of appearance here at the subcommittee be Senator Reed, Senator Moran, Senator Mikulski, Senator Brown.

Senator Reed.

## GLOBAL COMPETITIVENESS

Senator REED. Thank you very much, Mr. Chairman, and thank you, doctors.

Dr. Collins, just a quick point, that Chinese facility that you mentioned to is supported by the Chinese Government or do we know?

Dr. COLLINS. Interesting. It is partly supported by the Government, but they actually have put this in place by taking out a bank-supported loan to allow them to purchase 128 of these——

Senator MIKULSKI. They didn't get it here.

Dr. COLLINS. Senator Mikulski is correct. It was not at an American bank. And they have purchased 128 of these sequencing machines, the largest collection in the world, and they are quite confident that the value economically will fully justify the cost of buying the machines.

They've also hired about 4,000 of the smartest young scientists that I've ever seen in one place from all over China who are in their 20s and who are prepared to change the world and probably are going to.

And we should celebrate that. I don't mean in any way to say I think this is a bad thing, but it worries me to see that China has taken that kind of initiative and we have not.

Senator REED. But the financing might be considered quasi private and public together, but this is clearly an initiative at the highest levels of the Chinese Government to get this done.

Dr. COLLINS. Yes.

Senator REED. And we are at this debate here in the United States about what we will commit as a Government to not only the genome sequencing, but so many of the innovative proposals you've talked about.

Dr. COLLINS. That's correct——

NIC VOLKER TREATMENT DETAILS

Senator REED. Just want to clarify that.

I thought also, joining the chairman, that the poignant story of Nic—I wonder did he or his doctors avail themselves to the National Cord Blood Registry, CDC's the MATCH? Was that a——

Dr. COLLINS. I don't know in terms of where his stem cell transplant came from. I can find that out for you, Senator.

PEDIATRIC RESEARCH

Senator REED. But that's an initiative that Senator Hatch and I worked on and I hope it contributed to that great story.

[The information follows:]

NIC AND THE NATIONAL BLOOD CORD REGISTRY

David A. Margolis, M.D., professor of pediatrics and director of the Bone Marrow Transplant Program at the Children's Hospital of Wisconsin, said, "Our donor coordinator says 'Yes. If it were not for the National Marrow Donor Program, and the single access that it provides, the search (for Nic's cord blood stem cell donor) would have been more difficult, time consuming, and may not have yielded the same results.'"

Senator REED. But this raises a larger question, then, in terms—that I have with respect to the amount of resources going to pediatric research. You've cited several examples. Dr. Rodgers, Dr. Shurin have talked about, you know, the research you're doing in children's obesity, et cetera.

For example, I'm told that only about 4 percent of the funds in the National Cancer Institute are for pediatric cancers. That might be good news, because it might represent that it's a relatively healthy population, but just generally a sense do you think we're making the right allocation of resources to pediatric research?

If we're not, are there structural issues; that is, is the peer-based review tilted toward adult experts rather than pediatric experts? Any comments I'd appreciate.

Dr. COLLINS. Well, quickly, and then I'll ask Dr. Varmus to address the pediatric oncology issue, but we have an entire Institute at NIH, the National Institute of Child Health and Human Development, which has as its major focus pediatric research and which certainly is a place of a great deal of interest and excitement right now because there are so many promising developments in childhood illness.

We also are investing in a very large national project, an unprecedented one, the National Children's Study, which will enroll 100,000 kids beginning even before conception through pregnancy and up to age 21 in order to comprehensively collect the kind of information about environmental exposures and genetics that may shed light on diseases like autism and diabetes that have continued to vex us.

I would say, yes, there's a lot of investment. Could there be more? You bet there could, but that would probably be true in virtually every area that we're looking at. With these 17 to 18 percent success rates that were mentioned by the chairman, we are clearly not able to support a lot of great science that we'd like to support.

Senator REED. Before Dr. Varmus, I must say that Brown University Medical School is participating along with Women and Infants Hospital, and Dr. Rodgers is their commencement speaker, because he's one of the most illustrious Brown University medical graduates in the history of the program. I had to put that in the record. Forgive me, Dr. Collins.

Dr. Varmus.

Dr. VARMUS. Senator Reed, thank you very much, and I appreciate your honoring my colleague, Dr. Rodgers.

You're correct that the amount of money we specifically identify as being devoted to pediatric cancer research is about 4 percent of our budget, which is about $200 million a year, but, of course, a great deal of other funding that we're involved in addresses cancer more generally and is applicable to pediatric problems.

Let me say a few words more broadly about pediatric cancer. Chairman Harkin alluded to the fact that we do cure most patients with leukemia. Pediatric cancers, in general, are much more effectively treated, whether they're brain tumors or neuroblastomas or Wilms tumor or leukemias, but, nevertheless, there still is an increased incidence of childhood cancers over the last several years by about 30 percent, but a continuing decline in mortality.

Nevertheless, mortality figures do not tell us the whole story. There are severe consequences of being treated for cancer at an early age—developmental defects, loss of mental capacity in some individuals, and, of course, a very high incidence of second tumors, particularly in survivors' 20s and 30s.

We're trying to address these problems in a variety of ways. We're trying to understand the cancers more profoundly with some of the genomic-sequencing techniques that Dr. Collins alluded to.

We, in fact, have spent Recovery Act money on a new project to study pediatric cancers in great detail. And we have new therapeutic maneuvers that are based on more targeted, bullet-specific drugs and antibodies that have been very effective in reducing mortality rates in neuroblastoma and leukemias with therapies that are less toxic.

We have paid a lot of attention to the survivors of pediatric cancer. We have a nationwide survivors study for pediatric cancer that has enrolled over 20,000 patients in roughly 37 different centers. So with these and other projects, we think we're making a pretty good effort to control the consequences of treatment of pediatric cancer and to do a better job in treating pediatric cancers in a less toxic manner.

But you're correct, we could do more, but, as you know, we have budget constraints this year. It's unlikely that we'll see a very significant increase in that domain or any other in the coming year.

BIOMEDICAL RESEARCH RESOURCES AND WORKFORCE

Senator REED. Thank you very much. Thank you, gentlemen. Thank you, Dr. Shurin. Thank you, Mr. Chairman.

Senator MORAN. Chairman Harkin, thank you.

Dr. Collins and your colleagues, fellow doctors, I appreciate the opportunity to have this conversation with you this morning.

This is a beginning course for me. I have 4 months of being a United States Senator and being a member of this subcommittee, but I'm excited about joining Senator Harkin and Senator Shelby and my colleagues here.

I think medical research is a huge component of the future of our country. I think it matters greatly, and I commend you for your efforts to date.

In my healthcare reform bill, we would support medical research in a dramatic way. I think it's a cost-saving measure. It's about saving people's lives, improving the quality of their life. And so from an economic—as you point out—but also from a personal, humanitarian point of view, what we do here in this subcommittee and what you do at NIH matters greatly.

And I would welcome the opportunity to become better acquainted with NIH, its personnel, its mission. Maybe the people in the rows behind you—I want my doctors out there doing the research, but I'm happy to have others at NIH devote some time to educating me so that I can better understand how we can advance the cause of medical research here in the United States.

I would ask first if there is something missing. We're here in an appropriations subcommittee, but other than money, is there something missing at NIH or here in our country, in the United States, that makes it much more difficult or makes it difficult for you to reach the goals that you outlined for us today or is this just a financial issue, how many dollars do we devote? What are the other, if any, impediments toward success?

Dr. COLLINS. Well, Senator, I appreciate the question and certainly appreciate your strong statement of support, and you are most welcome to come and visit us at NIH. We'd love to host you for a visit and show you some of the things that are going on in the laboratories and in the clinical center, the largest research hospital in the world, that's up there in Bethesda.

Senator MORAN. Thank you.

Dr. COLLINS. But as you know, most of the money that NIH sends out in grants goes to the 50 States, including Kansas, and we're very proud of the research that's going on there in your State.

Senator MORAN. Thank you.

Dr. COLLINS. In terms of other things that potentially are barriers, certainly we do not have what I would call a vigorous pipeline of young scientists coming into our field, and part of that is the sad state of K through 12 science education in this country, which has certainly, by any measure, slipped badly over where it

used to be back in the—30 or 40 years ago in the sort of post-Sputnik arena where science education was really emphasized.

Now, in many schools, it is unfortunately quite rudimentary, and I think we lose, therefore, the chance to capture young people's imagination that science would be a place they wanted to spend their own careers. And that means we have fewer American-born individuals who are clamoring to come in to our laboratories and make the next great discoveries.

We have lots of interest from individuals born in other countries to do that, but that interest has actually declined a bit as more opportunities are present in their own countries.

Some of them, certainly in large numbers, still come to train in our universities, but they often now go back to their original homes and carry out research instead of staying in the United States. And some of our visa practices have not helped in that regard in terms of making such talented scientists from other countries feel less welcome than we wish they were.

It seems to me that would be a very important area for us to, again, try to get right, because it is to our advantage to recruit such individuals—and our universities are still seen as the very best in the world—to come and do their research, but then for us to also be able to capture their talents in an ongoing way I think would be a great advantage. That is just one of the areas.

But, frankly, the major concern that I think we have is just the lack of sufficient resources to chase down all of the great ideas that are now potentially possible.

INTERDISCIPLINARY RESEARCH

Senator MORAN. I appreciate that answer and look forward to finding solutions in that regard and understand now the importance you place upon the resources.

I did visit the University of Kansas last week and one of the research facilities there, the Molecular Libraries Program, and I'm very interested in what the ranking member pursued in regard to NCATS.

And when I heard your testimony today, my assumption is that this will take a lot of different kinds of scientists engaged in this effort, and I guess an initial question would be what steps would you anticipate being taken to ensure that the best of American science in as many areas will have that opportunity to contribute to this new program?

Dr. COLLINS. Well, a very appropriate point. It will take an interdisciplinary effort of a considerably revolutionary sort.

It means bringing together biologists and chemists—as no doubt you saw at the Molecular Libraries Program in Kansas—along with computational experts, structural biologists who can actually figure out the shape of molecules and figure out which shapes fit together in a way that might make a particular drug work, immunologists who can help us with monoclonal antibody development, engineers who can work on devices that will be the next generation of what we need for all manner of medical applications, and those disciplines traditionally haven't had such an easy time talking to each other, and one of our goals through this program and many others is to do that.

Maybe this is also partly in answer to your first question about what are some of the barriers. In some way our own traditional disciplines have presented some of that problem, although I think those barriers are coming down.

Clearly, there's a lot of excitement—and I suspect you perceived that in your visit to the Kansas center—about the potential here of bringing those disciplines together with these new comprehensive sciences to enable academic investigators to play a larger role in reengineering this broken pipeline to try to make it possible to come up with therapeutics and devices and diagnostics in a shorter time period.

This resonates with me for the same kind of feeling I had about the Genome Project 20 years ago. It was controversial then, too, of course. A lot of people wondered whether this was biting off more than the Government could chew, but it recruited into the effort some of the best and brightest minds of that generation because they could see the potential.

I think that same atmosphere is beginning to appear in translational science, and I suspect once we have the programs in place it will not be hard to recruit some really brilliant minds to play a role in this.

Harold, did you want to add to that?

Dr. VARMUS. I think it might be important to reassure you, Mr. Moran, about the effort that's being made in translational research across the institutes.

As Francis alluded to in his testimony, a great deal of work—interdisciplinary work, indeed—has gone on in the Institutes and will continue to go on, while NCATS provides a catalytic advantage to the efforts that we're making by providing new methodologies, ways to analyze how translational research is done, some core facilities.

But, as you probably know from going to your cancer center at the University of Kansas, that there is a lot of translational research going on there, and that's done by interdisciplinary teams.

So all of us at the NIH are engaged in this process and we've had a lot of experience in gathering multidisciplinary teams over the last decade or so to do this kind of work.

Senator MORAN. So it's not new and we know it can be done. It's being done today.

Dr. VARMUS. But we're all engaged in the process, and it's not going to fall solely on the head of NCATS.

Senator MORAN. And, unfortunately, I'm on the social science in my education and I detect that the same thing may be there between chemistry and biology as there is between history and political science.

Dr. VARMUS. Well, there could well be. Yes——

Senator MORAN. But I appreciate that, and I did see the enthusiasm. That was perhaps the takeaway of my visit is the excitement that is there and the belief in the potential of what can be accomplished.

Dr. VARMUS. Yes.

Senator MORAN. It's very appealing to me.

Dr. COLLINS. Dr. Fauci wants to add something.

Dr. FAUCI. There is one other thing that sometimes gets misunderstood. We mention—and Dr. Varmus mentioned also that there's a lot of translational research going on.

What the center is going to be directing itself at is to really advance what we call the discipline of translational research, in other words, to help us to do more innovative ways of approaching translational research. So translational research goes on to the tune of many billions of dollars at the NIH, mostly in the big Institutes, but some of the smaller Institutes also.

What we want to do is advance the discipline of how it's done, making it a 21st century approach toward translational research as opposed to relying on many of the methodologies that have been good, but that we think we can do better on. That's what it's really all about, putting forth the discipline and improving the discipline of translational research.

Senator HARKIN. Thank you. Thank you, Senator Moran.

Senator Mikulski.

SUPPORT OF NIH

Senator MIKULSKI. Thank you very much, Mr. Chairman. I'm very proud of the fact that NIH is located in the State of Maryland. And for more than 25 years, I've visited NIH regularly, and every time I come, my eyes pop with wonder, my heart beats with excitement and I just—one of the reasons I wanted to be here today was to tell you and all of the people who work at NIH how proud I am of you, and how America ought to be proud of you.

Dr. Collins, you did path-breaking pioneering work when mapping the genome. And we were in a race. You had another competitor down the street. You broke the code and we invented—not only mapped the code, but came up with new fields called computational biology, bioinformatics, new exciting careers that help both us in particularly the private sector be able to come up with new products.

And, Dr. Fauci, you, what you've done. You were the guy who broke the AIDS code. You were the guy that came here when we were gripped in fear and near panic when we were shut down due to anthrax and we had no place to turn in our United States Government for information, but we turned to you and you kept us on the right path, so that we could keep the doors of the Capitol——

Dr. Varmus, a former head of NIH. You know, NIH Directors don't leave. They leave legacies, and then they come back to create new ones, and we're so glad to see you. And we note that when you were at Sloan-Kettering you had a lot of other zeros behind your compensation package, which says something about why you came back.

And to Dr. Rodgers and Dr. Shurin, who also was educated at Hopkins, we're just glad to see you.

And, Mr. Chairman, and what they do is the work that helps us manage the biggest budget busters in our healthcare budget—diabetes, heart disease, the chronic conditions that lead to chronic problems in the way we live, in the way we have to fund healthcare.

So I wanted to be here today to say for all the people work at the institutes, all the people work at the various offices, all the lab

techs, the security guards, the fire department, we're really proud of you.

So having said that, I want to make sure we help NIH be NIH. So I want to stick to the basic mission in addition to these exciting new ideas.

Dr. Collins, how many research grants did NIH fund last year, and how many requests did you get for funding? In other words, what is the funding gap, and particularly not only with the tried and true research, but also with those promising young, maybe more upstart type thinking?

Dr. COLLINS. So in fiscal year 2010, we funded approximately 9,300 research grants. The success rate in fiscal year 2010 came out at just about 20 percent; that is, one out of five that were able to be supported.

With the fiscal year 2011 budget now in front of us, now that it's been decided, we won't do that well, because, of course, as you know, after the dust all settled, we ended up with a 1-percent cut of $320 million, although I really want to express my appreciation——

Senator MIKULSKI. So that's what one percent means, $320 million?

Dr. COLLINS. That's correct. But I do want to express my appreciation to members of this subcommittee, because I know there was a great deal of debate about exactly where the dust would all settle out, and certainly many of the proposals were vastly worse than this, and I know many people really went to bat for NIH, and we appreciate that enormously.

But we do believe that in fiscal year 2011—with some uncertainty in the number, because we don't actually know how many grants we will receive, and, of course, we're talking about a proportionality here—that the success rate will fall to approximately 17 to 18 percent, and that will be the lowest in history.

We will do our best to try to manage the resources that we've got, and we've made a number of adjustments to try to keep that number——

Senator MIKULSKI. But for every one grant that you can fund, let's even go to before fiscal 2011, how many are unfunded?

Dr. COLLINS. So it would be five out of the six. If you have six grants in front of you, we're going to fund one of them and five of them are going to go begging.

## WORKFORCE PIPELINE

Senator MIKULSKI. All of which are quite promising.

Now, let's go to much is made about recruiting young people into science, and we want a lot of initiatives in that, but young people follow opportunity. So when we look at your internship, your fellowship program, both for high school, undergraduates and so on, again, how many students can you have come in to NIH? And how many—In other words, how many can you take and how many apply? What's the enthusiasm gap here?

Dr. COLLINS. Well, there is enormous enthusiasm. Certainly, we run a number of internship programs on the NIH campus. We have a program for high school students and college students who come and spend 10 weeks in the summer. That is always oversubscribed

by at least a factor of five in terms of the number of slots that we have available and the space that's in the labs.

We also have a program for individuals who are finishing college, who are really interested in science, but they're not sure whether they want to go to graduate school or medical school. They come and spend 1 year, sometimes 2 years doing full-time research in the lab.

I have three of those students in my lab right now. They're enormously energized, excited about what they're doing, and they go on to do great things. This is a really important program.

But there again, the number of applications we have for that so-called post bac program is at least four or five times greater than the number of slots that we have available to offer.

Senator MIKULSKI. So while we're busy—You know, we like to pound our chest and come up with all kinds of things in education to encourage people for science, but our young people are going in it, but they need opportunity, both in the public as well as in the private sector.

Dr. COLLINS. So, Senator, I've just set up, as part of my advisory committee to the Director, a working group to look at our workforce issues, and I've asked Dr. Shirley Tilghman, the president of Princeton, to co-chair that, because I think we need a better handle on what the supply-and-demand issues are in terms of the biomedical research workforce.

We want to be sure that we're looking forward with a clear eye toward all of the different pathways that are going to need well-trained, doctoral-level biomedical researchers and that we, NIH, as a major source of training support are appropriately tuning our programs so that we have the numbers right in terms of how many people we are bringing in and what kinds of careers we're preparing them for.

## EFFECTS OF A GOVERNMENT SHUTDOWN

Senator MIKULSKI. Well, I think this would be enormously useful to this subcommittee, Mr. Chairman, because, as you know, this is a topic—a big public-policy topic they ponder all of the time.

My last just comment or question is with all the talk of the shutdown and during H.R. 1, a cut to the National Cancer Institute, which was stunning to many people, including me, what is the morale at NIH now that they thought that they might be sent home and told that they were non-essential and the cuts might be coming?

I mean, I must say both the chairman and the ranking member were enormously supported to minimize the disaster, but it was not a victory.

Dr. COLLINS. So I would say this was a very difficult period to go through. We were required, of course, in preparation for what appeared to be a very high likelihood of a shutdown, to define how we would manage that, and that meant defining which particular employees were considered essential and which were excepted, was the term that was used, and which were non-excepted.

And, of course, those who were involved in patient care or management of animals couldn't very well just not come to work, but

others were told, "I'm sorry. If there is a shutdown, you can't come to work."

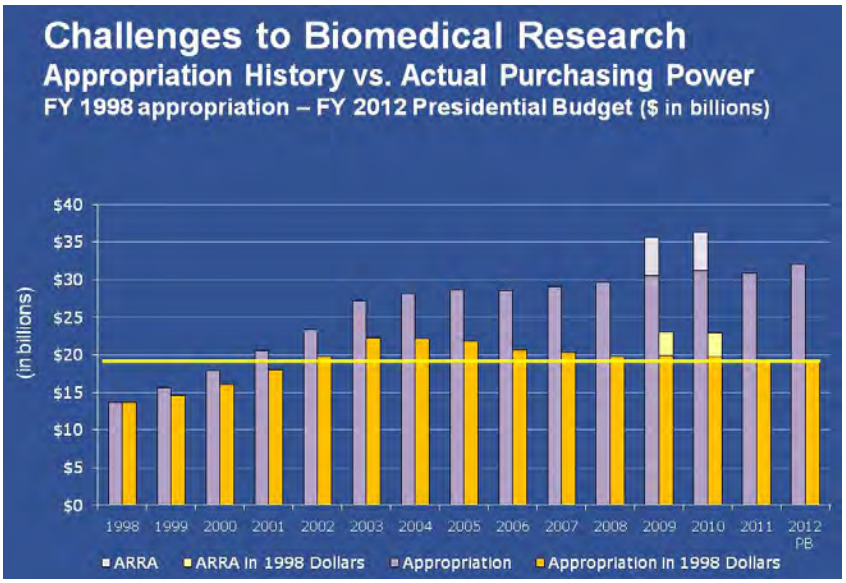
Think about how that feels if you're a post-doctoral fellow who's in the middle of an experiment that you've been working on for 2 or 3 weeks and has another couple of weeks to go and you're being told, "I'm sorry. You're not allowed to come to work tomorrow if the Government shuts down." It did have a very significant effect. People were quite shaken up by that.

I think people are—in the aftermath of that—feeling a little uncertain about what it's like to work in this environment and hoping that we won't face that again. But, again, I think everybody understands these are terribly, terribly difficult times for our country.

INFLATION EFFECTS ON PURCHASING POWER

I just want to show you one image because I think it might be actually useful.

[The information follows:]




Senator MIKULSKI. Okay. I'm going to just—chairman regulate the time, but I'm fine with it, but if that's okay with the chairman.

Dr. COLLINS. It'll take 1 second. This is basically why we are in such a crunch.

Senator MIKULSKI. Well this is a terrific slide.

Dr. COLLINS. So this is—this shows——

Senator MIKULSKI. It's more like the way my heart went up during the shutdown mode.

Dr. COLLINS. So in blue, you see the appropriations for NIH going back to 1998. You see the doubling that happened between 1998 and 2003, and then you see that since 2003 the NIH budget has been much more in a flat trajectory.

But in yellow, you see the effects of inflation, the biomedical research and development index, which has been eating away at our

buying power since 2003, placing us now, even with the President's budget, in the range of what we were at 2001. So we're sort of where we were 10 years ago.

You see the Recovery Act dollars there in 2009 and 2010, which were a wonderful boost to the scientific community, but, of course, that was 2-year money.

That is why the success rates are now dropping to where they are. It's all pretty much clear what the consequences would be once one considers what's happened to buying power for research.

Senator MIKULSKI. Thank you. Mr. Chairman, thank you.

Senator HARKIN. Senator Mikulski.

Senator MIKULSKI. You are the genius club. I mean, you really are. So thank you.

Dr. COLLINS. Thanks.

Senator HARKIN. Senator Brown.

NEW INVESTIGATORS

Senator BROWN. Thank you, Mr. Chairman. And I've always so enjoyed having panels from NIH, some of the smartest people in the country, especially those who used to teach in Cleveland, Dr. Shurin.

But thank you. I mean, it really is illuminating and we thank you so much for your service. This is such an example of public service and why government matters.

And when I hear some of the know-nothings that hold jobs like we hold say that the Government is broke and that Government can't function and Government doesn't contribute anything and Government doesn't create jobs, you know, I think about the special forces. Those were Government employees that were in Abbottabad, but I think primarily of what NIH does and what you contribute to public health and to wealth of our country.

I want to take up on what Senator Mikulski said, and Dr. Collins' response, on the one out of five grants. I was in the House, ranking Democrat on the subcommittee back when we actually wanted to fund public health bipartisanly in this country 15 years ago, doubled the budget at NIH.

And I remember in those days those numbers that some of your predecessors—well, some of you and some of your predecessors—would cite, now that we fund one out of five grants or one out of six grants. It's gotten a bit worse than what Senator Mikulski said.

The other part of that story that I remember is the young researchers that you are always looking to attract when you teach at med schools and you counsel people and you mentor people, those are the least likely to be the one out of five that gets the grants—or the one out of six—because my understanding is that people that have done these grants over time kind of know how to win the grants better than the young, bright researcher also applying for the grant. So the numbers, in some sense, among younger, hungry researchers are even worse, the ratios, and too many of these young people leave the field.

And I think that's, to me, the most compelling reason that this fervor to cut budgets as—we need to address our budget deficit, but we're creating terrible deficits in young scientists and terrible deficits in the public body of knowledge, I just want to say.

COST OF PHARMACEUTICALS

Let me go—two issues I want to talk briefly about. One is the issue of the Makena drug, the progesterone that was developed over time into a—produced by compounding pharmacies as you know, has made a huge difference, provable huge difference, clinically trialed—if that's a verb or adverb—huge difference in preventing early birth, pre-term births.

We know what this KV Pharmaceuticals in St. Louis did. We also know that you at NIH have invested $21 million on now four clinical trials, in the midst of the fourth one and still investing in this and finding, I think, more indications, perhaps, to use this drug, this progesterone, this compounded pharmacy drug.

Well, just give me your thoughts, briefly, if you would, how do we prevent this from happening? The Food and Drug Administration (FDA) has stepped in and done something pretty unusual and pretty gutsy by saying they're not going to enforce the cease-and-desist order on compounding pharmacies.

So when I talk to obgyns and visit hospitals—I was at University Hospitals yesterday in Cleveland—2 days ago—talking about they're still compounding it, still producing this.

When taxpayers invest in this and it's clearly a drug in the public interest and one company can get exclusivity for 7 years, while you continue to do these clinical trials expanding—in a sense expanding their market on this fourth clinical trial you're doing—and I know this cuts across FDA, HHS as a whole and you and CDC and all, but what do we do about this?

Dr. COLLINS. Well, Senator, I think you spoke out quite strongly about the Makena situation and I think brought a lot of attention to a circumstance that really was deeply troubling, that a drug—let's just call it 17P—that was previously available and compounded by pharmacists and then was put into a clinical trial, ultimately ended up, after FDA approval and orphan-drug status, going up in cost from something that cost $10 or $20 to something that costs $1,500.

We were also deeply alarmed to see that and quite pleased to see FDA step in and say they were not going to go after pharmacists that continued to provide the compounded material.

And that, by the way, also, and along with your strong statements and that from some of the professional groups, did cause KV Pharmaceuticals to drop their costs, but still at a much higher level than they were in the old days.

NIH has its hands a bit tied in this situation. Back in the 1990s, when Harold Varmus was NIH Director, we had a big discussion about whether drugs that NIH plays a role in developing should have some sort of reasonable pricing clause attached to any kind of licensing that we would do to a company.

And while that might have seemed like a way to avoid another kind of Makena outcome, it was a poison pill for any serious relationship that NIH would have with a company. No company in this country or elsewhere would be interested in a partnership with NIH under those circumstances.

What we can do is to make sure that if profits ensue and NIH has made a contribution to that, in terms of genuine intellectual

property discoveries, that there should be royalty sharing on that basis.

But when it comes to setting the price, as KV did, even though we supported the clinical research, we are probably not the agency in a position to be able to do something to step in and interfere with their pricing decision.

It was the public outcry, your outcry, Representative DeLauro, the professional societies that I think actually turned the tide.

Senator BROWN. But that outcry only brought the price from $1,500 multiplied times 20, with 20 weeks of treatment, as you know——

Dr. COLLINS. Yes.

Senator BROWN [continuing]. $1,500, $30,000, when it was 20 times $10 or $20—depending on the compounded pharmacy's charge—down to $690. So the outcry worked with FDA. The outcry barely worked with KV.

But is there a way to sort of cross the—I understand that you don't want to engage in partnering and price-setting and all that, but—or maybe you do—but when a company so overreaches like this, it was such an affront to the public interest, if there's a way, sort of across help agencies we could find some solutions or——

I mean, Dr. Hamburg was in here and she said, well, you know, FDA didn't do this. She wasn't defensive at all, but then FDA did something. This was before they made that decision.

But I just will follow up with you, but I'd like to see if there's a way to——

CANCER CLUSTERS

My other question—I'm sorry to go over the 5 minutes, Mr. Chairman—Dr. Varmus, you had talked about pediatric cancers and Senator Reed had asked you about that.

There's a cancer cluster in Clyde, Ohio, where many, many children, under 12 in most cases, have developed cancer, and I know you see these. There are four or five believed to be cancer clusters. I don't know if that's a particular medical term, but is certainly what we talk about.

What is NIH's role in sort of examining these, exploring these, finding out the environmental cause, if it is that, as I presume—I guess I presume it is. What is your role in that?

Dr. VARMUS. Well, we do investigate that. We have a Division of Epidemiological Cancer Research that will look at these clusters to ascertain whether or not the cluster is real. Because, as you might expect, if cancers are distributed in their frequency across the country, there are going to be some places that just, by chance, have a particularly high or particularly low incidence, and there are several classical examples of clusters that turned out only to be arithmetic aberrations, but without any clear indication of causes.

On the other hand, there have been clusters of cancers that are linked to certain practices or to exposure to industrial mutagens, and we would go in with collaboration with the National Institute of Environmental Health Sciences and try to ascertain what might be a precipitating cause.

So we do have a role and we would—I don't know about the one you're citing, but we can certainly look into it and report back to you on what——

Senator BROWN. We have talked to NIH overall, but we will specifically talk to you.

Thank you, Mr. Chairman.

[The information follows:]

CLYDE, OHIO CANCER CLUSTER

*State and Federal Responses to Cancer Cluster Reports*.—State and local health departments respond to cancer cluster reports and provide the first level of response and review of the most current local data for the area. If needed, these local health departments can request assistance from Federal agencies, including the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) of the Centers for Disease Control and Prevention (CDC), the Agency for Toxic Substances and Disease Registry (ATSDR), and the U.S. Environmental Protection Agency (EPA). CDC's role in investigating potential cancer clusters is to provide technical assistance to States at their request as they conduct their investigations. In State cancer registries, States have the data needed to determine whether a cluster exists.

*National Cancer Institute (NCI)*.—NCI does not investigate anecdotal clusters of individual cancer cases in neighborhoods, but rather clusters of counties with elevated rates as part of the geographic mapping strategy to identify and investigate high-risk populations for etiologic insights. However, upon occasion NCI's Division of Cancer Epidemiology and Genetics (DCEG) may be called upon to consult with local and State health officials and CDC experts as they investigate purported cancer clusters.

DCEG's research portfolio includes analysis of cancer treands in human populations, and DCEG investigators conduct studies both within the U.S. and around the world where the incidence of certain cancers is significantly higher than might be expected. Examples of such investigations include lung cancer in coastal communities in the U.S., which was linked to asbestos exposure in ship yards, and oral cancer in women in the rural south, which was linked to smokeless tobacco use. DCEG researchers are currently investigating the reasons for the very high rates of bladder cancer in northern New England; they will soon be reporting data from this effort. They are also conducting a study to explore the elevated rates of Burkitt's lymphoma in regions in Africa.

*Regarding the Clyde, Ohio Investigations*.—It is our understanding that there was a multi-year analysis of a suspected cancer cluster in Clyde, Ohio by the Ohio Department of Health (ODH). Both CDC and ATSDR provided technical assistance to the State officials over the course of the multi-year assessment. While NCI has not received any reports or conclusions, it is our understanding that the assessment's final conclusion was that the data were inconclusive and there was no cancer cluster identified. These Federal public health agencies are continuing their collaboration with ODH and are available to provide support as needed.

FLU VACCINE

Senator HARKIN. Thank you, Senator Brown.

Dr. Fauci, for years, you've been here, year after year, and we've talked about flu vaccines, and, some time ago, I remember you talked about progress being made toward a—perhaps a universal type flu vaccine. You mentioned it in your written statement, which I read last night. Again, how close are we?

Dr. FAUCI. Well, I can't give you an exact time in years, because every time a vaccinologist does that, he or she gets burned. So I'll refrain from that, but I can tell you that we clearly are considerably closer than when I spoke to you last time at a hearing when we were talking about the possibility of getting away from that very frustrating situation where each year you have to hopefully guess right, and we do most of the time, but not all the time.

But even more importantly, when we're faced with a pandemic flu like we were with the 2009 H1N1, when we made a vaccine

after isolating the virus, but the production issues were such that by the time we got enough to distribute, unfortunately, the pandemic had already peaked. Fortunately for us, it was a relatively mild one, but that's not going to happen all the time.

So what's happened in the last year since we spoke, Mr. Chairman, is that there have been a number of experiments that have been conducted both at the NIH and by our grantees and contractors, which have really identified components of the influenza virus that the body generally does not make a very good response to readily, and that part of the virus is the one that would give you protection against virtually all strains.

And one of the reasons is is that it's sort of hidden from the view of the immune system. The thing that the immune system sees really clearly is the part of the virus that changes from season to season, and that really changes a lot when you get a pandemic. There's a part of the virus that the body can make an immune response to that it doesn't usually see very well.

So what investigators have done, in a very simple way, is that to put that particular component of the virus in a form that the body would see it much more sharply and clearly. This has been done in animal models and proven to be inducing responses that are good against decades of changes of influenza.

And, now, those studies are being done in what we call phase I trials in humans, and the early work indicates that, clearly, it looks quite safe, and, second, it is inducing responses that span multiple years.

So I believe it's really just a matter of time. As you know, clinical trials, when you want to prove safety and efficacy over a period of time, naturally would take years, but it's on a track that I believe it's going to happen. I don't think it's going to be a question of if. It's going to be a question of when. So we're really quite excited about it.

And that's a very good example of that transition from fundamental basic research observations on molecules and their confirmation and how that ultimately gets translated into something that, if successful, is going to have enormous public health benefit.

Senator HARKIN. Well it would. I mean, the amount of just savings alone on annual flu shots would be incredible, aside from the fact that you wouldn't—I would, from what I understand is if this was really developed, the threat of pandemics would not be as large as they are now either.

Dr. FAUCI. The ultimate goal is to have on the shelf, ready for utilization a vaccine that does have the universal characteristics to it, so that if you do get a change with a pandemic, that you can actually have that particular virus be covered by it.

So we'd like to get it to the form—I don't think it's going to be perfectly this way, Mr. Chairman, but it's going to be close. I don't think it's going to be one flu vaccine and that's it for the rest of your life.

It'll probably be having to be given every several years to continue to boost the immune system, but we would like to be the way we are, for example, with measles or hepatitis or polio, where you just make a lot of it, you have it available and when you need it,

you deploy it, as opposed to having to play catch up every single time a new virus emerges.

MEDICAL MILESTONES

Senator HARKIN. Very good.

Dr. Varmus, in 2001, Gleevec was on the cover of all our national news magazines, talked about it being the magic bullet that would herald in a new age in the war against cancer. For the first time, we had a drug that specifically targeted a known cancer gene. It took this deadly blood disease, turned it into a chronic, but survivable condition.

We were told that Gleevec was the promise of the future. We talked about it in our subcommittee hearings at that time, but that was 10 years ago. We haven't had any other Gleevecs. What's happened? How come no more Gleevecs?

Dr. VARMUS. Well, I wouldn't characterize it quite that way, Senator. Gleevec remains the poster child for targeted therapy.

Senator HARKIN. Yes.

Dr. VARMUS. And just to give you a brief update, it's used not only for the treatment of chronic myeloid leukemia, the leukemia you heard about, it's used for the treatment of several other diseases in which potential targets for the drug are mutated, and that includes gastrointestinal stromal tumors, a number of other blood diseases, and, indeed, a few other diseases in a few cases in which certain genes are known to be mutated as a result of analysis of the genome of those cancers.

Moreover, it's recently been shown that we can deal with drug resistance, a common problem in cancer therapy, by using drugs closely related to Gleevec but not identical to it and to treat patients who become resistant to Gleevec.

Second, it's been shown recently that a person in their 40s or 50s who develop—leukemia now have a normal life expectancy, which was previously 5 years. That's a dramatic change and it shows that the efficacy of Gleevec has been sustained over the last 10 years, and, actually, the evidence that it's effective is only strengthened.

There are a number of other targeted therapies. They tend to work quite well initially. Patients become—their tumors become resistant to therapy. Let me give you a couple of examples.

One happens to involve my own work on lung cancer, which is a significant percentage, perhaps 10 percent, of cancers have mutations in some specific genes against which we have effective inhibitors, but, generally speaking, within 1 year or so, on average, patients become resistant to those drugs. We don't have good therapies to counter the tumors that are resistant.

Recently, in the case of a disease called metastatic melanoma, a disease that is secondary to finding a skin tumor, but the tumor has spread to the liver, bones, and other sites, it's been found as recently as 7 or 8 years ago, that about 60 percent of those cancers have a mutation in a specific gene against which an inhibitor has been developed.

It's extremely effective, again, in inducing remissions in a fairly non-toxic way. This is, again, an orally available drug that promotes a dramatic regression in the size of tumors.

There are two drugs that do this. They are very likely soon to be approved by the FDA. They don't cause persistent regressions, but there's every reason to hope that additional drugs will be on the way to help counter drug resistance.

So I would say that we've had a number of other targeted therapies. They have not, in general, been quite as dramatic as Gleevec, but most of us who are working in this area are quite optimistic about a number of new drugs, some of which I haven't mentioned, that are in the pipeline.

Senator HARKIN. That drug you mentioned about metastatic melanoma, you mentioned it in your written testimony.

Dr. VARMUS. Correct.

Senator HARKIN. What's the name of the drug? I forget——

Dr. VARMUS. Well, there are two things that I mentioned in my testimony, Senator, first was these so-called inhibitors of BRAF. These drugs are not yet on the market. One comes from Flexicon, one from GlaxoSmithKline (GSK).

Senator HARKIN. Yes.

Dr. VARMUS. There's also a new immunotherapy called ipilimumab, which has been approved by the FDA. That's not the same kind of targeted therapy, but it's a dramatic development, because it's one of the first immunological approaches.

There are others, but this is one of the first that actually displays how we can manipulate our understanding of the immune system to galvanize the response of the immune system against a variety of cancers, including melanoma.

Senator HARKIN. But I can't even pronounce that word, ipilimumab?

Dr. VARMUS. Ipilimumab.

Senator HARKIN. Thank you very much.

Dr. VARMUS. Yes, I'm not responsible for that, Senator. It would not have been my choice. Ipi for short.

Senator HARKIN. It seems to me this is about as important as Gleevec. I mean, this attacks metastatic melanoma in later stages.

Dr. VARMUS. Correct.

Senator HARKIN. And this has always been a death sentence before.

Dr. VARMUS. As does the drug that inhibits the BRAF mutation. But ipilimumab does not work in all cases, but does prolong life significantly in a very substantial 15 to 30 percent of patients who have metastatic melanoma. It is a major development, no question about it.

One of the open questions is why do a certain subset of patients with this disease respond and others not respond.

There are other inhibitors of the so-called brakes on the immune system that are in development, and I think may be combined with ipilimumab or used as an alternative when ipilimumab doesn't work.

So we're quite optimistic after many years of trying to manipulate the immune system that we have some very serious handles on how the immune system works that we can use in cancer therapies.

Senator HARKIN. Very good. Thanks, Dr. Varmus.

Recognize Senator Shelby, then I see Senator Kirk has joined us. I'll go to Senator Kirk next.

ACADEMIA-INDUSTRY COLLABORATION TO REPURPOSE DRUG COMPOUND

Senator SHELBY. Thank you.

Dr. Collins, repurposing drugs, you alluded to that earlier. As we have searched for treatments, as you do, and others, investigators, to the healthcare challenges, one of the clear ways that some people believe we can continue drug development is by finding new uses for drugs that were discontinued or halted mid-development. By leveraging existing compounds, researchers in industry can develop and have new, novel treatments for patients.

It's my understanding that the NIH recently held a roundtable discussion regarding rescuing and repurposing compounds. Seems like that's an ideal opportunity for academia to team with industry to bring treatments to patients faster. Could you expand on that? What are you doing here and how?

Dr. COLLINS. I'd be happy to, Senator, because this is a really exciting potential area to speed up the process of developing new treatments for diseases that currently lack effective interventions, and it's another example of the kind of thing that NCATS will be able to catalyze just by its convening power.

Yes, we did have this meeting just about 10 days ago. We invited major leaders from pharmaceutical and biotech industries to meet with NIH investigators, with academic experts and to ask the question: Are there in fact, already sitting in medicine bottles or in freezers of companies that have tried various compounds and abandoned them along the way opportunities to take molecules about which we already know a lot and find a new use for them?

Senator SHELBY. Do you have any examples or is it too early?

Dr. COLLINS. We have some very striking examples. Maybe I'll even ask Dr. Shurin to tell the example of Marfan syndrome. So let me set this up.

Marfan syndrome is a genetic condition caused by a single glitch in a gene called fibrillin and is characterized by very tall stature, and, unfortunately, by a high risk of an aortic dissection, which is often fatal. So Flo Hyman, the volleyball star, died suddenly because of that condition, and it's not that rare.

And many of us thought, well, we'll never come up with a therapy for that in the next 50 years, because it's too rare for there to be much economic interest, but something pretty interesting happened. Do you want to tell that story?

Dr. SHURIN. One of our investigators at Johns Hopkins, Dr. Hal Dietz, discovered that a drug, losartan, which is used for blood pressure—it's an approved drug—actually cures Marfan syndrome, not only in the test tube, but also in mice.

And so we were able, using our existing Pediatric Heart Network, to rapidly launch a clinical trial. We had the first patient enrolled about 5 months after we had opened the trial and, working very closely with the Marfan Foundation, have been able to complete enrollment.

The results are not yet fully available. The trends are looking very good, and we've been very excited by this. But the ability to

do this with the cooperation of the drug manufacturer and the patient advocacy groups has been really quite spectacular.

Dr. COLLINS. So that's an example.

My own lab works on a disease called Progeria, the most dramatic form of premature aging. These kids age about seven times the normal rate and usually die by age 12 or 13 of heart attack or stroke.

By discovering the genetic cause of that disease, understanding the pathway that's involved, it became clear that a drug class developed for cancer might actually turn out to be beneficial in this premature-aging disease.

They've just completed a 2-year clinical trial on kids with Progeria using this supposed cancer drug, and while the results are not yet published, I'm hearing very encouraging noises. So it's repurposing a very different idea of what that drug would be used for for a new application.

I am sure that if we had a systematic way of trolling the landscape to identify other such opportunities there would be lots more.

INTER-AGENCY COLLABORATIONS

Senator SHELBY. Dr. Collins, dealing with NIH–FDA collaboration, which is, I think, is very important, what do you think would be the best results to come from increased NIH–FDA collaboration? Are there topics in particular that you're working on with the NIH and partnering there to move—I assume moving drugs to market and getting them approved safely is very important.

Dr. COLLINS. Commissioner Margaret Hamburg and I have been meeting for now almost 2 years to talk about ways that our agencies could work more closely together. And she is a strong advocate, and I share that same view with her, that regulatory science—that is, applying science to how reviews are done of drugs and devices—is very much a possible solution to the current logjam of trying to get products through that pipeline.

Senator SHELBY. We would all benefit from that, wouldn't we?

Dr. COLLINS. We would, indeed.

And so she and I have together started a regulatory science research program. We formed a leadership council between the two of us which involves the senior leadership of both of our agencies. We've identified six areas that we think are particularly ripe for progress, such things as how do you do toxicology more efficiently? How do you deal with combination therapies like Dr. Varmus was mentioning may be necessary for cancer when, in fact, that's hard to review. You have to come up with new ways to look at that.

And I think together, working as sister agencies, we can make progress that neither of us could have done alone, and we're totally committed to making that happen.

Senator SHELBY. How do you collaborate with CDC?

Dr. COLLINS. Oh, quite intensively.

Senator SHELBY. I know you do.

Dr. COLLINS. Tom Frieden, the head of CDC, and I were on the phone yesterday, and that happens regularly, about areas of shared interest, and that includes global health as well as domestic issues.

He and I have exchanged people by going back and forth to look at shared projects. We obviously work very closely in the area of infectious disease.

Maybe Dr. Fauci would want to make a comment about your relationship with CDC, because it's so important.

Dr. FAUCI. Yes. We have very strong and long-standing collaborations, particularly in the arena of global health with the emphasis on infectious diseases, even though global health certainly encompasses more than just infectious diseases.

An example of that is we share some of our sites. The CDC has epidemiological sites and posts for surveillance of disease. We are now incorporating many of those sites in our clinical trials of drugs, so many of the trials that take place are really strong collaborations between the CDC and the NIH, and that's worked very well.

CYSTIC FIBROSIS

Senator SHELBY. Dr. Collins, I enjoyed seeing you last night, and you know better than anybody that they've come out with a new drug in the treatment of lupus for many things. That's a breakthrough of many, many years.

What about cystic fibrosis? Where are you in this area? I know you've done a lot of research in that area, too.

Dr. COLLINS. Senator, I appreciate the question. I enjoyed the experience of chatting with you last night at the Lupus Foundation of America event. And they are very excited, and justifiably so, at the approval of Benlysta, this first drug for lupus in a long time.

Cystic fibrosis is an area of intense interest for me, because I was part of the team that found the cause of that in 1989, and that has now, finally, after many years of struggle, led to a very exciting time therapeutically.

So just in the last few months, a drug developed using this same approach to try to identify small molecules, the same kind of thing that Senator Moran was seeing in Kansas, this, in this case, done as a partnership with a company called Vertex, found a molecule which goes by a not terribly friendly name, VX–770, which, in fact, for that category of patients with cystic fibrosis who have a particular mutation in the gene, appears to be highly effective, and taken over the course of just a month improves lung function. It reduces the sweat chloride, which has been the diagnostic hallmark of cystic fibrosis——

Senator SHELBY. This has been out how long now?

Dr. COLLINS. This is still in clinical trials. It hasn't yet been approved by the FDA, but the phase III trial results look extremely promising.

Senator SHELBY. That would herald, if it were approved by FDA—It's in clinical trials now.

Dr. COLLINS. That would be an enormous step forward.

Senator SHELBY. A huge breakthrough, hopefully, for cystic fibrosis.

Dr. COLLINS. Now, the down side is that this particular drug is only likely to be effective in that subset of patients with cystic fibrosis who have a particular mutation in the cystic fibrosis gene. The common mutation would not necessarily respond to this drug. You wouldn't expect it would.

There is another drug in the pipeline a few steps behind, VX–809, which is targeted toward the common mutation. We all have high hopes that that will turn out to be just as effective, but we have to wait and see what the clinical trials show.

Senator SHELBY. But it holds promise for the people with cystic fibrosis and their families.

Dr. COLLINS. I've been in this field for 25 years. I've not seen more excitement and hope about a therapeutic intervention in that whole time until now.

Senator SHELBY. Thank you.

Senator HARKIN. Thank you.

Senator Kirk.

## HEALTHCARE SPENDING POLICY OPTIONS

Senator KIRK. Thank you, Mr. Chairman, and I'm sort of overawed to see this group here. I followed in the Congress Congressman John Porter, very much a supporter of NIH and Research!America.

And, to me, it's interesting, in these times of deficits and debt in which the largest bond purchaser in America, Pimco, has now divested itself of all U.S. Treasury securities, because he's worried about the long-term future of us being able to borrow money.

I just met with one of the Chinese top officials in meeting Secretary Clinton, and they also talked about how they were making moves to leave U.S. debt.

And so it's—over the long term, I wonder how we might be able to borrow the kind of monies that are being thought of.

With these kind of limitations, you wonder, then, what direction you take with regard to healthcare policy. And there are obviously two main directions, if the Government is to support it, and that is to subsidize care or to subsidize research.

Now, in subsidizing care, I guess the rough numbers are Medicare is now $370 billion and Medicaid is $300 billion. So that's very, very expensive now and growing quite rapidly, but $670 billion in the subsidizing care path.

In the subsidizing research, NIH comes in at $26 billion, and yet I think offers a much brighter future of a virtuous cycle of better and better patient outcomes, faster and faster innovation and dramatic reversals in disease outcomes, as we've seen in several cancers or, for example, in juvenile diabetes.

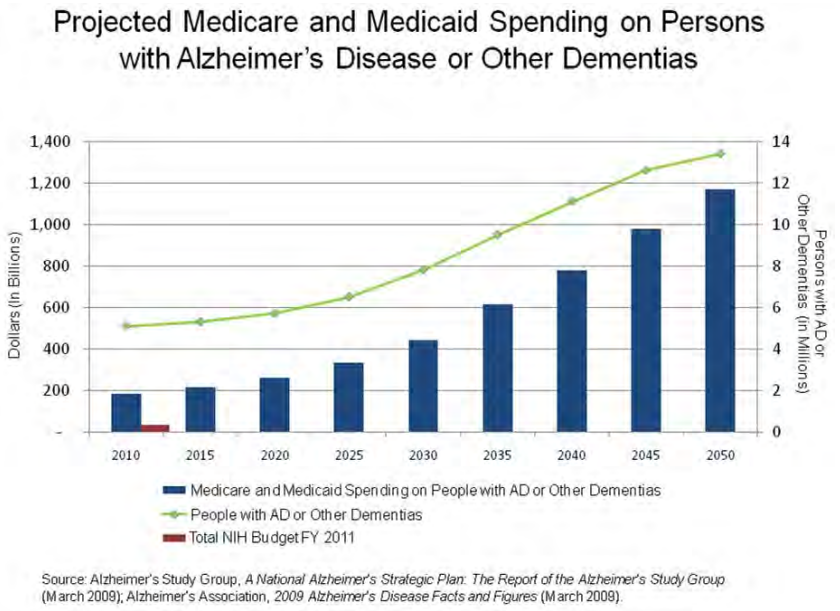
And so in a resource-constrained area—and I think either the Congress is going to make budget cuts or the bond market is going to make budget cuts to the Federal budget—you then say do we double down on subsidizing care or do we continue on the funding research side, and because this also has a huge economic benefit to the United States, I very much favor NIH, where I worry about the long-term sustainability of other parts of the budget.

So let me ask you somewhat of a theological question on how we move forward in this environment, which is the President's healthcare bill set up an independent payment advisory board to ration care and basically to deny care in several areas. Its goal, I think, over time will be to replicate the power and authority of the British NIH's NICE rationing board.

Have we thought about NIH's relationship to IPAB and how we would advise the people who would be denying care under Medicare how they would keep up with medical research and technology?

Dr. COLLINS. So these are difficult questions indeed, Senator. NIH's role as the prime supporter of biomedical research is to provide the evidence that is necessary for making wise healthcare decisions, but, obviously, those decisions depend on more than just the scientific evidence. They also depend on how society wants to expend its resources.

But I think we can help in substantial ways with the very frightening cost curve that otherwise faces us. If you'll permit me, I'd just like to show you one example of the kind of looming problem that we have in front of us if nothing is done.




Source: Alzheimer's Study Group, *A National Alzheimer's Strategic Plan: The Report of the Alzheimer's Study Group* (March 2009); Alzheimer's Association, *2009 Alzheimer's Disease Facts and Figures* (March 2009).

This curve shows you for one disease, Alzheimer's disease, what we are currently spending, which in 2010 is about $180 billion, and which by the projections that many people have made, if nothing is done, if research is unsuccessful or not supported, will rise to more than $1 trillion just for that one disease in 2050, and the number of effected individuals at that point will be in the neighborhood of 13 million. One disease.

And, yet, at the present time, our investments in research on Alzheimer's disease fall somewhat less than $1 billion. So, clearly, we feel a great responsibility to move that curve in a different direction. If we could even come up with a therapeutic approach that would slow the onset of disease, delay it by 5 years, you could cut these costs almost in half, and, obviously, something more dramatic would have an even more beneficial effect. That's what we see as our mission——

Senator KIRK. I'm just wondering—My time has run out, but if we—I think IPAB's future depends on the presidential election. Should the President prevail, then IPAB and the healthcare bill is with us. Should the President be defeated, I think that much of the healthcare bill will be wiped out and IPAB with it.

But on the potential that the President is reelected, have you thought about—because what I'm worried about is IPAB will become an incredibly bureaucratic, stultified organization. It will review diseases and protocols, but the danger is that they will be working on heart disease and a breakthrough comes in cancer that revolutionizes research and they will not have the bureaucratic means to switch and then advise for a new payment. And we have such a pace of innovation that a huge state bureaucracy inevitably will slow down and be unable to keep pace with medical innovation.

In fact, I would actually argue it probably will kill a lot of medical innovation as it locks in payment methodologies the way Medicare has.

But have you begun to think about how you might relate to this new bureaucracy?

Dr. COLLINS. Well, again, Senator, I think our best answer to that is to do the rigorous research that actually not only tries new therapeutic approaches, but also does comparisons, when there's more than one alternative, to see what works, and then to do what we do routinely, and which we believe is a strong part of our job, is to make that data immediately available, publish it, make sure it's propagated so that nobody is left in the dark about knowing what the results have been.

And then I guess I'm just enough of an optimist to think if the data is there and if it's compelling, it'll be hard to ignore. But I hear your concern.

Senator KIRK. I would just simply finish up by saying should IPAB not survive—I hope it doesn't, but should it survive I think we might want to think about a more formal data transmission between NIH and IPAB, because, otherwise, IPAB, I think, will rapidly cause Medicare to fall behind technology and innovation.

Thank you, Mr. Chairman.

Senator HARKIN. Senator Moran.

### EFFECTS OF RESEACH ON HEALTHCARE COSTS

Senator MORAN. Mr. Chairman, thank you again.

Dr. Collins, perhaps my question is in ways related to the Alzheimer's chart you just showed, which was a request that do you have information to substantiate my suggestion or a belief that money spent on biomedical research results in cost savings in healthcare? Is there that kind of science-based fact that substantiates my feelings?

Dr. COLLINS. So those are complex economic analyses, and even economists will tend to disagree with each other about the right way to do it. Let me just cite a couple of figures, though.

If you look, for instance, at heart disease, what's happened in the last 40 years, Dr. Shurin will tell you we've seen a 60-percent drop in mortality from heart attack during those 40 years. The cost of that, if you average it out per American per year, in terms of the

research that led to those advances, beginning with the Framingham Study, going through with the development of understanding about cholesterol and ultimately the development of statins, was about $3.70 per American per year, the cost of a latte, and not even a grande latte, that would be a tall, I think.

So and if you add up the economic benefits that have resulted from the increase in longevity that have occurred between 1970 and 2000, I am told credible economists believe that adds up to $91 trillion. Michael Milken, in a recent editorial in The Wall Street Journal runs through a lot of those figures and they seem to be cited by reasonable experts.

If we were to diminish the frequency of cancer by just one percent—and that's actually happening each year. Each time the frequency of cancer goes down by 1 percent, economists say that's saving our country $500 billion in terms of economy that is sustained as a result of having those people with us. So the return is enormous.

I could cite you specific examples of new technologies, but the big picture is quite compelling.

RARE AND NEGLECTED DISEASES

Senator MORAN. Well, I'm not surprised by that. It would be very helpful to have that—I don't like the word sound byte, but that phrase that says for every dollar spent, here's what we're able to save in otherwise spending on healthcare.

Let me go back to something more specific and just ask you to elaborate upon the value of academic and nonprofit research institutions' role in developing therapies and treatments for rare and neglected diseases through NCATS, as you propose, and through your therapeutic and rare neglected disease program that you already have.

I mean, is this something that you envision as having a significant role in the future as you develop NCATS are these neglected diseases?

Dr. COLLINS. Indeed. And, in fact, the 27 Institutes and Centers at NIH have been engaged in such efforts for rare and neglected diseases for some time.

We expect that the advent of NCATS serving as a hub of this activity will further encourage that and hopefully contribute innovations that will result in more rapid progress and also a lower failure rate.

The TRND Program, Therapeutics for Rare and Neglected Diseases, which the Congress authorized 2 years ago, is specifically devoted to identifying projects that might otherwise sit there untouched, where there's a real promise in taking a therapeutic and moving it into the preclinical space, which is often called the Valley of Death, because that's where often good projects go to die.

Take example sickle-cell disease. There's a TRND Program right now pursuing an interesting therapeutic for sickle-cell disease originally identified at a university, Virginia Commonwealth University, then licensed out to a biotech company, AESRX.

The biotech company carried it to a certain level and then ran out of money, and venture capital is hard to find these days unless

you have something that's going to result in profits within a couple of years.

So the company has now partnered with the NIH to move this forward. The preclinical studies look very good. This will, as I understand it, be submitted to the FDA for an IND application later this year, and clinical trials may well get under way within 1 year at our NIH Clinical Center.

If this were successful, this would be a radical new approach to sickle-cell disease. The way this molecule works is unlike anything that's been tried for this disease before.

And while this is certainly a neglected and relatively rare disease, it still affects tens of thousands, hundreds of thousands of individuals in this United States and many more across the world. So it's a good example of a way in which NIH may be able to assist in the current scientific environment to move projects forward that otherwise would have languished.

Senator MORAN. Thank you very much. Mr. Chairman, thank you. And let me express my gratitude to all of you for your public service.

Senator HARKIN. Well, I want to thank you all for being here, again, for another enlightening session.

## ADDITIONAL COMMITTEE QUESTIONS

I have some other questions I won't propound now, but I'll submit those in writing, and the record will remain open for a week for other Senators to submit further questions or statements.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

### QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

#### NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE (NCCAM) ADVISORY COUNCIL

*Question.* The statute for the NCCAM stipulates that of the 18 appointed members of the Center's Advisory Council, 9 must be practitioners licensed in one or more of the major systems with which the Center is concerned, and at least three shall represent the interests of individual consumers of complementary and alternative medicine. Is the NCCAM meeting this requirement? Of the four new members announced on June 6, 2011, how many meet one of the two categories described above?

Answer. The composition of the National Advisory Council for Complementary and Alternative Medicine meets the statutory requirements concerning membership. Collectively, its membership includes the expertise required for it to carry out its requirements to provide second level peer review and other advice across the broad and varied spectrum of clinical practice and scientific disciplines which fall under the Center's mandate.

On Friday, June 3, 2011, four new members joined the NCCAM Advisory Council. Brian M. Berman, MD, LAC, is a licensed physician and acupuncturist. James Lloyd Michener, MD, is professor and chairman of the Department of Community and Family Medicine and Director of the Duke Center for Community Research. Dr. Michener also represents the interests of individual consumers of complementary and alternative medicine (CAM). Daniel C. Cherkin, Ph.D., is an epidemiologist and highly experienced clinical researcher who has conducted a number of major studies that have provided evidence for benefit of CAM therapies (including chiropractic manipulation, acupuncture, and massage) for low back pain. David G.I. Kingston, Ph.D., is a widely respected natural products chemist whose research focuses on the chemistry of biologically active natural products and the discovery of new therapies for cancer and malaria from plants.

THE NCCAM RESEARCH SUCCESSES

*Question.* Under the statute that created the NCCAM, the general purposes of the Center include "identifying, investigating, and validating complementary and alternative treatment, diagnostic and prevention modalities, disciplines and systems." Please identify all instances in the past 10 years in which the NCCAM-supported research has validated complementary and alternative treatment, diagnostic and prevention modalities, disciplines and systems.

Answer. The NCCAM is strongly committed to the highest standards of evidence-based medicine. Validating health interventions is a process that begins with evidence developed in peer-reviewed basic and clinical research. Next, the evidence from multiple studies is collectively assessed through formal systematic review methods. Finally, if these earlier steps indicate sufficient usefulness and safety, professional organizations and health policy makers undertake the development of guidelines and recommendations regarding use and clinical practice. This process, collectively referred to as evidence-based medicine, entails assimilation of the body of scientific evidence; almost never does a single study result in consensus that an intervention is valid.

Eleven years ago, when the NCCAM was created, there was no significant evidence-base on the biological properties, safety, and efficacy of the vast majority of CAM modalities. The Center's first decade was therefore focused on the conduct and support of basic and applied research that addressed this lack of scientific information. The results of that investment now include an emerging evidence base that is dramatically stronger in terms of both quality and quantity. Basic research and clinical trials, large and small, have yielded results—both "positive" and "negative"—regarding the effects, efficacy, safety, and in some cases, promise regarding CAM interventions.

Critically, sufficient evidence regarding some CAM interventions has now been developed to permit informative evidence-based analyses and systematic reviews by independent organizations (e.g., the Cochrane Collaboration) using the rigorous standards of evidence-based medicine. Indeed, such analyses now point increasingly toward clinically helpful conclusions regarding usefulness and safety—or lack thereof—of specific CAM interventions and practices.

Notably, the expanding evidence base now includes a large body of science that points toward specific, very promising opportunities to improve healthcare and health promotion using CAM-inclusive strategies. These opportunities are reflected directly in the NCCAM's recently-released third strategic plan. Important examples include the following:

*Mind and Body Practices*

—Developing better, comprehensive strategies for management of chronic back pain and defining the roles of acupuncture, spinal manipulation, and massage in those strategies
—Exploring the role of specific promising CAM practices or disciplines (e.g., meditation, yoga, or acupuncture) in developing better strategies for alleviating symptoms (e.g., chronic pain, stress) or in promoting healthier lifestyles
—Exploring the associations between well-characterized pathways of pain processing and acupuncture analgesia or the placebo response
—Exploring the associations of major pathways of cognitive processing and emotion regulation by meditative practices
—Studying the influence of the provider-patient/client interaction, context effects, and the placebo response on outcomes of CAM interventions

*Natural Products*

—Studying the molecular targets and biological effects of potentially beneficial small molecules that are constituents of natural products or diet (e.g., quercetin, curcumin, or other polyphenols and flavonoids)
—Defining the anti-inflammatory actions of omega-3 fatty acids
—Employing state-of-the-art tools and technologies to study the effects of probiotics on the human microbiome
—Developing evidence regarding the safety profile of certain widely used natural products, including interactions with drugs and other herbals or dietary supplements

The growing evidence base is clearly influencing professional practice guidelines of mainstream professional medical societies, and the practice of integrative medicine. Complementary and alternative therapies are increasingly being accepted and integrated into conventional healthcare systems. For example, recent data show that approximately half the hospices in the United States and 9 out of 10 Department of Veterans Affairs facilities offer some complementary or alternative therapies. The

Consortium of Academic Health Centers in Integrative Medicine, an organization of integrative medicine departments at academic medical centers, has grown from 11 members in 2002 to 43 members in 2011. Medical societies such as the American College of Physicians, the American Academy of Pediatrics and the American Academy of Family Physicians have formulated policies regarding complementary therapies and offer educational material about these forms of treatment. The Departments of Defense and Veterans Affairs are also actively pursuing care and research initiatives that include various CAM interventions in treatment and prevention of problems such as chronic pain and post-traumatic stress disorder afflicting our wounded warriors.

In the appendices, we have included a status report on the process of validation of selected interventions. In Appendix A, we present examples of specific complementary and alternative interventions for which a sufficient number of individual studies exist for systematic reviews to conclude the interventions appear to offer benefit. In Appendix B, we list numerous additional examples of individual NCCAM-supported studies that provide preliminary evidence of benefit in other indications. We feel it important to provide both types of information in addressing the subcommittee's specific questions because the processes of evidence-based validation of health practices and decisionmaking regarding their use are iterative, and draw on a variety of such sources rather than merely single studies.

APPENDIX A: THE STATUS OF THE EVIDENCE BASED REVIEWS AND PROFESSIONAL GUIDELINES FOR SELECT COMPLEMENTARY AND ALTERNATIVE THERAPIES

The examples of systematic reviews and professional assessments cited here all include evidence derived from clinical and mechanistic research supported by the NCCAM. As is true with the evidence in most areas of healthcare, there continues to be controversy about some of these conclusions, and not all systematic reviews come to the same conclusions.

*Role of Complementary Therapies in the Management of Chronic Low Back Pain*

Management of chronic low back pain is a critical challenge for our healthcare system and a major driver of healthcare costs. Complementary interventions are increasingly being integrated into the care of chronic back pain patients, and there is substantial recognition, supported by findings from the NCCAM research, that complementary therapies, particularly chiropractic and osteopathic spinal manipulation, massage, acupuncture, and meditative exercise forms such as yoga, can make important contributions to improved outcomes for patients. Many systematic reviews have assessed these therapeutic approaches. The Joint Clinical Practice Guideline for low back pain, developed by the American College of Physicians and the American Pain Society, reflects the strength of this evidence base and the emerging professional consensus for the value of the incorporation of complementary approaches. To quote directly from the summary:

"For patients who do not improve with self-care options, clinicians should consider the addition of nonpharmacologic therapy with proven benefits-for acute low back pain, spinal manipulation; for chronic or sub-acute low back pain, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation."—Joint Clinical Practice Guideline, American College of Physicians and American Pain Society. Annals of Internal Medicine, 2007: 147,478.

Nevertheless, there is also a consensus among healthcare providers, both conventional and complementary, that, current approaches are not satisfactory for many patients suffering with back pain. Moving forward, a major area of emphasis for the NCCAM, as described in the NCCAM's 2011 Strategic Plan, will be improving management of chronic back pain. Research is needed to optimize complementary therapies, to understand better who benefits from them, and to develop better systems of integrated care that improve real world application of these helpful therapeutic techniques.

*Role of Natural Products in Promotion of Health and Wellness*

The NCCAM's natural product research portfolio, carefully assessed during our strategic planning process, has yielded many important lessons that will guide us moving forward. Fundamental scientific understanding of potential beneficial mechanisms of many dietary supplements and natural products has increased markedly, with some notable examples described below. New high-throughput technologies and modern genomic tools have created important new scientific opportunities. We have learned much about the challenges of translation of these findings to clinical efficacy research. The future emphasis, as described in our strategic plan and strongly sup-

ported by both academic investigators and leaders of the botanical and dietary supplement industry, is on the development of strong biological mechanistic hypotheses, sensitive biological signatures of effect, and carefully optimized trial designs.

A few examples of the independent systematic reviews that have provided validation of the potential value of natural products or other dietary supplements are as follows:

—*Fish Oil for the Prevention of Cardiovascular Disease*.—"Dietary supplementation with omega-3 fatty acids should be considered in the secondary prevention of cardiovascular events."—Clinical Cardiol. 2009: 32, 365.

—*Melatonin for the Prevention and Treatment of Jet Lag*.—"Melatonin is remarkably effective in preventing or reducing jet lag, and occasional short-term use appears to be safe."—Cochrane Database Syst Rev 2002: 1520.

—*Probiotics for Prevention of Necrotizing Enterocolitis in Preterm Infants*.—"Enteral supplementation of probiotics prevents severe necrotizing enterocolitis and all cause mortality in preterm infants."—Cochrane Database Syst Rev 2008: 5496.

—*Prebiotics and Probiotics for Hepatic Encephalopathy*.—"The use of prebiotics, probiotics and synbiotics was associated with significant improvement in minimal hepatic encephalopathy."—Ailment Pharmacol Ther 2011: 33.

—*Probiotics for Acute Infectious Diarrhea*.—"Used alongside rehydration therapy, probiotics appear to be safe and have clear beneficial effects in shortening the duration and reducing stool frequency in acute infectious diarrhea."—Cochrane Database Syst Rev 2010: 3048.

—*Zinc for the Common Cold*.—"Zinc administered within 24 hours of onset of symptoms reduces the duration and severity of the common cold in healthy people."—Cochrane Database Syst Rev 2006: 1364.

*Role of Complementary Therapies in the Management of Pain and Other Troublesome Symptoms*

Concern is often voiced that the processes of evidence-based medicine could not accommodate the evidence emerging from research on many complementary therapies. In fact, this is a challenge common to evaluation of the evidence of many nonpharmacological interventions, including psychotherapy and surgery. The NCCAM's strategic plan addresses this challenge by calling for increased use of outcomes and effectiveness research methodology, and collaboration with experts who work in other fields facing similar challenges. Nonetheless, several examples are provided below which illustrate that rigorous research on these complicated therapies is possible and can meet the exacting standards of evidence-based review.

—The Cochrane Collaborative has reviewed the evidence that acupuncture may provide benefit for migraine prophylaxis and for treatment of tension-type headache, and concluded that it has value in both situations.—Cochrane Database Syst Rev 2009: 1218, Cochrane Database Syst Rev 2009: 7587.

—The Cochrane Collaborative has reviewed the evidence that acupuncture may be useful for postoperative nausea and vomiting, as well as for nausea and vomiting which has been induced by cancer chemotherapy. Systematic reviews conclude benefit in both cases.—Cochrane Database Syst Rev 2009, 3281, National Cancer Institute, PDQ summary.

—A systematic review published in the British Journal of Anesthesia concluded that perioperative acupuncture is a useful adjunct for acute postoperative pain management.—Br. J Anaesth 2008: 101, 151.

APPENDIX B: THE NCCAM-SUPPORTED STUDIES THAT CONTAIN EVIDENCE OF VALUE OF CAM

Listed below are the NCCAM-supported studies, which contain evidence of the value of CAM. Consistent with the priorities of the NCCAM's strategic plan, these findings are grouped into three major categories: Mind and Body Interventions; Natural Products Interventions; and Population-Based Research. Within each category, the findings are listed in reverse chronological order by the publication date.

*Mind and Body Interventions*

*Chronic Pain*

*Review of CAM Practices for Back and Neck Pain Shows Modest Benefit.*—According to a recent review published by the Agency for Healthcare Research and Quality, the benefits of complementary and alternative therapies for back and neck pain—such as acupuncture, massage, and spinal manipulation—are modest in size but provide more benefit than usual medical care. While these effects are most evident following the end of treatment, the authors of the report noted that very few

studies looked at long-term outcomes. Back and neck pain are important health problems that affect millions of Americans, and back pain is the most common medical condition for which people use complementary and alternative medicine (CAM). They noted that more well-designed studies are needed to draw more definitive conclusions regarding the benefits of CAM therapies for pain. http://nccam.nih.gov/research/results/spotlight/100110.htm.—AHRQ Publication No. 10(11)E007. Rockville, MD: Agency for Healthcare Research and Quality. October 2010.

*Tai Chi May Benefit Patients With Fibromyalgia.*—Fibromyalgia is a disorder characterized by muscle pain, fatigue, and other symptoms. Researchers, funded in part by the NCCAM, evaluated the physical and psychological benefits of tai chi (which combines meditation, slow movements, deep breathing, and relaxation) in 66 people with fibromyalgia. The participants were assigned to one of two groups: an attention control group that received wellness education and practiced stretching exercises, or a tai chi group that received instruction in tai chi principles and techniques and practiced 10 forms of Yang-style tai chi. Compared with the attention control group, the tai chi group had a significantly greater decrease in total score on the Fibromyalgia Impact Questionnaire at 12 weeks. In addition, the tai chi group demonstrated greater improvement in sleep quality, mood, and quality of life. Improvements were still present at 24 weeks. No adverse events were reported. The researchers concluded that these findings support previous research indicating benefits of tai chi for musculoskeletal pain, depression, and quality of life. The underlying mechanisms are unknown, and the researchers noted that larger, longer term studies are needed to evaluate the potential benefits of tai chi for patients with fibromyalgia. http://nccam.nih.gov/research/results/spotlight/081810.htm.—New England Journal of Medicine. 2010;363(8):743–754 and 783–784.

*Analysis of National Survey Reveals Perceived Benefit of CAM for Back Pain*.—According to an analysis of the 2002 National Health Interview Survey, approximately 6 percent of U.S. adults used complementary and alternative medicine (CAM) to treat their back pain during the previous year. The data from this analysis also revealed that a majority (60 percent) of survey respondents who used the most common CAM therapies for back pain perceived "a great deal" of benefit. The most common CAM therapies used for back pain—in descending order of perceived benefit—were chiropractic (66 percent), massage (56 percent), yoga/tai chi/qi gong (56 percent), acupuncture (42 percent), herbal therapies (32 percent), and relaxation techniques (28 percent). The specific factors associated with a greater perception of benefit from CAM use were having an improved self-reported health status, and using CAM because "conventional medical treatment would not help." Back pain is the most common medical condition for which people use CAM, and these data give more insight into the use and perceived benefit of CAM therapies for this condition. The researchers suggested that this analysis demonstrates the need for future studies that include both self-reported outcomes and observer-based performance measures of patients using CAM therapies for back pain. http://nccam.nih.gov/research/results/spotlight/060110.htm.—Journal of the American Board of Family Medicine. 2010;23(3):354–362.

*Study of Spinal Manipulative Therapy for Neck-related Headaches Reports Findings on Dose and Efficacy*.—Previous research suggests that spinal manipulative therapy (SMT) may be helpful for various types of chronic headaches, including cervicogenic headache (CGH), which is associated with neck pain and dysfunction. This randomized controlled trial evaluated the dose (number of treatments) and relative efficacy of SMT in a group of 80 patients with chronic CGH. Compared with massage, participants receiving SMT had greater improvements in CGH-related pain and disability, lasting to 24 weeks. These differences were clinically important and statistically significant. The dose effects of SMT treatments (i.e., differences between 8 and 16 treatments) were small but significant. The mean number of headaches reported by SMT subjects decreased by more than half during the study. The researchers concluded that their findings support SMT as a viable option for treating CGH, but also point out that these findings should be considered preliminary. They suggest additional research to determine whether SMT results for patients with CGH are affected by treatment intensity and duration, use of other therapies, lifestyle changes, and an integrative care approach. http://nccam.nih.gov/research/results/spotlight/041310.htm.—Spine Journal. 2010;10(2):117–128.

*Preliminary Trial Finds Possible Benefits of Osteopathic Treatment for Back Pain During the Third Trimester of Pregnancy*.—Most pregnant women experience low-back pain, which often is associated with sleep disturbance and can affect daily activities. Researchers investigated the effects of osteopathic manipulative treatment on back pain during the third trimester of pregnancy. They found that back-specific functioning deteriorated significantly less in the osteopathic manipulative treatment group than in the usual care or usual care with sham treatment groups. Although

the results of this preliminary study suggest that osteopathic manipulation may have benefits for back-specific functioning, but not pain, in the third trimester of pregnancy, larger trials are needed before definitive conclusions can be drawn about its efficacy or effectiveness for this purpose. http://nccam.nih.gov/research/results/spotlight/032210.htm.—American Journal of Obstetrics and Gynecology. 2010;202(1):43.e1–43.e8.

*Tai Chi May Benefit Older Adults With Knee Osteoarthritis*.—Knee osteoarthritis (OA) is an increasing problem among older adults, causing pain, functional limitations, and reduced quality of life. Researchers conducted a long-term, randomized, controlled trial comparing tai chi and conventional exercise in a group of 40 adults (mean age 65) with symptomatic knee OA. The tai chi group learned and practiced Yang-style tai chi, modified slightly to eliminate excess stress on the knees. The control group received wellness education and did stretching exercises. Compared with the control group, tai chi patients had greater improvement in measures of pain, physical function, self-efficacy (belief in one's own abilities), depression, and health-related quality of life. Although most differences between the two groups were statistically significant only at 12 weeks, the differences for self-efficacy and depression remained statistically significant at 24 and 48 weeks. No serious adverse events were reported. The researchers recommend additional studies of biologic mechanisms and approaches of tai chi, so its benefits can be extended to a broader population. http://nccam.nih.gov/research/results/spotlight/011510.htm.—Arthritis & Rheumatism. 2009;61(11):1545–1553.

*Iyengar Yoga for Chronic Low-back Pain Shows Promising Results*.—Researchers conducted a clinical trial to evaluate the effects of Iyengar yoga (a popular style of yoga that uses props to help support the body during postures) on chronic low-back pain. They found that compared with the control group, the yoga group had significantly greater reductions in functional disability, pain, and depression, at weeks 12 and 24 and at the 6-month followup. There were no significant differences in pain medication usage between the groups; however, there appeared to be a trend toward decreased usage in the yoga group. The researchers concluded from their results that yoga decreases functional disability, pain, and depression in people with chronic low-back pain. However, they noted potential limitations of their study (e.g., heavy reliance on self-report instruments, and differential demands on yoga vs. control groups in terms of attention and group support) and suggest design considerations for future research. http://nccam.nih.gov/research/results/spotlight/112409.htm.—Spine. 2009;34(19):2066–2076.

*Managing Low-Back Pain: an Evidence-Based Approach for Primary Care Physicians*.—A physician's response to a patient with low-back pain (LBP) should take into account psychological and social factors as well as physical symptoms, according to an article that looked at two case studies in light of evidence-based clinical guidelines developed by Roger Chou et al. for the American Pain Society and the American College of Physicians. The article's authors, recommend a measured approach to the use of imaging (x-rays and MRI/CT scans) and medication. The authors outline considerations in evaluating each patient and choosing action steps. The authors also noted that most people with chronic LBP will not become pain free. Physicians can help patients have a realistic outlook that focuses on improving functioning in addition to reducing pain. http://nccam.nih.gov/research/results/spotlight/040209.htm.—Journal of Family Practice. 2009;58(4):180–186.

*Study Finds Benefits of Therapeutic Massage for Chronic Neck Pain*.—In a research study, 64 adults with neck pain persisting for at least 12 weeks were randomly assigned to receive either massage or a self-care book. The massage group had up to 10 treatments over a 10-week period, provided by licensed practitioners who used a variety of common Swedish and clinical massage techniques and also made typical self-care suggestions. After 10 weeks, the massage group was more likely than the self-care-book group to have clinically significant improvement in function and symptoms. At 26 weeks, the massage group tended to be more likely to report improvement in function but not in specific symptoms. For both function and symptoms, mean differences between the two groups were strongest at 4 weeks and not evident by 26 weeks. At all followup points, the massage group was more likely than the self-care-book group to report global improvement ratings of "better" or "much better." At 26 weeks, medication use had increased 14 percent for the self-care-book group but had not changed for the massage group. The researchers concluded that therapeutic massage is safe and may have benefits for treating chronic neck pain, at least in the short term. They recommended studies to determine optimal massage treatment, as well as larger, more comprehensive studies to follow patients for at least 1 year. http://nccam.nih.gov/research/results/spotlight/051809.htm.—Clinical Journal of Pain. 2009;25(3):233–238.

*Massage Therapy May Ease Pain and Improve Mood in Advanced Cancer Patients*.—Researchers investigated the benefits of massage versus simple touch therapy (placing both hands on specific body sites) in patients with advanced cancer. This multisite study—conducted at 15 U.S. hospices in the Population-based Palliative Care Research Network—included 380 participants with advanced cancer who were experiencing moderate-to-severe pain. Results of the study showed that both the massage and simple touch therapy groups experienced statistically significant improvements in pain relief, physical and emotional distress, and quality of life. Immediate improvement in pain and mood was greater with massage than with simple touch; however, sustained effects of these therapies were not observed. The researchers concluded that massage therapy may provide some immediate relief for patients with advanced cancer. They also suggest that simple touch, which can be provided by family members and volunteers, may benefit these patients. http://nccam.nih.gov/research/results/spotlight/110608.htm.—Annals of Internal Medicine. 2008;149(6):369–379.

*Study Points to Cost-effectiveness of Naturopathic Care for Low-Back Pain*.—Researchers who studied treatment alternatives for low-back pain in a group of 70 warehouse workers found that a naturopathic approach (incorporating a range of treatment options—acupuncture, exercise and dietary advice, relaxation training, and a back-care booklet) was more cost-effective than the employer's usual patient education program. Both the workers and the employer benefited from the naturopathic approach, which was associated with better health-related quality of life, less absenteeism, and lower costs for other treatments and pain medication. The study consisted of workers ages 18 to 65 who had experienced low-back pain for at least 6 weeks. The workers were randomly assigned to receive naturopathic care or patient education visits over a 3-month period. The 30-minute, onsite visits were conducted semiweekly (naturopathic) or biweekly (patient education). The researchers conclude that naturopathic care is more cost-effective than a patient education program in treating low-back pain. They also recommend further studies of the economic impact of naturopathic medicine, particularly to address the limitations of their evaluation. http://nccam.nih.gov/research/results/spotlight/070708.htm.—Alternative Therapies in Health and Medicine. 2008;14(2):32–39.

*Acupuncture Relieves Pain and Improves Function in Knee Osteoarthritis*.—Acupuncture provides pain relief and improves function for people with osteoarthritis of the knee and serves as an effective addition to standard care, according to a landmark study. The researchers enrolled 570 patients with osteoarthritis of the knee, aged 50 and older, to receive one of three treatments: acupuncture, simulated acupuncture (procedures that mimic acupuncture, sometimes also referred to as "placebo" or "sham"), or participation in a control group. The control group followed the Arthritis Foundation's self-help course for managing their condition over 12 weeks. Participants in the actual and simulated acupuncture groups received 23 treatment sessions over 26 weeks. All study participants continued to receive standard medical care from their primary physicians, including anti-inflammatory medications and opioid pain relievers. At the start of the study, participants' pain and knee function were assessed using standard arthritis research survey instruments and measurement tools. After 26 weeks participants in the acupuncture group had a 40 percent decrease in pain and a nearly 40 percent improvement in function compared to their assessments at the start of the study. Findings from this study begin to shed more light on acupuncture's possible mechanisms and potential benefits, especially in treating painful conditions such as arthritis. http://nccam.nih.gov/research/results/spotlight/052504.htm.—Annals of Internal Medicine. 2004;141(12):901–910.

*Stress/Anxiety*

*Long-term Yoga Practice May Decrease Women's Stress*.—Research has shown that women who practice hatha yoga (a common type of yoga involving body postures, breath control, and meditation) regularly recover from stress faster than women who are considered yoga "novices." The research also showed that yoga may boost the mood of both yoga experts and novices. The researchers found that the novices' blood had 41 percent higher levels of the cytokine interleukin-6 (IL–6) than those of the experts. IL–6 is a stress-related compound that is thought to play a role in certain conditions such as cardiovascular disease and type 2 diabetes. In addition, the novices' levels of C-reactive protein, which serves as a general marker for inflammation, were nearly five times that of the yoga experts. Experts had lower heart rates in response to stress events than novices. The researchers suggested that this study offers insight into how yoga and its related practices may affect health. Regularly performing yoga could have health benefits, which may only become evident after years of practice. http://nccam.nih.gov/research/results/spotlight/051510.htm.—Psychosomatic Medicine. Feb 2010;72(2):113–121.

*A Form of Acupuncture May Help in Opioid Addiction*.—Transcutaneous electric acupoint stimulation (TEAS), a form of acupuncture that uses skin electrodes to apply electrical stimulation at different points on the body, may help people addicted to opioid drugs. This study, supported in part by the NCCAM, also suggests that combining this technique with prescribed drugs that ease withdrawal symptoms may improve other outcomes for people addicted to opioids. Further, participants who received active TEAS were more than two times less likely to have used any drugs than those who received simulated TEAS. In addition, patients in the active TEAS group reported they were less bothered by pain and that they experienced greater improvements in overall health. However, the researchers noted that drug abstinence may have contributed to these improvements. The researchers noted several limitations of this study, including a small number of participants and brief duration of treatment. Despite these limitations, they suggested that additional studies with larger, more diverse populations and longer treatment durations are needed. http://nccam.nih.gov/research/results/spotlight/010410.htm.—Journal of Substance Abuse Treatment. 2010;38(1):12–21.

*Transcendental Meditation Helps Young Adults Cope With Stress*.—A study found that Transcendental Meditation (TM) helped college students decrease psychological distress and increase coping ability. For a group of students at high risk for developing hypertension, these changes also were associated with decreases in blood pressure. Compared with controls, the TM group had significant improvement in total psychological distress, anxiety, depression, anger/hostility, and coping ability. Changes in psychological distress and coping paralleled changes in blood pressure. According to the researchers, these findings suggest that young adults at risk of developing hypertension may be able to reduce that risk by practicing TM. The researchers recommend that future studies of TM in college students evaluate long-term effects on blood pressure and psychological distress. http://nccam.nih.gov/research/results/spotlight/051410.htm.—American Journal of Hypertension. Dec 2009;22(12):1326–1331.

*Mantram Instruction May Help HIV-positive Individuals Handle Stress*.—Repeating a mantram (also known as a mantra—the practice of silently focusing on a spiritual word or phrase frequently throughout the day)—may help HIV-positive individuals develop coping skills and reduce anger. Researchers analyzed the effects of a group-based mantram training program, based on data from a study involving 93 HIV-positive individuals. After the 5-week intervention, the mantram group reported a significant increase (25 percent on average) in use of positive reappraisal coping (handling stressful situations by focusing on positive aspects), while the control group reported a significant decrease. At a 22-week followup, anger levels had decreased in the mantram group (13 percent on average) but not in the control group. According to the researchers, these findings suggest that repeating a mantram may help HIV-positive individuals examine stressful situations in a more nonjudgmental and accepting way, reducing the likelihood of an angry response. This is significant because reducing reactive anger may help individuals preserve supportive social relationships as well as maintain adherence to antiretroviral treatments. The researchers suggested additional studies to explore the effects of mantram on attention, cognitive processing, and acceptance-based responding. http://nccam.nih.gov/research/results/spotlight/010609.htm.—International Journal of Behavioral Medicine. 2009;16(1):74–80.

*Stress Management Interventions May Enhance Immune Function in People With HIV*.—Stress management interventions may help to improve immune function and coping skills in HIV-positive individuals. Researchers assessed three interventions: cognitive-behavioral relaxation training (physical and mental relaxation techniques and active coping skills); focused tai chi training (exercises for balance, breathing, posturing and movement, and relaxation); and spiritual growth (discussions and personal journals to enhance spiritual awareness). None of the intervention groups differed from controls on measures of HIV-related psychological distress, quality of life, and health status, or on physiological stress response (cortisol levels). However, compared with controls, all three treatment groups had significant increases in lymphocyte proliferation (production of white blood cells), indicating enhanced immune function. The researchers noted the potentially important clinical implications of this finding. They recommend additional research to examine specific effects of stress management interventions in people with HIV. http://nccam.nih.gov/research/results/spotlight/060208.htm.—Journal of Consulting and Clinical Psychology. 2008;76(3):431–441.

*Acupuncture May Help Symptoms of Post-traumatic Stress Disorder*.—A pilot study shows that acupuncture may help people with post-traumatic stress disorder. Post-traumatic stress disorder (PTSD) is an anxiety disorder that can develop after exposure to a terrifying event or ordeal in which grave physical harm occurred or

was threatened. Traumatic events that may trigger PTSD include violent personal assaults, natural or human-caused disasters, accidents, or military combat. Researchers conducted a clinical trial examining the effect of acupuncture on the symptoms of PTSD. The researchers analyzed depression, anxiety, and impairment in 73 people with a diagnosis of PTSD. The participants were assigned to receive either acupuncture, group cognitive-behavioral therapy, or were put on the wait list as a control group. The people in the control group were offered treatment or referral for treatment at the end of their participation. The researchers found that acupuncture provided treatment effects similar to group cognitive-behavioral therapy; both interventions were superior to the control group. Additionally, treatment effects of both the acupuncture and the group therapy were maintained for 3 months after the end of treatment. The limitations are that the study consisted of a small group of participants that lacked diversity and that the results do not account for outside factors that may have affected the treatments' results. http://nccam.nih.gov/research/results/spotlight/092107.htm.—The Journal of Nervous and Mental Disease, June 2007.

*Self-hypnosis Beneficial for Women Undergoing Breast Biopsy*.—Researchers have found that women who used self-hypnosis during a type of core needle breast biopsy experienced anxiety relief and reduced pain when compared with standard care. A large core needle breast biopsy is usually an outpatient procedure that limits the use of anesthetic. Women having this procedure often experience anxiety because of the possibility of a cancer diagnosis in addition to the anxiety that patients typically experience during a medical procedure. In this randomized, controlled trial researchers recruited 236 women who were randomly assigned to receive standard care, structured empathic attention from a research assistant, or guided self-hypnotic relaxation during the biopsy. The study found that both self-hypnosis and empathic attention reduced pain and anxiety during the procedure. Self-hypnosis provided greater anxiety relief than empathic attention. Neither intervention increased procedure time or significantly increased cost. As a result, the researchers suggest that self-hypnosis appears attractive for outpatient pain management. http://nccam.nih.gov/research/results/spotlight/122606.htm.—Pain, December 2006.

*Basic and Translational Research*

Basic and translational research provides important insights into how CAM interventions can benefit human health. For example, animal studies help to identify biomarkers or signatures of biological effects that can be applied to future studies in humans.

*Mindfulness Meditation is Associated With Structural Changes in the Brain*.—Practicing mindfulness meditation appears to be associated with measurable changes in the brain regions involved in memory, learning, and emotion, according to a research study that compared brain images of participants who participated in a mindfulness-based stress reduction program with those who did not. Specifically brain images in the meditation group revealed increases in gray matter concentration in the left hippocampus, which is an area of the brain involved in learning, memory, and emotional control, and is suspected of playing a role in producing some of the positive effects of meditation. The researchers concluded that these findings may represent an underlying brain mechanism associated with mindfulness-based improvements in mental health. Additional studies are needed to determine the associations between specific types of brain change and behavioral mechanisms thought to improve a variety of disorders. http://nccam.nih.gov/research/results/spotlight/012311.htm.—Psychiatry Research: Neuroimaging. 2011;191(1):36–43.

*Study Examines the Effects of Swedish Massage Therapy on Hormones, Immune Function*.—Massage is used for many health purposes, but little is known about how it works on a biological level. This study examined the effects of one session of Swedish massage therapy—a form of massage using long strokes, kneading, deep circular movements, vibration, and tapping—on the body's hormonal response and immune function. Researchers randomly assigned 53 healthy adults to receive one session of either Swedish massage or light touch (in which the therapist used only a light touch with the back of the hand). The researchers found that participants who received Swedish massage had a significant decrease in the hormone arginine-vasopressin (which plays a role in regulating blood pressure and water retention) compared with those who were treated with light touch. Study data, although preliminary data, led the researchers to conclude that a single session of Swedish massage produces measurable biological effects and may have an effect on the immune system. However, more research is needed to determine the specific mechanisms and pathways behind these changes. http://nccam.nih.gov/research/results/spotlight/090110.htm.—The Journal of Alternative and Complementary Medicine. 2010;16(10):1–10.

*Electroacupuncture Relieves Cancer Pain in Laboratory Rats*.—Electroacupuncture (acupuncture combined with electrical stimulation) has been used to treat cancer pain; however, the existing data on its efficacy and how it works are unclear. Researchers investigated the effects of electroacupuncture on cancer pain in rats and also looked at the underlying biomechanisms. The results showed that compared with the sham control, electroacupuncture significantly reduced cancer-induced bone pain. The researchers also examined the rats spinal cords to see whether electroacupuncture affected chemical processes thought to play a role in pain. They found that compared with the sham control, electroacupuncture inhibited up-regulation of two substances involved in these processes: spinal cord preprodynorphin mRNA and dynorphin. In a separate experiment, they found that injection of an antiserum against dynorphin also inhibited cancer-induced pain in the rats. The researchers concluded that electroacupuncture eases cancer pain in rats, at least in part by inhibiting spinal dynorphin. They note that their findings support the clinical use of electroacupuncture in the treatment of cancer pain. http://nccam.nih.gov/research/results/spotlight/040109.htm.—European Journal of Pain. 2008;12(7):870–878.

*Brain-Imaging Study Explores Analgesic Effect of Acupuncture*.—Researchers used two imaging technologies—functional magnetic resonance imaging (fMRI) and positron emission tomography (PET)—to investigate how specific areas of the brain might be involved in acupuncture analgesia. The imaging results showed acupuncture-related changes in both of the brain's pain networks: the lateral network, which is associated with sensory aspects of pain perception, and the medial network, which is associated with affective aspects. However, the fMRI and PET results pointed to different areas in these networks, with one exception: both imaging technologies showed changes in the right medial orbitofrontal cortex—an indication that this area of the brain may be important in acupuncture analgesia. The researchers note that their preliminary findings demonstrate that imaging studies using more than one imaging technique have potential for clarifying the neural mechanisms of acupuncture. They point out that similar studies with much larger samples might reveal other areas of the brain where fMRI and PET results converge. http://nccam.nih.gov/research/results/spotlight/121208.htm.—Behavioural Brain Research. 2008;193(1):63–68.

*Green Tea May Help Protect Against Rheumatoid Arthritis*.—Investigators examined the effects of green tea polyphenols on rheumatoid arthritis (RA) by using an animal (rat) model. The animals consumed green tea in their drinking water (controls drank water only) for 1 to 3 weeks before being injected with heat-killed Mycobacterium tuberculosis H37Ra to induce arthritis. The researchers found that green tea significantly reduced the severity of arthritis. They suggest that green tea affects arthritis by causing changes in various arthritis-related immune responses—it suppresses both cytokine IL–17 (an inflammatory substance) and antibodies to Bhsp65 (a disease-related antigen), and increases cytokine IL–10 (an anti-inflammatory substance). Therefore, they recommend that green tea be further explored as a dietary therapy for use together with conventional treatment for managing RA. http://nccam.nih.gov/research/results/spotlight/120808.htm.—The Journal of Nutrition. 2008:138(11):2111–2116.

*Electroacupuncture May Help Alcohol Addiction*.—Researchers examined the effects of electroacupuncture on alcohol intake by alcohol-preferring rats. After being trained to drink alcohol voluntarily and then subjected to alcohol deprivation, the rats received either electroacupuncture or sham electroacupuncture, and their alcohol intake was monitored after the intervention. Some rats were also pretreated with naltrexone (a drug that blocks the effects of opiates), so researchers could look for evidence that opiate mechanisms are involved in electroacupuncture's effects. The results showed that electroacupuncture reduced the rats' alcohol intake. The researchers also found that injecting the rats with naltrexone blocked the effect of electroacupuncture on alcohol intake-an indication that this effect may be through the brain's opiate system. On the basis of their findings, the researchers recommend rigorous clinical trials to study the effects of electroacupuncture in alcohol-addicted people. They also recommend further investigation of how electroacupuncture affects the brain. http://nccam.nih.gov/research/results/spotlight/022609.htm.—Neurochemical Research. 2008;33(10):2166–2170.

*Lifestyle Changes May Affect Cell-level Processes Related to Disease*.—Disease risk, progression, and premature mortality—in many types of cancer and in cardiovascular and infectious diseases—have been linked to telomeres, which are protective DNA-protein complexes that keep cells genetically stable. The cellular enzyme telomerase is an important part of the body's maintenance system for these essential complexes. In a pilot study researchers investigated the effects of lifestyle changes on telomerase levels in 24 men with low-risk prostate cancer. The partici-

pants underwent a comprehensive lifestyle modification that included: improved nutrition, moderate aerobic exercise, stress management, and increased social support. After 3 months, the study participants' telomerase activity had increased 29.8 percent. Decreases in psychological distress and low-density lipoprotein (LDL) cholesterol were associated with the increase in telomerase activity. This is the first longitudinal study to suggest that lifestyle modifications (or any intervention) might significantly increase telomerase activity. The researchers emphasize that additional research is needed and recommend larger randomized controlled trials to confirm the findings. http://nccam.nih.gov/research/results/spotlight/100908.htm. The Lancet Oncology. Published online September 16, 2008.—Journal of Immunology. 2007;179(6):4249–4254.

*New Research Gives Insight Into How Acupuncture May Relieve Pain*.—In the first study of its kind, researchers evaluated the effects of acupuncture on brain activity following active stimulation. The researchers used functional magnetic resonance imagery (fMRI) to monitor brain activity in 15 healthy adults before and after true acupuncture and sham acupuncture. The procedure lasted 150 seconds, and the rest period was 5.5 minutes. Analysis of the fMRI images showed that following true acupuncture—but not sham—there were increased connections among the parts of the brain involved in the perception and memory of pain. The subjects also reported stronger sensations with true acupuncture than with sham. The researchers concluded that acupuncture changes resting-state brain activity in ways that may account for its analgesic and other therapeutic effects. http://nccam.nih.gov/research/results/spotlight/111408.htm.—Pain. 2008;136(3):407–418.

*Prostate Genes Altered by Intensive Diet and Lifestyle Changes*.—A pilot study suggests that intensive lifestyle and diet changes may alter gene expression (the way a gene acts) in the prostate—possibly affecting the progression of prostate cancer. This pilot study included a group of 31 men with low-risk prostate cancer. These men declined immediate surgery, hormonal therapy, or radiation, and participated in an intensive 3-month nutritional and lifestyle intervention while researchers monitored their tumor progression. The men stuck to a low-fat, plant-based diet and took dietary supplements including fish oil, selenium, and vitamins C and E. They also participated in stress management activities, did moderate aerobic exercise, and attended group support sessions. The researchers found that there were changes in the men's RNA following the lifestyle and diet modifications. Certain RNA transcripts that play a critical role in tumor formation had "up-regulated" (increased) and others "down-regulated" (decreased). The researchers concluded that intensive nutrition and lifestyle changes may alter gene expression in the prostate. They believe that understanding how these changes affect the prostate may lead to more effective prevention and treatment for prostate cancer, and recommend larger, randomized controlled trials to confirm the results of this pilot study. http://nccam.nih.gov/research/results/spotlight/100808.htm.—Proceedings of the National Academy of Sciences of the United States of America. 2008;105(24):8369–8374.

*Meditation May Increase Empathy*.—Previous brain studies have shown that when a person witnesses someone else in an emotional state—such as disgust or pain—similar activity is seen in both people's brains. This shows a physiological base for empathy, defined as the ability to understand and share another person's experience. Now, research using advanced brain images (functional magnetic resonance imaging) have shown that compassion meditation—a specific form of Buddhist meditation—may increase the human capacity for empathy. In the study, researchers compared brain activity in meditation experts with that of subjects just learning the technique (16 in each group). They measured brain activity during meditation and at rest, in response to sounds designed to evoke a negative, positive, or neutral emotional response. The researchers found that both the novice and the expert meditators showed an increased empathy reaction when in a meditative state. However, the expert meditators showed a much greater reaction, especially to the negative sound, which may indicate a greater capacity for empathy as a result of their extensive meditation training. An increased capacity for empathy, the authors say, may have clinical and social importance. The next step, they add, is to investigate whether compassion meditation results in more altruistic behavior or other changes in social interaction. http://nccam.nih.gov/research/results/spotlight/060608.htm.—PLoS ONE [online journal], 2008.

*Meditation May Make Information Processing in the Brain More Efficient*.—"Attentional-blink" occurs when two pieces of information are presented to a person in very close succession, and the brain doesn't perceive the second piece of information because it is still processing the first. Researchers attempted to determine if intensive mental training through meditation could extend the brain's limits on information processing, reducing "attentional-blink." Two groups of people—17 expert meditators and 23 novices—were compared to see if either was better at recognizing two

pieces of information shown in quick succession. The participants were tested at the beginning and end of a 3-month period. For the intervening 3 months, the meditation practitioners participated in a retreat, during which they meditated for 10–12 hours a day. The novices participated in a 1-hour meditation class, and were asked to meditate for 20 minutes a day for the week before each test. The researchers found that intensive training did reduce "attentional-blink." The participants who had gone through the mental training were more likely to perceive both pieces of information instead of just the first because the brain used fewer resources to detect the first piece of information—leaving more resources available to detect the second. The researchers also note that this study supports the idea that brain plasticity, or the ability of the brain to adapt, exists throughout life. http://nccam.nih.gov/research/results/spotlight/082307.htm.—PLOS Biology, June 2007.

*Quality of Life and Other Factors*

*Quality of Life and Safety of Tai Chi and Green Tea Extracts in Postmenopausal Women*.—For postmenopausal women with osteopenia (low bone mineral density), practicing tai chi and/or taking green tea polyphenols appears to be safe. Further, practicing tai chi by itself or in combination with green tea polyphenol supplements may improve quality of life; however, taking green tea supplements by themselves has no significant improvement in quality of life. The researchers noted that this is the first placebo-controlled, randomized study to evaluate the safety of long-term use of green tea supplements in postmenopausal women. Based on these findings, the researchers concluded that green tea polyphenols at a dose of 500 mg daily for 24 weeks, alone or in combination with tai chi, appears to be safe in postmenopausal women with low bone mineral density. http://nccam.nih.gov/research/results/spotlight/121410.htm.—BMC Complementary and Alternative Medicine. 2010;10(1):76. [Epub ahead of print]

*Tai Chi and Qi Gong Show Some Beneficial Health Effects*.—A review of scientific literature suggests that there is strong evidence of beneficial health effects of tai chi and qi gong, including for bone health, cardiopulmonary fitness, balance, and quality of life. Both tai chi and qi gong (also known as qigong) have origins in China and involve physical movement, mental focus, and deep breathing. Researchers analyzed 77 articles reporting the results of 66 randomized controlled trials of tai chi and qi gong. The studies involved a total of 6,410 participants. Of the many outcomes identified by the reviewers, current research suggests that the strongest and most consistent evidence of health benefits for tai chi or qi gong is for bone health, cardiopulmonary fitness, balance and factors associated with preventing falls, quality of life, and self-efficacy (the confidence in and perceived ability to perform a behavior). The reviewers concluded that the evidence is sufficient to suggest that tai chi and qi gong are a viable alternative to conventional forms of exercise. http://nccam.nih.gov/research/results/spotlight/071910.htm.—American Journal of Health Promotion. 2010;24(6):e1–e25.

*Hypnosis May Reduce Hot Flashes in Breast Cancer Survivors*.—Researchers investigated the effects of hypnosis on hot flashes among women with a history of primary breast cancer, no current evidence of detectable disease, and at least 14 hot flashes per week over a 1-month period. Sixty women were assigned to receive either hypnosis (weekly 50-minute sessions, plus instructions for at-home self-hypnosis) or no treatment. The women who received hypnosis had a 68-percent reduction in self-reported hot flash frequency/severity and experienced an average of 4.39 fewer hot flashes per day. Compared with controls, they also had significant improvements in self-reported anxiety, depression, interference with daily activities, and sleep. The researchers concluded that hypnosis appears to reduce perceived hot flashes in breast cancer survivors and may have additional benefits such as improved mood and sleep. They recommend long-term, randomized, placebo-controlled studies to further explore the benefits of hypnosis for breast cancer survivors. The researchers are currently conducting a randomized clinical trial with 200 participants. http://nccam.nih.gov/research/results/spotlight/102308.htm.—Journal of Clinical Oncology. Published online September 22, 2008.

*Tai Chi May Help Heart Failure Patients Sleep Better*.—People with heart failure may benefit from practicing tai chi, according to researchers who analyzed sleep in 18 patients with chronic heart failure. All patients were on maximal medical therapy. The patients were assigned into one of two groups: a usual care group (the control) that received medication and diet/exercise counseling, or a tai chi group that received usual care plus 12 weeks of tai chi training. Compared with the usual care group, the tai chi group had significant improvements in sleep stability. The tai chi group also demonstrated significant quality-of-life improvements over the usual care group. The researchers concluded that a 12-week tai chi exercise program may help heart failure patients sleep better. They noted that it remains to be determined if

any single component of tai chi—meditation, relaxation, or physical activity—may be responsible for the observed benefit. They suggested further research to better understand the mechanisms of tai chi's effects on sleep should include more conventional sleep testing to document sleep stages and patterns of sleep disruption. http://nccam.nih.gov/research/results/spotlight/072508.htm.—Sleep Medicine. 2008;9(5):527–536.

*Tai Chi Chih Improves Sleep Quality in Older Adults*.—Researchers conducted a randomized controlled trial to determine whether tai chi chih could improve sleep quality in healthy, older adults with moderate sleep complaints. In the study, 112 individuals aged 59 to 86 participated in either tai chi chih training or health education classes for 25 weeks. Participants rated their sleep quality based on the Pittsburgh Sleep Quality Index, a self-rate questionnaire that assesses sleep quality, duration, and disturbances. The results of the study showed that the people who participated in tai chi chih sessions experienced slightly greater improvements in self-reported sleep quality. The researchers concluded that tai chi chih can be a useful nonpharmacologic approach to improving sleep quality in older adults with moderate sleep complaints, and may help to prevent the onset of insomnia. http://nccam.nih.gov/research/results/spotlight/031109.htm.—Sleep. 2008;31(7):1001–1008.

*Acupuncture Shows Promise in Improving Rates of Pregnancy Following IVF*.—A review of seven clinical trials of acupuncture given with embryo transfer in women undergoing in vitro fertilization (IVF) suggests that acupuncture may improve rates of pregnancy. An estimated 10 to 15 percent of couples experience reproductive difficulty and seek specialist fertility treatments, such as IVF. According to researchers who conducted the systematic review, acupuncture has been used in China for centuries to regulate the female reproductive system. With this in mind, the reviewers analyzed results from seven clinical trials of acupuncture in women who underwent IVF to see if rates of pregnancy were improved with acupuncture. The studies encompassed data on over 1,366 women and compared acupuncture, given within 1 day of embryo transfer, with sham acupuncture, or no additional treatment. The reviewers found that acupuncture given as a complement to IVF increased the odds of achieving pregnancy. According to the researchers, the results indicate that 10 women undergoing IVF would need to be treated with acupuncture to bring about one additional pregnancy. The results, considered preliminary, point to a potential complementary treatment that may improve the success of IVF and the need to conduct additional clinical trials to confirm these findings. http://nccam.nih.gov/research/results/spotlight/020808.htm.—British Medical Journal. Published online February 2008.

*Tai Chi May Help Maintain Bone Mineral Density in Postmenopausal Women*.—Tai chi may be a safe alternative to conventional exercise for maintaining bone mineral density (BMD) in postmenopausal women. Bone mineral density is one of the key indicators of bone strength and low BMD is associated with osteoporosis. Exercise is an important component of osteoporosis prevention and treatment. Researchers conducted a systematic review of research looking at the effect of tai chi, a mind-body practice that originated in China, on BMD. They found that tai chi may be an effective, safe, and practical intervention for maintaining BMD in postmenopausal women. The authors further note that the benefits of tai chi appeared similar to those of conventional exercise. However, tai chi may also improve balance, reduce fall frequency, and increase musculoskeletal strength. They note that the evidence is preliminary because the research they reviewed was of limited scope and quality, but enough evidence of effectiveness exists to warrant further research. http://nccam.nih.gov/research/results/spotlight/081407.htm. Archives of Physical Medicine and Rehabilitation, May 2007.

*Tai Chi Boosts Immunity to Shingles Virus in Older Adults*.—Tai chi, a traditional Chinese form of exercise, may help older adults avoid getting shingles by increasing immunity to varicella-zoster virus and boosting the immune response to varicella vaccine. The study is the first rigorous clinical trial to suggest that a behavioral intervention, alone or together with a vaccine, can help protect older adults from the varicella virus, which causes both chickenpox and shingles. The randomized, controlled trial included 112 healthy adults ages 59 to 86. Each person took part in a 16-week program of either tai chi or health education with 120 minutes of instruction weekly. After the tai chi and health education programs, with periodic blood tests to determine levels of varicella virus immunity, people in both groups received a single injection of the chickenpox vaccine, VARIVAX. Nine weeks later, the investigators assessed each participant's level of varicella immunity and compared it to immunity at the start of the study. Tai chi alone was found to increase participants' immunity to varicella, and tai chi combined with the vaccine produced a significantly higher level of immunity, about a 40 percent increase, over the vaccine alone. The study also showed that the tai chi group's rate of increase in immu-

nity over the course of the study was double that of the health education group. Finally, the tai chi group reported significant improvements in physical functioning, bodily pain, vitality and mental health. http://nccam.nih.gov/research/results/spotlight/040607.htm.—Journal of the American Geriatrics Society, April 2007.

*Study Compares Year-long Effectiveness of Four Weight-loss Plans*.—The very low carbohydrate diet known as the Atkins diet may contribute to greater weight loss than higher carbohydrate plans without negative effects such as increased cholesterol. The study consisted of 311 premenopausal women, all of whom were overweight or obese who were randomly assigned to 1 of 4 diets. Each of the diets used were selected for their different levels of carbohydrate consumption: the Atkins diet, the Zone diet, the LEARN diet and the Ornish diet. Participants in each group received books that accompanied their assigned diet plan, and attended hour-long classes with a registered dietitian once a week for the first 8 weeks. The researchers recorded body mass index (BMI); percent body fat; waist-hip ratio; as well as metabolic measures such as, insulin, cholesterol, glucose, triglyceride, and blood pressure levels. The Atkins diet group reported the most weight loss at 12 months with an average loss of just over 10 pounds. They also had more favorable overall metabolic effects. Average weight loss across all four groups ranged from 3.5 to 10.4 pounds. The authors note that "even modest reductions in excess weight have clinically significant effects on risk factors such as triglycerides and blood pressure." http://nccam.nih.gov/research/results/spotlight/030607.htm.—Journal of the American Medical Association. March 2007.

*Natural Products Interventions*

*Treatment or Enhancement of Treatment*

*New Approach for Peanut Allergy in Children Holds Promise*.—Currently, there are no treatments available for people with peanut allergy. A new treatment may be a safe and effective form of immunotherapy for those children. The double-blind, placebo-controlled study investigated the safety, clinical effectiveness, and immunologic changes with sublingual immunotherapy—a treatment that involves administering very small amounts of the allergen extract under a person's tongue. Though these findings are promising, more study is needed to determine whether sublingual immunotherapy can increase long-term tolerance to peanuts in children with peanut allergy. http://nccam.nih.gov/research/results/spotlight/022011.htm.—The Journal of Allergy and Clinical Immunology. 2011.

*Magnesium Supplements May Benefit People With Asthma*.—Some previous studies have reported associations between low magnesium consumption and the development of asthma. This study provides additional evidence that adults with mild-to-moderate asthma may benefit from taking magnesium supplements. Researchers found that participants who took magnesium experienced significant improvement in lung activity and the ability to move air in and out of their lungs. Those taking magnesium also reported other improvements in asthma control and quality of life compared with people who received placebo. The researchers noted that this study adds to the body of research that shows subjective and objective benefits of magnesium supplements in people with mild-to-moderate asthma. http://nccam.nih.gov/research/results/spotlight/021110.htm.—Journal of Asthma. 2010;47(1):83–92.

*Study Shows Chamomile Capsules Ease Anxiety Symptoms*.—Researchers conducted a randomized, double-blind, placebo-controlled trial to test the effects of chamomile extract in patients diagnosed with mild to moderate generalized anxiety disorder (GAD). Researchers used the Hamilton Anxiety Rating (HAM–A) and other tests to measure changes in anxiety symptoms over the course of the study; dosage adjustments were based on HAM–A scores. Compared with placebo, chamomile was associated with a greater reduction in mean HAM–A scores—the study's primary outcome measure. The difference was clinically meaningful and statistically significant. Chamomile also compared favorably with placebo on other outcome measures (although the differences were not statistically significant), and was well tolerated by participants. These results suggest that chamomile may have modest benefits for some people with mild to moderate GAD. As this was the first controlled trial of chamomile extract for anxiety, the researchers note that additional studies using larger samples and studying effects for longer periods of time would be helpful. They also point out that other chamomile species, preparations (e.g., extracts standardized to constituents other than apigenin), and formulations (e.g., oil or tea) might produce different results. http://nccam.nih.gov/research/results/spotlight/040310.htm.—Journal of Clinical Psychopharmacology. 2009 Aug;29(4):378–382.

*Study Indicates Cranberry Juice Does Not Interfere With Two Antibiotics Women Take for Recurrent Urinary Tract Infections*.—Cranberry juice, a popular home remedy for urinary tract infections (UT), is often taken along with low-dose antibiotics as a preventive measure. Because little is known about the potential of cranberry

juice to interact with drugs, researchers studied cranberry's effects on two antibiotics frequently prescribed for UTI: amoxicillin and cefaclor. The data showed that cranberry juice did not significantly affect either antibiotic's oral absorption or renal clearance (i.e., how completely the body processed the drugs in the intestine and kidneys). Absorption took somewhat longer with cranberry juice, but the delay was small, and the total amount of antibiotic absorbed was not affected. Based on these results, the researchers concluded that cranberry juice cocktail, consumed in usual quantities, is unlikely to change the effects of these two antibiotics on UTIs. They noted that the same may or may not be true of other antibiotics, or when people who take antibiotics also drink a large quantity of concentrated cranberry juice. http://nccam.nih.gov/research/results/spotlight/081009.htm.—Antimicrobial Agents and Chemotherapy. 2009 Jul;53(7):2725–32.

*Traditional Chinese Herbs May Benefit People With Asthma*.—Scientists reviewed research evidence on traditional Chinese medicine (TCM) herbs for asthma, focusing on studies reported since 2005. They determined that preliminary clinical trials of formulas containing Radix glycyrrhizae in combination with various other TCM herbs have had positive results. Laboratory findings on TCM herbal remedies suggest several possible mechanisms of action against asthma, including an anti-inflammatory effect, inhibition of smooth-muscle contraction in the airway, and modulation of immune system responses. http://nccam.nih.gov/research/results/spotlight/061609.htm.—Journal of Allergy and Clinical Immunology. 2009;123(2):297–306.

*A Review of St. John's Wort Extracts for Major Depression*.—Researchers reviewed the scientific literature on St. John's wort for major depression and analyzed findings from randomized, double-blind studies comparing St. John's wort extracts with placebo and standard antidepressants. The researchers reviewed a total of 29 studies in 5,489 people. The studies came from a variety of countries, tested several different St. John's wort extracts, and mainly included people with minor to moderately severe symptoms of depression. According to this literature review, St. John's wort extracts appeared to be superior to placebo, were as effective as standard antidepressants, and had fewer side effects than antidepressants. However, the findings from studies in German-speaking countries were disproportionately favorable, possibly because some subjects had slightly different types of depression, or because some of the small studies were flawed and overly optimistic in reporting their results. The authors noted the need to investigate the reasons for the differences between study findings from German-speaking countries and those from other countries. http://nccam.nih.gov/research/results/spotlight/120908.htm.—Cochrane Database of Systematic Reviews. 2008 8;(4):CD000448.

*Study Suggests Vitamin E May Help People With Asthma*.—A form of vitamin E (gamma-tocopherol) commonly found in foods may be a useful additional treatment for asthma, according to preliminary research. Researchers investigated the biological activity of a gamma-tocopherol supplement in asthma patients. The researchers gave a daily dose of a vitamin E preparation rich in gamma-tocopherol to 16 volunteers. Eight healthy volunteers and eight volunteers with allergic asthma received one supplement daily during the first week, followed by a week with no treatment, and then two supplements daily for another week. They found similar results for both doses—the vitamin E supplements prevented inflammation and decreased oxidative stress without any adverse health effects. This research was an initial step in extending previous findings of gamma-tocopherol's anti-inflammatory effects in animals. Further research on vitamin E in patients with asthma is under way. http://nccam.nih.gov/research/results/spotlight/070208.htm.—Free Radical Biology & Medicine. 2008;45(1):40–49.

*Omega-3 Fatty Acids May Be Helpful in Psychiatric Care*.—Omega-3 fatty acids may hold promise for use in psychiatry, particularly for depression and bipolar disorder. Researchers conducted a meta-analysis of research looking at omega-3 fatty acid supplements as treatments for psychiatric conditions, such as depression, bipolar disorder, schizophrenia, dementia, and attention-deficit hyperactivity disorder. Omega-3 fatty acids are essential nutrients that the body cannot make on its own, so they must come from food sources. The richest source of these fatty acids is fish and seafood, but they can also be found in flaxseeds and some eggs. The authors suggest that omega-3 supplements may be helpful for people with depression or bipolar disorder as a complement to standard care. However, they were unable to determine benefits for other conditions such as schizophrenia and dementia. They also "strongly recommend that patients with psychiatric disorders should not elect supplementation with omega-3 fatty acids in lieu of established psychiatric treatment options." They further recommend studies to look at how the nutrient may work, and large trials to conclusively determine the utility of omega-3 fatty acids in psychiatric care. http://nccam.nih.gov/research/results/spotlight/121506.htm.—Journal of Clinical Psychiatry, December 2006.

*Polyunsaturated Fatty Acids for Depression*.—Omega-6 and omega-3 fatty acids (also called PUFAs, short for polyunsaturated fatty acids) are among the CAM therapies used with the intent to help symptoms of depression. A team reviewing the evidence found five randomized controlled trials to be of sufficient quality for review, although all were small and of short duration. All but one of these trials found some improvement from using PUFAs for symptoms of depression, particularly from omega-3 fatty acids. The authors concluded that while the evidence to support using PUFA supplements as a treatment for depression is not strong, enough potential exists to merit further research. http://nccam.nih.gov/research/results/spotlight/050106.htm.—Journal of Affective Disorders, May 2006.

*Disease Prevention*

*Ginkgo Does Not Shield Seniors' Hearts, But It May Protect Their Leg Arteries*.—While findings from the Ginkgo Evaluation of Memory (GEM) study show that the herbal supplement Ginkgo biloba did not prevent heart attack, stroke, or death in a group of older adults, the herb may reduce the risk of developing peripheral arterial disease (also known as peripheral vascular disease), a painful and potentially life-threatening condition affecting blood circulation in the legs, arms, stomach, and kidneys. Of the 35 cases of peripheral arterial disease observed in the study, 23 patients received placebo and 12 patients received ginkgo, a difference that was statistically significant. The researchers reported that this finding was consistent with European studies that reported improvements in patients with peripheral arterial disease who received ginkgo versus placebo. But, due to the small number of patients in whom this was seen, the researchers suggest larger trials to evaluate the herb before they would recommend it as a treatment for peripheral arterial disease. This study was a planned secondary outcome of the GEM study. http://nccam.nih.gov/research/results/spotlight/052110.htm.—Circulation: Cardiovascular Quality and Outcomes. 2010;3(1):41–47.

*Chinese Herbal Medicine May Benefit People With Pre-Diabetes*.—In China and other Asian countries, Chinese herbal medicines have long been used to prevent or delay the onset of diabetes, and there is anecdotal evidence regarding efficacy for this purpose. A recent review, funded in part by the NCCAM, examined related clinical trials to see whether scientific evidence supports recommending Chinese herbal medicine as a treatment option for people with pre-diabetes. The review looked at 16 clinical trials involving 1,391 participants with pre-diabetes, 15 different herbal formulations, and various comparisons (i.e., lifestyle modification, drug interventions, placebo). Analysis of data from eight trials that included lifestyle modification as a comparison found that lifestyle modification combined with Chinese herbs was twice as effective as lifestyle modification alone in normalizing blood sugar levels. Participants who received herbal formulations were also less likely to develop full-blown diabetes during the study period. Due to limitations among the studies reviewed, the reviewers concluded that while their findings are promising, further, well-designed trials are needed to clarify the potential role of Chinese herbal medicines in glucose control and diabetes prevention. http://nccam.nih.gov/research/results/spotlight/110309.htm.—Cochrane Database of Systematic Reviews. 2009(4):CD00066690.

*Red Yeast Rice May Help Patients With High Cholesterol Who Cannot Take Statin Drugs*.—In light of previous findings that red yeast rice can reduce levels of low-density lipoprotein (LDL, or "bad" cholesterol), researchers investigated the effects of this supplement in patients with high cholesterol and a history of statin-associated myalgia (SAM). Compared with placebo, red yeast rice significantly decreased blood levels of LDL and total cholesterol over a 24-week period, without increasing the incidence of myalgia. Red yeast rice did not significantly affect levels of high-density lipoprotein (HDL, or "good" cholesterol), triglycerides, weight loss, or pain severity. This was the first randomized, double-blind, placebo-controlled trial to evaluate red yeast rice in patients who cannot take statin drugs because of muscle pain. The results suggest that red yeast rice may be a cholesterol-lowering alternative for these patients, but additional, larger studies are needed to establish long-term safety and efficacy. The researchers also suggest studies to compare red yeast rice directly with statins and to explore the role of lifestyle change therapy. http://nccam.nih.gov/research/results/spotlight/071709.htm.—Annals of Internal Medicine. 2009;150(12):830–839.

*Flaxseed Reduces Some Risk Factors of Cardiovascular Disease*.—Flaxseed is rich in alpha linolenic acid (ALA), a plant-based omega-3 fatty acid, as well as fiber and lignans (phytoestrogens), making it a possible functional food for reducing cardiovascular risk factors. A double blind, randomized, controlled clinical trial by researchers explored the effects of flaxseed on various cardiovascular risk factors in adults. Researchers found that flaxseed positively affected lipoprotein A and insulin

sensitivity. They also found a modest but short-lived lowering effect in participants' LDL ("bad") cholesterol levels. However, the researchers also noted that flaxseed significantly lowers HDL ("good") cholesterol levels in men, although not in women. There were no changes noted in markers of inflammation or oxidative stress. The authors suggest that additional investigation of the HDL lowering effect among men may be warranted. http://nccam.nih.gov/research/results/spotlight/062308.htm.—Nutrition, 2008.

*Basic and Translational Research*

Basic and translational research provides important insights into how CAM interventions can benefit human health. For example, animal studies help to identify biomarkers or signatures of biological effects that can be applied to future studies in humans.

*Laboratory Study Suggests Potential Anti-cancer Benefit of White Tea Extract*.—White tea extract increased a specific type of cell death in laboratory cultures of two different types of nonsmall cell lung cancer cells, indicating that the tea may have an anti-cancer effect. Although white tea comes from the same plant as green and black teas (Camellia sinensis), white tea goes through much less processing, resulting in a higher concentration of polyphenols. This study, for the first time, showed the roles of the PPAR-gamma and 15-LOX signaling pathways in white tea-induced apoptosis. (A reduction in PPAR-gamma in a tumor is linked to poor prognosis in patients with lung cancer.) The researchers also compared green tea extract with white tea extract and found that white tea extract was significantly more effective in increasing certain RNA transcripts (e.g., PPAR-gamma) that play a critical role in cell death. They noted, however, that the components in white tea extract that may be responsible for this outcome are not yet known. They noted that the findings from this preliminary study provide an important basis for more investigation of the anti-cancer properties of white tea extract and whether it may help prevent the development of lung cancer. http://nccam.nih.gov/research/results/spotlight/092110.htm.—Cancer Prevention Research. 2010;3(9):1132–1140.

*Laboratory Study Shows Turmeric May Have Bone-Protective Effects*.—Turmeric—an herb commonly used in curry powders, mustards, and cheeses—may protect bones against osteoporosis. This study, which used an animal (rat) model of postmenopausal osteoporosis, builds on previous laboratory research examining turmeric's anti-arthritic properties. Funded in part by the NCCAM, the study tested two turmeric extracts containing different amounts of curcuminoids—(components of the herb) in female rats whose ovaries had been surgically removed (ovariectomy—a procedure that causes changes associated with menopause, including bone loss). Tests showed that while nonenriched turmeric extract did not have bone-protective effects, curcuminoid-enriched turmeric extract prevented up to 50 percent of bone loss, and also preserved bone structure and connectivity. Other physiological changes associated with ovariectomy (weight gain and shrinking of the uterus) were unaffected—an indication that the bone-protective effects did not involve an estrogen-based chemical pathway. The researchers concluded that turmeric may protect bones, but that the effect depends on the amount of curcuminoids present. However, they emphasized that clinical research is needed to evaluate the use of turmeric-derived curcuminoid products to guard against osteoporosis in humans. http://nccam.nih.gov/research/results/spotlight/093010.htm.—Journal of Agricultural and Food Chemistry. 2010;58(17):9498–9504.

*Effects of Milk Thistle Extract on the Hepatitis C Virus Lifecycle*.—A laboratory study suggests that silymarin—an extract from the milk thistle plant—has multiple effects against the lifecycle of the hepatitis C virus. Hepatitis C is a chronic (long lasting) disease that primarily affects the liver and is often difficult to cure. This study examined the antiviral properties and mechanisms of silymarin on cultured (grown in a lab) human liver cells infected with the virus. By analyzing the interactions between silymarin and the virus, the researchers observed that silymarin prevented the entry and fusion of the hepatitis C virus into the target liver cells. They also found that silymarin inhibited the ability of the virus to produce RNA (a chemical that plays an important role in protein synthesis and other chemical activities of the cell), interfering with a portion of the virus's lifecycle. These findings build on previous research of silymarin's antiviral and anti-inflammatory properties and provide more information about the potential mechanisms involved in silymarin's antiviral actions. Further research, particularly in clinical trials, is needed to determine if silymarin could be a safe and effective supplement for treating hepatitis C in humans. http://nccam.nih.gov/research/results/spotlight/061610.htm.—Hepatology. 2010;51(6):1912–1921.

*Fish Oil Enhances Effects of Green Tea on Alzheimer's Disease in Mice*.—Fish oil, when combined with epigallocatechin-3-gallate (EGCG—a polyphenol and anti-

oxidant found in green tea), may affect chemical processes in the brain associated with Alzheimer's disease. This study, which used an animal (mouse) model of Alzheimer's disease, builds on previous research linking the disease to peptides (amino acid chains) called beta-amyloids and laboratory studies suggesting that EGCG decreases memory problems and beta-amyloid deposits in mice. Researchers found that the mice fed the combination of fish oil and EGCG had a significant reduction in amyloid deposits that have been linked with Alzheimer's disease. Upon examination of blood and brain tissues of the mice, the researchers found high levels of EGCG in the mice that were fed the combination of fish oil and low-dose EGCG compared with those fed low-dose EGCG alone. A possible explanation, according to the researchers, is that fish oil enhances the bioavailability of EGCG—that is, the degree to which EGCG was absorbed into the body and made available to the brain. This effect, in turn, may contribute to the increased effectiveness of this combination. Further research is necessary, however, to determine if the combination of fish oil and EGCG affects memory or cognition, and whether it might have potential as an option for people at risk of developing Alzheimer's disease. http://nccam.nih.gov/research/results/spotlight/031610.htm.—Neuroscience Letters. 2010;471(3):134–138.

*Laboratory Study Suggests Potential Anti-Cancer Benefit of Ginseng*.—American ginseng (Panax quinquefolius) extract caused laboratory cultures of colorectal cancer cells to die, indicating that the herb may have an anti-cancer effect. Although results from the study suggest that combining ginseng with antioxidants such as vitamin C may potentially enhance this effect, there is no evidence yet that this laboratory research can be extended to treatments in people. Researchers treated two types of colorectal cancer cells with steamed American ginseng root extract. This caused damage to the cells' mitochondria, the internal structures that are involved with energy production, and led to apoptosis (cell death). It also increased levels of reactive oxygen species (ROS)—a byproduct of the processes in which cells use and break down oxygen (increased levels of ROS can either bring on cell death or activate the survival pathways that protect against it). Whether ROS acts to induce cell death or survival in response to ginseng depends on the specific biochemical pathways that are activated, and how this happens remains unknown. Further studies are needed. The researchers also noted the need for additional investigations to test whether combining ginseng and antioxidants might help prevent the development of colorectal cancers. http://nccam.nih.gov/research/results/spotlight/032510.htm.—Cancer Letters. 2010;289(1):62–70.

*Mouse Study Shows Green Tea Polyphenols May Repair DNA Damage Caused by Ultraviolet (UV) Radiation*.—Antioxidants found in green tea may help repair DNA damage caused by sun exposure, according to a recent study in mice. Exposure to UV radiation can damage DNA and, in turn, trigger suppression of the immune system—a risk factor for developing skin cancer. The study, funded in part by the NCCAM, examined the effects of polyphenols from the leaves of the green tea plant, which are thought to fight free radicals (highly unstable molecules that can damage cells) and have anticarcinogenic activity. Compared with the control group, the mice treated with green tea polyphenols had reduced immunosuppression from the UV radiation. This same group of mice also showed more rapid repair of DNA damaged by UV radiation. Further, the study showed that green tea polyphenols increased the levels of some nucleotide excision repair genes, which allow for DNA repair. The researchers noted that this study is the first to show that preventing skin cancer with green tea polyphenols in water may be due to the blocking of UV-induced immunosuppression in mice. More studies are needed to determine if green tea has any potential chemopreventive effect on skin cancer in people. http://nccam.nih.gov/research/results/spotlight/022110.htm.—Cancer Prevention Research. 2010;3(2):179–189.

*Cinnamon Bark and Ginseng in Herbal Formulas Increase Life Span of Roundworms*.—Researchers used a roundworm that has some genetic and biochemical similarities to humans to examine complex herbal preparations thought to combat adverse effects of aging. The worms, called Caenorhabditis elegans, or C. elegans, have a brief life span (about 20 days). The researchers assessed two traditional Chinese multiherbal formulas—Huo Luo Xiao Ling Dan (HLXL), taken for chronic inflammatory pain (e.g., joint pain from arthritis); and Shi Quan Da Bu Tang (SQDB), taken to reduce fatigue and improve general wellness. They found that cinnamon bark, a component of both formulas, increased the worms' life span. Of all the individual components tested, two significantly prolonged life span: Cinnamomum cassia bark (present in both formulas) and Panax ginseng root (present in SQDB only). In light of these findings, the researchers concluded that C. elegans is a valid model for evaluating complex herbal preparations and may provide insight for future studies on longevity-promoting herbs. http://nccam.nih.gov/research/results/spotlight/052510.htm.—PLoS ONE [online journal]. 2010;5(2):9339.

*Laboratory Study Explores Anti-HIV Potential of Palmitic Acid*.—In a laboratory study, a fatty acid from seaweed reduced the ability of HIV-1 viruses to enter immune system cells. Researchers evaluated palmitic acid (from Sargassum fusiforme, a type of seaweed that grows off the coasts of Japan and China) to see if palmitic acid reduced the ability of HIV-1 viruses to enter CD4+ T-cells (white blood cells that are HIV-1's main target). Palmitic acid blocked both X4-tropic and R5-tropic viruses, the HIV viruses that use a particular receptor (X4 or R5) to enter a cell. In addition, the study's findings showed that palmitic acid protected other cells against HIV-1, reducing X4 infection in primary peripheral blood lymphocytes and R5 infection in primary macrophages (white blood cells). In all cases, the extent of the blocking effect depended on the concentration of palmitic acid, and most cells remained viable (alive) after treatment. The researchers noted that understanding the relationship between palmitic acid and CD4 may lead to development of an effective microbicide product for preventing sexual transmission of HIV. http://nccam.nih.gov/research/results/spotlight/121409.htm.—AIDS Research and Human Retroviruses. 2009;25(12):1231–1241.

*Study Uses Rat Liver Cells To Explore Cholesterol-Lowering Mechanisms of Tea*.—There is evidence that tea consumption can reduce the risk of cardiovascular disease, apparently by lowering cholesterol levels in the blood. Researchers examined extracts from both green tea and black tea, as well as some components of green tea, for their effects on the synthesis of cholesterol in liver cells from rats. The study's finding that black tea was more effective than green tea in decreasing cholesterol synthesis in rat liver cells was unexpected, as was the finding that EGCG alone was less effective than whole green tea. Additional research may reveal more about the cholesterol-lowering mechanisms of both kinds of tea. http://nccam.nih.gov/research/results/spotlight/040510.htm.—Journal of Nutritional Biochemistry. 2009 Oct;20(10):816–822.

*Evidence in Mice May Spur More Research on Fish Oil and Curcumin for Alzheimer's Disease*.—A popular dietary supplement and a curry spice may affect Alzheimer's disease—related chemical processes in the brain, according to research findings. This study, which used an animal (mouse) model of Alzheimer's disease, builds on previous research linking the disease to peptides (amino acid chains) called β-amyloids and to defective insulin-processing by the brain. A particular β-amyloid, Aβ–42, is associated with Alzheimer's disease. Funded in part by the NCCAM, the study looked at two dietary supplements: fish oil rich in the omega-3 fatty acid docosahexaenoic acid (DHA); and curcumin, a component of turmeric. Researchers fed the Alzheimer's disease—model mice a regular or fatty diet; some of the mice also received fish oil and/or curcumin. They found that the high-fat diet increased Alzheimer's disease—related chemical processes in the brain, and that fish oil and curcumin, alone or in combination, counteracted this effect. DHA and curcumin also protected cognitive performance for mice on the high-fat diet—i.e., how well the mice remembered a maze. http://nccam.nih.gov/research/results/spotlight/070109.htm.—Journal of Neuroscience. 2009;29(28):9078–9089.

*Animal Study Shows Connection Between Vitamin E, Lung Inflammation, and Asthma*.—Citing study results in mice, researchers reported for the first time that the form of vitamin E found primarily in food (gamma-tocopherol) increased lung inflammation in induced asthma, while the form of vitamin E found primarily in dietary supplements (alpha-tocopherol) reduced inflammation. The researchers found that compared with placebo, alpha-tocopherol significantly reduced inflammation while gamma-tocopherol significantly increased inflammation. The researchers also found that the mechanism by which both forms of vitamin E work involves the regulation of endothelial cell signals during leukocyte (white blood cell) recruitment—a process that occurs during inflammation. Endothelial cells line the inner walls of blood vessels. The researchers concluded that the opposing activities of the two common forms of vitamin E on inflammation found in this study are consistent with the contradictory outcomes of vitamin E on asthma in previous clinical trials. They also noted that the information gained from this study could have a significant impact on designing and interpreting future clinical studies on vitamin E. http://nccam.nih.gov/research/results/spotlight/041109.htm.—The Journal of Immunology. 2009;182(7):4395–4405.

*Researchers Investigate Anti-inflammatory Effects of Pineapple Extract*.—Previous research indicates that bromelain—an enzyme extracted from pineapple stems—may help inflammatory conditions such as allergic airway disease. Bromelain's anti-inflammatory effects have been attributed to its ability to alter the activation and expansion of the immune system's CD4+ T cells (a type of lymphocyte). To better understand the processes involved, the NCCAM-funded researchers conducted in vitro experiments with mouse cells, using bromelain derived from a commercially available, quality-tested product. The results show that bromelain reduces CD25 (a

protein involved in inflammation) expression via proteolytic (enzymatic) action, in a dose- and time-dependent manner. The researchers' analysis of the mechanism involved found that bromelain apparently splits CD25 from the CD4+ T cells, and that the T cells remain functional—i.e., they can still divide—after bromelain treatment. The researchers concluded that the novel mechanism of action demonstrated in their experiment explains how bromelain may exert its therapeutic benefits in inflammatory conditions. http://nccam.nih.gov/research/results/spotlight/080309.htm.—International Immunopharmacology. 2009;9(3):340–346.

*Grape Seed Extract May Help Neurodegenerative Diseases*.—In light of previous studies indicating that grape-derived polyphenols may inhibit protein misfolding, researchers examined the potential role of a particular grape seed polyphenol extract (GSPE) in preventing and treating tau-associated neurodegenerative disorders. The results of their in vitro study showed that GSPE is capable of interfering with the generation of tau protein aggregates and also disassociating preformed aggregates, suggesting that GSPE may affect processes critical to the onset and progression of neurodegeneration and cognitive dysfunctions in tauopathies. The researchers concluded that their laboratory findings, together with indications that this GSPE is likely to be safe and well-tolerated in people, support its development and testing as a therapy for Alzheimer's disease. http://nccam.nih.gov/research/results/spotlight/031209.htm.—Journal of Alzheimer's Disease. 2009;16(2):433–439.

*Chinese Herbal Formula Shows Anti-Arthritis Effects in Animal Study*.—Researchers analyzed the effects of a modified version of the classic Chinese formula Huo Luo Xiao Ling Dan (HLXL) in an animal (rat) model of adjuvant arthritis, which shares some features with human rheumatoid arthritis. The researchers induced adjuvant arthritis in male rats by injecting them with a complete Freund's adjuvant solution containing heat-killed Mycobacterium tuberculosis. On days 16 to 25, the rats were given a daily oral dose of either a quality controlled, 11-herb HLXL preparation or liquid only. Compared with controls, the HLXL-treated rats had significantly decreased arthritis symptom scores; reduced paw edema; and lower TNF-$\alpha$ and IL-1$\beta$ levels. No adverse effects were observed. Based on their results, the researchers concluded that this HLXL formula may have benefits for treating arthritis and related inflammatory disorders. http://nccam.nih.gov/research/results/spotlight/071609.htm.—Journal of Ethnopharmacology. 2009;121(3):366–371.

*Echium Oil Reduces Triglyceride Levels in Mice*.—In light of previous research indicating that oil from the seeds of the Echium plantagineum plant can lower triglycerides in people, researchers used an animal model—mice with mildly elevated triglyceride levels—to investigate how echium oil achieves this effect. The researchers fed the mice diets supplemented with either echium oil, fish oil, or (as a control) palm oil. They found that both echium and fish oils had the following effects: reduced triglycerides in blood plasma and the liver; enriched EPA in plasma and the liver—echium less so than fish oil; and "down-regulated" (decreased the expression of) several genes involved in synthesis of triglycerides in the liver. The researchers concluded that echium oil may provide a botanical alternative to fish oil for reducing triglycerides. http://nccam.nih.gov/research/results/spotlight/022509.htm.—Journal of Nutritional Biochemistry. 2008;19(10):655–663.

*Laboratory Study Shows Black Cohosh Promotes Bone Formation in Mouse Cells*.—Results of laboratory research are the first to indicate that extracts of the herb black cohosh (Actaea racemosa) may stimulate bone formation. Researchers added an extract of black cohosh to a culture of bone-forming mouse cells. The researchers observed that a high dose (1,000 ng/mL) of the extract suppressed the production of these bone-forming cells, yet a lower dose (500 ng/mL) significantly increased the formation of bone nodules. When the cells were treated with a protein whose molecules attach to estrogen receptors in place of estrogen, this effect on bone nodule formation disappeared. Thus, the researchers suggest that ingredients within black cohosh contain a component that acts through estrogen receptors. The researchers concluded that their results provide a scientific explanation at the molecular level for claims that black cohosh may protect against postmenopausal osteoporosis. They also noted that studying extraction methods and identifying black cohosh's active components may make it possible to develop new ways to prevent and treat this condition. Although results from the study suggest that black cohosh may have potential implications for the prevention or treatment of postmenopausal bone loss, there is no evidence yet that this laboratory research can be extended to treatments in people. http://nccam.nih.gov/research/results/spotlight/090408.htm.—Bone. 2008;43(3):567–573.

*Pomegranate Extract May Be Helpful for Rheumatoid Arthritis (RA)*.—RA is an autoimmune disease characterized by joint pain, stiffness, inflammation, swelling, and sometimes joint destruction. The pomegranate has been used for centuries to treat inflammatory diseases, and people with RA sometimes take dietary supple-

ments containing a pomegranate extract called POMx. However, little is known about the efficacy of POMx in suppressing joint problems associated with RA. Researchers used an animal model of RA—collagen-induced arthritis (CIA) in mice—to evaluate the effects of POMx. They found that POMx significantly reduced the incidence and severity of CIA in the mice. The arthritic joints of the POMx-fed mice had less inflammation, and destruction of bone and cartilage were alleviated. Consumption of POMx, the researchers also concluded, selectively inhibited signal transduction pathways and cytokines critical to development and maintenance of inflammation in RA. Although previous studies of POMx found cartilage-protective effects in human cell cultures, this is the first study to observe positive effects in a live model. The researchers note that the data from this study suggest the potential efficacy of POMx for arthritis prevention, but not for treatment in the presence of active inflammation; future studies will address disease-modifying effects of POMx. They also note that clinical trials are needed before POMx can be recommended as safe and effective for RA-related use in people. http://nccam.nih.gov/research/results/spotlight/120508.htm.—Nutrition. 2008;24(7—8):733–743.

*Two Studies Explore the Potential Health Benefits of Probiotics*.—In two studies, researchers investigated how probiotics may have a role in treating gastrointestinal illnesses, boosting immunity, and preventing or slowing the development of certain types of cancer. In one study, researchers investigated how Lactobacillus reuteri ATCC PTA 6475 might work to slow the growth of certain cancerous tumors. Their study documented the molecular mechanisms of the probiotic's effects in human myeloid leukemia-derived cells—i.e., how it regulates the proliferation of cancer cells and promotes cancer cell death. The researchers noted that a better understanding of these effects may lead to development of probiotic-based regimens for preventing colorectal cancer and inflammatory bowel disease. In another study, researchers looked at whether Lactobacillus acidophilus might enhance the immune-potentiating effects of an attenuated vaccine (a vaccine prepared from a weakened live virus) against human rotavirus infection—the most common cause of severe dehydrating diarrhea in infants and children worldwide. The investigators' tests on newborn pigs found that animals given both a vaccine and the probiotic had a better immune response than the animals given the vaccine alone. The researchers concluded that probiotics may offer a safe way to increase the effectiveness of rotavirus vaccine in humans. In both studies, the investigators called for additional research into the mechanisms behind the health-related effects of probiotics. http://nccam.nih.gov/research/results/spotlight/110508.htm.—Cellular Microbiology. 2008;10(7):1442–1452.—Vaccine. 2008;26(29—30):3655–3661.

*Research Shows Promise of Pineapple Extract for Inflammatory Bowel Disease (IBD)*.—IBD, including Crohn's Disease (CD) and ulcerative colitis (UC), are characterized by inflammation of the gastrointestinal tract. Researchers have found that bromelain—an enzyme derived from pineapple stems—might be able to reduce inflammation in IBD. Researchers recruited patients with a confirmed diagnosis of CD or UC as well as a normal, non-IBD control group. In total, this pilot study recruited 51 participants: 8 controls, 20 with UC, and 23 with CD. To assess the effect of a bromelain preparation on the production of cytokines, colon biopsies obtained from patients with UC, CD, and normal controls were treated in the lab (in vitro) with bromelain. The researchers report that bromelain reduced production of several proinflammatory cytokines and chemokines that are elevated in IBD and play a role in the progression of IBD. The authors conclude that bromelain treatment could potentially benefit IBD patients if similar changes also occur when colon tissues are exposed to bromelain inside the body. The researchers also suggest that additional research is needed to understand how bromelain influences chemokine and cytokine production. http://nccam.nih.gov/research/results/spotlight/070108.htm.—Clinical Immunology (2008) 126, 345–352.

*Grape Seed Extract May Help Prevent and Treat Alzheimer's*.—Emerging research shows a correlation between red wine consumption and reduced risk of Alzheimer's disease-type cognitive decline. Researchers found that grape seed-derived polyphenolics—similar to that in red wine—significantly reduced Alzheimer's disease-type cognitive deterioration in mice. Researchers conducted experiments in mice with Alzheimer's disease to see if a highly purified polyphenolic extract from Vitis vinifera (cabernet sauvignon) grape seeds, could affect Alzheimer's disease-type cognitive deterioration. The mice received 5 months of either water containing grape seed extract or water alone as a placebo treatment. The mice were then given behavioral maze tests to determine cognitive function and brain tissue samples were tested to determine evidence of disease. The researchers found that mice treated with grape seed extract had significantly reduced Alzheimer's disease-type cognitive deterioration compared to the control mice. This is due to the prevention of a molecule called amyloid forming in the brain that has been shown to cause Alzheimer's

disease-type cognitive impairment. http://nccam.nih.gov/research/results/spotlight/062408.htm.—The Journal of Neuroscience. 2008. 28(25);6388–6392.

*Chinese Herbal Formula May Be Helpful for Peanut Allergies*.—A study in mice shows that a Chinese herbal formula may help prevent dangerous reactions to peanuts. Peanut allergies affect as many as 6 percent of young children and are a major cause of anaphylaxis—a severe allergic reaction with respiratory symptoms that can be fatal. Researchers conducted experiments in mice with established peanut allergies to see if a formula of nine Chinese herbs, called FAHF–2, could reduce sensitivity to peanuts. The peanut-sensitive mice received 7 weeks of oral treatment with FAHF–2 or water as a placebo treatment. The mice were then exposed to peanuts at 2 different times to see if they would have anaphylactic reactions. The researchers found that FAHF–2 completely protected the mice from a dangerous reaction on both occasions—showing that protection lasted at least 4 weeks after the treatment finished. The mice treated with the placebo (water) had anaphylactic reactions. The researchers note that the protection of FAHF–2 may result from a shift in the immune balance away from the allergic response. http://nccam.nih.gov/research/results/spotlight/012908.htm.—Clinical and Experimental Allergy, June 2007.

*Turmeric and Rheumatoid Arthritis Symptoms*.—More than 2 million Americans suffer from rheumatoid arthritis (RA), a condition in which the body's immune system attacks the joints, causing pain, swelling, stiffness, and loss of function. The herb turmeric has been used for centuries in Ayurvedic medicine (a whole medical system that originated in India) as a treatment for inflammatory disorders, including RA. To study the effects of turmeric, researchers created symptoms in rats that mimic those of RA in humans. In a series of experiments, they treated the rats with different preparations and dosages of turmeric extracts. The results, measured in terms of joint swelling, suggested that an extract containing only curcuminoids (a family of chemicals that is the major component of turmeric) may be more effective for preventing RA symptoms than a more complex extract containing curcuminoids plus other turmeric compounds. They also noted that the curcuminoids-only formulas appeared safer and more effective at lower doses. Also, the researchers found that the compounds had greater effectiveness when the rats were treated before instead of after the onset of inflammation. The authors identified a need for well-designed preclinical and clinical studies to look further into turmeric for anti-inflammatory use. http://nccam.nih.gov/research/results/spotlight/030106.htm.—Journal of Natural Products, March 2006.

*Other Research*

*Botanicals May Help Conditions Associated With Aging*.—To evaluate the effectiveness of botanicals in relation to conditions such as high blood pressure, cardiovascular disease, cognitive decline, insulin resistance, and excess fats in the blood, researchers conducted a literature review and examined studies from their own laboratory. The researchers looked at effects of dietary soy; soy isoflavones (daidzein and genistein); grape seed extract, which has a high concentration of polyphenols; and puerarin, an isoflavone found in kudzu. The literature review found that soy seemed to lower blood pressure in men and postmenopausal women, help protect against cardiovascular diseases (including heart disease and atherosclerosis), and benefit people with diabetes. The researchers' own animal studies found that soy isoflavones protected against salt-sensitive hypertension in male rats and in female rats whose ovaries had been removed (OVX); grape seed extract reduced blood pressure and improved cognitive functioning in OVX female rats; and puerarin improved glucose control in male mice. The researchers concluded that the botanical compounds reviewed appear to have beneficial effects in animal models of disease (soy also has shown benefits in humans), and that the compounds may be more effective in relation to cardiovascular, metabolic, and cognitive function than for menopausal symptoms. They recommended that the compounds' safety and mechanisms of action should be carefully tested in the context of the disease status of potential users. http://nccam.nih.gov/research/results/spotlight/121008.htm.—Gender Medicine. 2008; 5(suppl A):76S–90S.

*Botanical Research Centers Featured in American Journal of Clinical Nutrition*.—The February 2008 issue of the American Journal of Clinical Nutrition features eight articles from the NIH Botanical Research Centers Program, which is co-funded by the NIH Office of Dietary Supplements and the NCCAM. The articles highlight different areas related to the Centers' research into botanical use, safety, and efficacy. They include evaluation of botanicals for improving health; technologies and experimental approaches to evaluating botanicals; botanicals and metabolic syndrome; echinacea in infection; botanicals for age-related diseases; ways in which botanical lipids affect inflammatory disorders; botanicals to improve women's health; and ensuring botanical dietary supplement safety. The Botanical Centers are in-

tended to advance research activities in plant identification, as well as preclinical research and early phase clinical studies. Each Center has a broad interdisciplinary research program that focuses on collaborative activities. Each of the Centers was created with a high potential for translating findings into public health benefits. http://nccam.nih.gov/research/results/spotlight/042308.htm.—American Journal of Clinical Nutrition, 2008. Volume 87, Number 2, 463.

*Population-based Research*

*Cancer Survivors Are More Likely Than General Population To Use CAM, According to National Survey Analysis*

A recent analysis of the 2007 National Health Interview Survey revealed that cancer survivors are more likely to use complementary and alternative medicine (CAM) compared with the general population. Cancer survivors are also more likely to use CAM based on a recommendation by their healthcare providers and to talk to their healthcare providers about their CAM use. Although cancer survivors communicated more about their CAM use than the general population, the study authors emphasized the overall need for improving communication between patients and providers about CAM use to help ensure coordinated care. http://nccam.nih.gov/research/results/spotlight/032011.htm.—Journal of Cancer Survivorship: Research and Practice. 2011;5(1):8–17.

*Analysis of National Survey Shows CAM Use in People With Pain or Neurological Conditions*

According to an analysis of the 2007 National Health Interview Survey, approximately 44 percent of American adults with pain or neurological conditions, compared to about 33 percent of people without those conditions, used complementary and alternative medicine (CAM) during the previous year. The most common CAM therapies used by people with these conditions were mind-body therapies (25 percent), such as deep breathing exercises, meditation, and yoga; biologically based therapies (21 percent), such as herbal therapies; manipulative and body-based therapies (19 percent), such as massage and chiropractic care; and alternative medical systems (4 percent). In addition, respondents with pain or neurological conditions indicated that they used CAM because conventional treatment did not work (20 percent vs. 10 percent) and was too expensive (9 percent vs. 4 percent). The researchers noted that this analysis demonstrates the need for more robust studies on the efficacy of CAM therapies for people with these conditions. http://nccam.nih.gov/research/results/spotlight/111010.htm.—Journal of Neurology. 2010;257:1822–1831.

*Study Asks Adolescents With Inflammatory Bowel Disease About Use of Complementary and Alternative Medicine (CAM) Mind-body Therapies*

This study found that many adolescents with inflammatory bowel disease are currently using or would consider using CAM—specifically mind-body therapies such as relaxation and guided imagery—to help manage their symptoms. This disease is actually a group of disorders (including Crohn's disease and ulcerative colitis) that cause inflammation of the intestines. The physical and emotional problems associated with irritable bowel disease in adolescents often affect quality of life. The researchers noted that their findings provide groundwork for future studies to determine the effect of CAM therapies on health outcomes in adolescents with inflammatory bowel disease. http://nccam.nih.gov/research/results/spotlight/031110.htm.—Inflammatory Bowel Disease. 2010;16(3):501–506.

*Certain Categories of Complementary Therapies Appear To Benefit Older Adults*

According to a recent analysis of data from the 2002 National Health Interview Survey and the 2003 Medical Expenditure Panel Survey, use of biologically based therapies (e.g., herbs or megavitamins) and manipulative/body-based therapies (e.g., chiropractic or massage) may be associated with better health outcomes among individuals age 55 years and older. The analysis showed a statistical association between ability to function and use of biologically based therapies and manipulative/body-based therapies. The researchers concluded that some categories of complementary therapies may be more beneficial than others for older adults. They cautioned that these findings should not be interpreted as evidence for the efficacy of specific therapies. Although the findings indicate that the use of certain kinds of CAM therapies is associated with better health outcomes for older adults, only clinical trials can determine the efficacy of specific therapies. The researchers also noted that this is the first longitudinal assessment (analysis of data collected from the same people at different points in time) of possible connections between com-

plementary therapy use and health outcomes in a national sample of older adults. They recommended additional population-based research in this area. http://nccam.nih.gov/research/results/spotlight/070810.htm.—Journal of Alternative and Complementary Medicine. 2010;16(7):701–706.

*Many Older People Use Both Prescription Drugs and Dietary Supplements*

Researchers analyzed the use of prescription drugs and dietary supplements in a sample of 3,070 people aged 75 and older. The data had been gathered during the Gingko for the Evaluation of Memory (GEM) study, a clinical trial that examined the effects of Gingko biloba on the development of dementia. Nearly 75 percent of the GEM study participants took at least one prescription drug and one dietary supplement. Approximately 33 percent used three or more prescription drugs and three or more supplements. Furthermore, 10 percent of the participants combined five or more prescription drugs with five or more dietary supplements. Although supplements were taken along with all types of prescription drugs, individuals using prescribed nonsteroidal anti-inflammatory drugs (NSAIDs), thyroid drugs, and estrogens were more likely to use dietary supplements. Individuals who used prescription drugs for high blood pressure and diabetes were less likely to use dietary supplements. Based on these data, they recommend that patients discuss dietary supplement use with their healthcare providers. In addition, the researchers emphasized the need for further investigations to better define the clinical importance of interactions between drugs and supplements. http://nccam.nih.gov/research/results/spotlight/071509.htm.—Journal of the American Geriatric Society. 2009;57(7):1197–1205.

*Translating CAM Research Results Into Clinical Practice: Results From a National Survey of Physicians and CAM Providers*

In an initial investigation of the potential for information from CAM research to influence clinical practice, a 2007 national survey asked acupuncturists, naturopaths, internists, and rheumatologists about their awareness of CAM clinical trials, their ability to interpret research results, and their use of research evidence in decisionmaking. The survey focused on awareness of two major NCCAM-funded clinical trials that studied acupuncture or glucosamine/chondroitin for osteoarthritis of the knee. Fifty-nine percent of the 1,561 respondents were aware of at least one of the two clinical trials but only 23 percent were aware of both trials. The acupuncture trial was most familiar to acupuncturists and rheumatologists, the glucosamine/chondroitin trial to internists and rheumatologists. Overall, awareness was greatest among rheumatologists and those practicing in institutional or academic settings. All groups regarded clinical experience as "very important" in their decisionmaking, although CAM providers were more likely to rate it "most important." Physicians were much more likely than CAM providers to consider research results very important or "very useful" in their clinical decisionmaking. The survey team concluded that CAM research has the potential to make a difference in both conventional and alternative medicine clinical practice. They recommend concerted efforts to better train all clinicians in interpretation and use of evidence from research studies, and to improve the dissemination of research results. http://nccam.nih.gov/research/results/spotlight/041309.htm.—Archives of Internal Medicine. 2009;169(7): 670–677.

*National Survey Reports on CAM Use by Adults and Children*

The 2007 The National Health Interview Survey (NHIS) found that approximately 38 percent of adults and 12 percent of children use some form of CAM. Among both adults and children, the most commonly used CAM therapy is nonvitamin/nonmineral natural products; fish oil/omega-3 is the most popular natural product for adults, while echinacea is the most popular for children. Back pain is by far the most common condition prompting adults to use CAM. Among children, back or neck pain is the most common reason for using CAM, followed closely by head/chest colds. The 2002 NHIS also included a supplement on CAM use by adults. Overall usage among adults in 2002 (36 percent) was about the same as in 2007. Since 2002, usage has increased for some therapies, including deep breathing, meditation, massage, and yoga. Adult use of CAM for head/chest colds showed a marked decrease between 2002 and 2007. The 2007 survey was the first to ask about CAM use by children. http://nccam.nih.gov/research/results/spotlight/123108.htm.—CDC National Health Statistics Report #12. 2008.

*New Findings on Sleep Disorders and CAM*

Based on a national survey, the NCCAM scientists found that over 1.6 million American adults use some form of CAM to treat insomnia or trouble sleeping. The authors key findings are:

—More than 17 percent of adults reported insomnia or trouble sleeping in the past 12 months. In this group, 4.5 percent used some form of CAM to treat these problems.
—The CAM users were most likely to use biologically based therapies (nearly 65 percent), such as herbal therapies, or mind-body therapies (more than 39 percent), such as relaxation techniques. Most who used these two types of therapies said they were at least somewhat helpful for insomnia or trouble sleeping.

http://nccam.nih.gov/research/results/spotlight/090106.htm.—Archives of Internal Medicine, September 2006.

*CAM Use High Among Adolescents*

Researchers conducting the first national survey of CAM use among adolescents in the United States analyzed responses from 1,280 adolescents aged 14 to 19. They found that 79 percent had used at least one form of CAM during their lifetime and that females used CAM more than males. Among all participants, almost 30 percent had used one or more dietary supplements, and almost 10 percent had used supplements along with prescription medications in the preceding month. Many of the supplements the teens reported using were related to attempts to change body shape (e.g., creatine and weight-loss products). The authors urged that healthcare providers be aware of CAM and dietary supplement use by their adolescent patients, because of the lack of standardization in supplements, as well as their potential for safety risks and interactions with prescription medications.http://nccam.nih.gov/research/results/spotlight/040106.htm.—Journal of Adolescent Health April 2006.

*More Than One-third of U.S. Adults Use Complementary and Alternative Medicine, According to a 2002 Government Survey*

According to the 2002 National Health Interview Survey (NHIS), 36 percent of U.S. adults use some form of CAM. The most commonly used form of CAM was natural products (such as herbs and other botanicals). Other popular CAM therapies included deep breathing, meditation, chiropractic care, yoga, massage, and special diets. Echinacea was the most commonly used natural product. CAM was most often used to treat back pain, colds, neck pain, joint pain, and anxiety or depression. The survey also revealed variations in CAM use by population subgroups. For example, CAM use overall was more common among women, people with higher education, people who had been hospitalized in the past year, and former smokers (compared to current smokers or those who had never smoked). The authors noted that the information from this survey is a foundation for future studies of CAM as it relates to health and disease among population subgroups. http://nccam.nih.gov/research/results/spotlight/050810.htm.—CDC Advance Data Report #343. 2004.

THE NCCAM RESEARCH APPROACHES

*Question.* Individualized therapies that involve multiple approaches often do not lend themselves to traditional double-blind studies but are frequently used in integrative medicine. Please describe work that the NCCAM is doing to support research on these kinds of treatments.

Answer. The NCCAM recognizes that assessing some of the individualized therapies used in integrative medicine in double-blind studies is challenging. Similar challenges confront other disciplines of healthcare research that employ individualized or multifaceted interventions, complex procedures, or system approaches (e.g. cognitive-behavioral therapy, surgery, or behavior change strategies). There is broad interest within the biomedical and behavioral research communities in applying effectiveness and outcomes approaches and pragmatic trial designs to such questions.

Addressing this challenge is a high priority for the NCCAM as evidenced by its inclusion as one of our strategic plan objectives: to "develop research examining the contributions of specific promising CAM approaches to better treatment and health promotion using the real-world methods and tools of the disciplines of observational, outcomes, health services, and effectiveness research." These methods and approaches also offer potential to address the challenges of conducting CAM research that reflects practice in the real world.

Health provider networks, practice-based clinical research networks, and integrative medicine practices provide important venues in which to develop real-world evidence across a broad array of outcome measures regarding the effects and effectiveness of CAM approaches and their integration into strategies for treatment and health promotion. Practice-based research provides an important setting in which to study the complex interplay of intervention, the patient-provider relationship, and other important contextual and environmental factors involved in healthcare and health promotion. Indeed, many CAM and integrative care practices actively seek to employ these factors. Population-based and practice-based research strate-

gies also offer great potential for developing evidence regarding the effectiveness of CAM-related interventions in engaging individuals in health-promoting behaviors and practices.

The NCCAM is pursuing these approaches in the context of CAM and integrative medicine practice through collaboration with experts who confront similar challenges and opportunities. For example, the NCCAM is working with our colleagues at the Departments of Defense and Veterans Affairs to explore ways that CAM mind and body approaches can be used in integrative approaches to treat pain, stress disorders, and other symptoms. Further, the NCCAM has released a funding opportunity announcement to foster development of CAM research methodology titled, "Translational Tools for Clinical Studies of Mind/Body and Manual Therapy CAM Interventions." It will "encourage the development of improved research methodology to study safety, efficacy, and clinical effectiveness of mind-body interventions."

Additionally, the NCCAM has substantially increased its investment in research which advances our understanding of the usefulness of CAM interventions in real world settings. For example, in one promising study being funded by the NCCAM at the Mount Sinai School of Medicine, researchers are studying methods to utilize all available information regarding CAM treatments in patients with HIV. By utilizing randomized controlled trials along with observational studies, expert judgment and other types of data, they seek to develop a clinical prediction model to determine which CAM interventions are beneficial. Another study, this one at Brigham and Women's Hospital, is looking at the effectiveness of an integrative healthcare team at improving outcomes for chronic low back pain by focusing on observational data. These are just two examples of studies funded by the NCCAM that go beyond traditional double-blind studies by using real world data to support CAM research.

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS) AND PREVENTATIVE MEDICINE

*Question.* One goal of the NCATS is to accelerate the process by which scientific discoveries are turned into treatments and cures—moving discoveries more quickly through the "valley of death" or the time between discovery and available cures. In particular, the NIH has indicated that the NCATS would focus on the drug development pipeline with a hope of understanding and addressing the reasons that so many drugs fail in development. Meanwhile, research has increasingly shown how a healthy lifestyle, exercise or better nutrition can help prevent the onset of disease or the use of expensive medicines or treatments. Will translational research that focuses on prevention or disease control through lifestyle changes be incorporated into the new vision for the NCATS? If so, how? Or will the NCATS focus exclusively on drug development?

Answer. As you point out, the prevention of diseases as well as their successful treatment may often require behavioral and lifestyle interventions or strategies. As such, a clear understanding of, and further research into, the role of behavioral and lifestyle factors in human health will be critical to the NCATS' success in catalyzing the development of new strategies to address human health and disease. The NCATS will support research to generate new methods and approaches aimed at accelerating the development, testing, and implementation of diagnostics, therapeutics, and prevention strategies. The NCATS prevention and behavioral research will be coordinated with the related work of the other NIH Institutes and Centers as well as with the Office of Disease Prevention and the Office of Behavioral and Social Sciences Research and carried out in part through the 60 institutions with Clinical and Translational Science Awards.

BUDGETARY CONSTRAINTS ON UNIVERSAL FLU VACCINE

*Question.* The NIH-supported scientists are making significant progress toward developing a universal flu vaccine that would confer longer term protection against multiple influenza virus strains and make yearly flu shots a thing of the past. What would be the impact on public health if research on the universal flu vaccine were delayed or scaled back due to budget constraints at the NIH?

Answer. The costly and time-consuming annual process of manufacturing, distributing, and administering millions of doses of seasonal influenza vaccine would become obsolete if researchers could design a vaccine that provides protection against a broad range of influenza strains over multiple influenza seasons. One strategy to overcome the need for a yearly influenza vaccine is to develop a vaccine against the common components of the influenza virus that do not change from year to year or from strain to strain. Recently, researchers supported by the National Institute of Allergy and Infectious Diseases (NIAID) have made significant breakthroughs in

identifying the specific parts of influenza viral proteins that are unchanged among both seasonal and pandemic strains. So-called "universal" influenza vaccines that capitalize on these findings might one day provide protection against the broad range of viruses arising from seasonal antigenic drift (minor changes) and pandemic antigenic shift (major changes) that are the hallmark of influenza viruses.

The NIAID is supporting a number of research projects to develop a vaccine that induces a potent immune response to the common elements of the influenza A virus that undergo very few changes from season to season and from strain to strain. Conserved internal proteins of the virus such as the M2 protein and conserved regions of the influenza envelope protein hemagglutinin (HA) have been identified as promising vaccine targets. For example, the NIAID-supported researchers found that a vaccine based on the M2 protein of H5N1 avian influenza virus elicited strong immune responses in mice. The HA protein of influenza virus, which is the protective antigen of the virus, has both a "head" region and a "stem" region. The NIAID-funded researchers recently generated a novel form of HA that elicited broadly cross-reactive antibodies against the stem region of a number of divergent seasonal and pandemic influenza subtypes and provided protection against disease in mouse challenge studies. In addition, the NIAID intramural researchers in the Vaccine Research Center demonstrated that a "prime-boost" vaccine strategy based on conserved regions of the HA protein could protect animals from infection with multiple strains of influenza that had been prevalent over many years. This "prime-boost" vaccine strategy involves first priming the immune system with a vaccine containing the DNA of an influenza surface protein (HA) and then administering a second vaccine made from a seasonal influenza virus or from a weakened cold virus, to amplify the immune response generated by the first vaccine.

Budget reductions could adversely affect the NIAID's ability to continue support of these activities in a robust and timely manner. Funding cuts could delay the development of new candidate vaccines for universal influenza and improved vaccines for seasonal influenza, as well as delay initiation of clinical trials necessary to test these vaccines. However, if budget reductions do materialize, the NIH would have to reevaluate its research priorities, and thus, the specific research areas to be impacted by such reductions would be determined at that time.

BUDGETARY CONSTRAINTS ON VACCINE RESEARCH

*Question.* What other types of vaccine research underway at the NIH might also have to be delayed or scaled back due to budget constraints?

Answer. Vaccines provide a safe, cost-effective, and efficient means of preventing illness, disability, and death from infectious diseases. The NIH is recognized as a worldwide leader in basic immunology research that underpins all vaccine development, and conducts or supports preclinical and clinical research on a broad spectrum of new and improved vaccine candidates. Recent progress in global vaccine research—from the RV 144 trial in Thailand that demonstrated that an HIV vaccine regimen provided a modest preventive effect, to the NIH-sponsored research advances that may unlock neutralizing antibody targets for a range of infectious diseases—highlights the need for a robust vaccine research portfolio at the NIH to pursue these and other advances in the field. A reduction in vaccine research funding at the NIH could slow the pace of ongoing efforts to develop new tools to prevent infectious diseases and could erode our ability to capitalize on scientific progress toward the development of vaccines.

HIV vaccine research activities that could be slowed by reduced funding levels include the conduct of additional and important Phase IIb trials that are planned to further assess and improve upon the results of the RV144 HIV vaccine trial, especially in other risk groups and in countries other than Thailand. Reduced funding could also undermine other important HIV vaccine trials. For example, investigators conducting the HIV Vaccine Trials Network (HVTN) 505 trial would likely be unable to expand the study to include 2,200 participants at 21 sites in 18 U.S. cities in order to assess whether the candidate vaccine regimen can prevent HIV infection and/or reduce viral load. Decreased funding could also limit the NIH's ability to support efforts to identify other promising HIV vaccine candidates, and curtail our ability to test those candidates that hold the most promise and advance them into clinical trials. Again, however, specific research areas that may be impacted by budget reductions are subject to priority assessments and cannot be precisely predetermined.

In addition to research to develop an HIV vaccine, the NIH is also supporting vaccine research across a range of other globally important diseases, including dengue, pandemic influenza, malaria, and tuberculosis, as well as diseases that might occur as a result of acts of bioterrorism. A reduction in funding could force the NIH to

scale back efforts across many of its infectious disease research programs. Potential adverse effects include a reduced ability to support preclinical product development, which is intended to assist companies and academic investigators in developing essential products to prevent and treat infectious diseases. Reduced funding levels could limit the development of new and improved preclinical products required to confront and keep pace with emerging and re-emerging infectious diseases, including a planned array of vaccine-related product development services. Funding constraints could also adversely affect clinical research efforts at the NIH, limiting our ability to support clinical trials designed to assess influenza and malaria vaccines, and slowing the progress of trials. Finally, budget constraints could result in significant delays in advancing research projects focused on the development of next-generation vaccines for biodefense purposes.

GUIDANCE FOR USE OF CLASS B CATS

*Question.* On March 18, the NIH released guidance on its plan to transition from the use of USDA Class B dogs to other legal sources (Notice NOT–OD–11–055). Why is there no mention of cats? The transition plan, as the NIH notes, is in accordance with the National Academy of Sciences report, Scientific and Humane Issues in the Use of Random Source Dogs and Cats in Research. The NIH notice also quotes from Senate report language regarding research on both dogs and cats, but the mention of cats was excised from the quotation. Does the NIH plan to issue a separate guidance dealing with cats?

Answer. The NIH believes that sufficient numbers of cats currently are available through Class A vendors to support the needs of the NIH-supported research. Therefore, no plan for phase out is needed nor a plan for developing sufficient animals from Class A vendors. At present, the NIH has no plans to issue separate guidance dealing with cats.

LUPUS RESEARCH

*Question.* How are the different NIH Institutes NIAID, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Heart, Lung, and Blood Institute (NHLBI), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), General Medicine, among others) working together to increase support for research on lupus? How will the new Translational Center work to address diseases like Lupus that cross multiple Institutes?

Answer. Lupus is an autoimmune disease that affects the lives of many Americans. Ninety percent of Americans with lupus are women. Lupus can affect many parts of the body, including the joints, skin, kidneys, heart, lungs, blood vessels, and brain. Although people with the disease may have different symptoms, some of the most common ones include extreme fatigue, painful or swollen joints (arthritis), unexplained fever, skin rashes, and kidney problems.

A wide range of basic, translational, and clinical research on lupus is being supported by many of the Institutes, Centers, and Offices at the NIH. Highlights of collaborative efforts include:

—The Lupus Federal Working Group, established on behalf of the Department of Health and Human Services (HHS) Secretary by the NIH, facilitates collaboration among the NIH components, other Federal agencies, voluntary and professional organizations, and industry groups with an interest in lupus. The group is coordinated by the NIAMS and includes participation from nine other NIH Institutes and Centers.

—The NIAID chairs the NIH Autoimmune Diseases Coordinating Committee, established by the Congress in fiscal year 1998 to increase collaboration and facilitate coordination of autoimmune diseases research among 21 NIH Institutes and Centers (ICs), other Federal agencies, and private health and patient advocacy groups.

—In September 2010, the NIAMS, the National Cancer Institute (NCI), the NIAID, and the NIH Office of Research on Women's Health (ORWH) hosted a 2-day scientific meeting in Bethesda, Maryland, "Systemic Lupus Erythematosus: From Mouse Models to Human Disease and Treatment." Clinicians and basic scientists from a variety of disciplines came together to discuss the clinical and molecular similarities and differences seen in human disease and animal models. Participants also discussed advances in lupus genetics, challenges and advances in the treatment of lupus, and emerging areas warranting further study.

—The Autoimmunity Centers of Excellence (ACEs), sponsored by the NIAID, the NIDDK, the NIAMS, the National Institute of Neurological Disorders and Stroke (NINDS), and the ORWH, conduct collaborative research on autoimmune

diseases, including lupus. This research includes clinical trials of immunomodulatory therapies and associated studies to understand the mechanism of disease and therapeutic effects.

—The Human Leukocyte Antigen (HLA) Region Genomics in Immune-Mediated Diseases Consortium, a cooperative research group sponsored by the NIAID and the NINDS, focuses on defining the association between variations in the HLA genetic region and immune-mediated diseases, including lupus.

—The Cooperative Study Group for Autoimmune Disease Prevention, sponsored by the NIAID, the NIDDK, and the Juvenile Diabetes Research Foundation International, focuses on research for the prevention of human autoimmune diseases, including lupus. Projects include the creation of improved models of disease pathogenesis and therapy to better understand immune mechanisms that will provide opportunities for prevention strategies.

—The NIDDK and the NIAMS organized an April 2010 meeting, "Novel Therapies to Enhance ESRD (End Stage Renal Disease) Patient Survival," which included a session on "Lessons for Nephrologists from Lupus." The NIDDK is planning a meeting in mid-2012 that will focus on glomerular disease, including that arising from lupus.

—The NIDDK-supported Chronic Kidney Disease Biomarkers Consortium—which seeks to discover and validate biomarkers for chronic kidney disease—is assessing inflammatory mediators as biomarkers for progression of kidney disease in patients with lupus who have had kidney biopsies. The Consortium will cross-validate its findings using a variety of patient cohorts, including those funded by the NIDDK (such as the Chronic Renal Insufficiency Cohort) and other ICs (such as the Atherosclerosis Risk in Communities Study, funded by the NHLBI).

The proposed NIH NCATS has been designed to catalyze the development of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of conditions, including diseases such as lupus. The NCATS will encourage collaborations across all sectors, provide resources to enable therapeutics development, and support and enhance training in the relevant translational science disciplines.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) RESEARCH

*Question.* COPD is the third leading cause of death in the United States, killing approximately 141,075 Americans annually. Despite the growing burden of COPD, the United States does not currently have a comprehensive public health action plan on the disease. What activities are the NIH currently conducting on COPD and what is missing from the Federal response? Would a Federal action plan on COPD provide insights on how we could better address this leading killer?

Answer. The NHLBI—the NIH component with primary responsibility for lung diseases—supports a wide range of research and education activities on COPD. Its programs include basic science and animal studies of underlying disease mechanisms; clinical studies of COPD risk factors, genetics, molecular and cellular defects, disease progression, and co-morbidities; translational studies of pathways and drugs that may lead to better treatments; clinical trials; comparative effectiveness research; and public and professional educational programs to increase awareness of COPD and knowledge about its symptoms, diagnosis, and treatment. Several other NIH components, including the NCI, the National Institute on Aging (NIA), the National Institute on Drug Abuse (NIDA), the National Institute of Environmental Health Sciences (NIEHS), the National Institute of General Medical Sciences (NIGMS), and the National Institute of Nursing Research (NINR), also support research relevant to COPD. For example, the NCI and the NHLBI are collaborating on an investigation of lung cancer and COPD. The NHLBI also cooperates with a number of other Federal agencies on this disease. The NHLBI Long Term Oxygen Treatment Trial is carried out in collaboration with CMS. The FDA collaborates with the NHLBI in a program called SPIROMICS, which is performing extensive molecular and clinical phenotyping of subjects with COPD to indentify biomarkers and characterize the heterogeneity in the patient population. VA Medical Centers participate in a number of the NHLBI clinical trials in COPD. The CDC is a partner in the NHLBI's COPD Learn More Breathe Better national public health education campaign. The NHLBI—CDC collaboration has led to the introduction of a module on COPD in the Behavioral Risk Factor Surveillance System Survey and to a recently released public health strategic framework for COPD prevention. Investigators supported jointly by the NHLBI and the AHRQ are setting up a large registry for comparative effectiveness research. Finally, the reports of the Surgeon General

on the health effects of smoking are a constant guide for the NHLBI programmatic directions for COPD.

These examples illustrate the extent and diversity of existing Government programs related to COPD, the cooperative and complementary interactions among Federal agencies in this area, and the central role that the NHLBI plays in the Government's efforts to control this disease. The NHLBI will continue to provide strong leadership for research and education activities to address this growing public health epidemic in collaboration with other components of the Federal Government. In particular, the NHLBI plans to host a forum of representatives from Federal Government agencies in fiscal year 2012 to share information regarding current activities related to COPD and to discuss opportunities for increasing cooperation among stakeholders and enhancing effectiveness of the Federal response to this debilitating and deadly disease. Whether a Federal action plan should be developed will almost certainly be a topic of discussion at the forum.

CLINICAL TRIALS COOPERATIVE GROUP PROGRAM REORGANIZATION IMPACT ON THE GYNECOLOGICAL COOPERATIVE GROUP

*Question.* The Institute of Medicine (IOM) of the National Academies was asked by the National Cancer Institute (NCI) to review the Institute's Clinical Trials Cooperative Group Program. One of the recommendations from that report is a reorganization of the Cooperative Group Structure that would entail restructuring and consolidating some of the cooperative groups. We understand that the reorganization may merge the Gynecological Cooperative Group (GOG) with the NSABP (National Surgical Adjuvant Breast and Bowel Project) and the RTOG (Radiation Therapy Oncology Group). Gynecological cancers are generally diagnosed by gynecologists and the GOG is the only cooperative group that studies gynecological cancers. Is our understanding of the reorganization plan for the GOG correct and, if so, what is the rationale for the planned merger of the GOG with these other groups? What is the scientific basis for it? If not, what is the current plan for the GOG? In general, what has been the process for making these reorganization decisions, what are the primary considerations and what is the timeframe and next steps for finalizing the reorganization decisions?

Answer. For more than 50 years, the NCI has supported a standing infrastructure—the NCI Cooperative Group Program—to conduct large scale cancer clinical trials across the Nation, with successful completion of many important trials that have led to new treatments for cancer patients. Over time, however, oncology has evolved into a more molecularly based discipline including genetic sub-classification of tumors and individualized treatments. Accordingly, the NCI must ensure that the Cooperative Groups are optimally situated and well-prepared to continue to design, enroll and complete state-of-the-art trials for cancer patients.

In 2009, the NCI commissioned the Institute of Medicine to review the Cooperative Group Program in order to gather independent and expert perspectives on the state of cancer clinical trials and to obtain advice about improvements in the NCI Cooperative Group Program. The IOM report "A National Cancer Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program" was issued in April 2010. The report called for a series of changes to the clinical trials program, including restructuring and consolidation of the adult Cooperative Groups.

Transforming the NCI's Cooperative Group System into a highly integrated National Clinical Trials Network is one of the Institute's major initiatives. Enhancing the scientific basis for the clinical trials that the NCI supports is essential if marked improvements in cancer diagnosis, prevention, and therapy are to continue unabated. The increasing need for molecular screening of large patient populations to define categories appropriate for intervention provides an important rationale for consolidating the NCI-supported clinical research groups into a coordinated network. Furthermore, the NCI's commitment to strategic consolidation includes the requirement for a shared, and standardized, clinical trials data management IT infrastructure, for a facile process by which the phase III clinical trials portfolio is prioritized, and for the conduct of clinical investigations that are multimodal in nature, and involve understudied and underserved patient populations. The NCI's restructured clinical trials network, as envisioned, will be organized to move such studies forward both efficiently and with the necessary resources to conduct correlative scientific investigations capable of increasing the potential of these trials to change current medical practice.

In addition to the ability to screen large patient populations, a coordinated network of a smaller number of consolidated Cooperative Groups will be better able to prioritize specific trials across all disease areas and to efficiently develop and complete multicenter trials. Consolidation will also enable optimal use of crucial bio-

specimens from the NCI-supported clinical trials. Finally, consolidation will address current disincentives to study less common diseases or to enroll patients to another Cooperative Group's trials.

The NCI began a discussion with the Cooperative Group Chairs in November 2010 about changes to the Group structure and has participated in multiple discussions with the public. Throughout the process, the NCI has been—and remains—committed to having an open dialogue about changes to the Cooperative Group Program. The NCI has not dictated mergers among groups and instead has encouraged groups to voluntarily consolidate on their own. The Gynecological Oncology Group (GOG), the National Surgical Adjuvant Breast and Bowel Project (NSABP), and the Radiation Therapy Oncology Group (RTOG) have entered negotiations about consolidation, and as background for those discussions, the NCI program leadership met with the GOG Chair in May 2011 to discuss GOG concerns and to provide assurances that funding for gynecological cancers will be protected. The NCI expects that consolidation will greatly strengthen the overall program and will provide each of the consolidated Cooperative Groups with unique capabilities and a greatly expanded network of clinical sites to recruit patients for trials across the entire program.

Since December 2010, the NCI has been gathering input from stakeholders and the cancer community about the plans to restructure the program. The comment period will close in July 2011, at which point the NCI will develop a concept proposal about the new structure and proceed with the NCI leadership review and presentation to the Board of Scientific Advisors in November 2011. The Funding Opportunity Announcement for the new Clinical Trials Program will be developed over the next several months, and released in July 2012. Applications will be accepted in November 2012 and reviewed over the next few months, with the consolidated Cooperative Groups being funded in fiscal year 2014.

CREATION OF SUAA

*Question.* Based on recommendations from the Scientific Management Review Board, the NIH has been considering the formation of a single institute that would be devoted to research related to substance use, abuse and addiction. The focus at the NIH seems to have turned away from this reorganization as attention has shifted to the creation of the NCATS. Is the NIH still considering the formation of this institute and, if so, what is the latest thinking on the creation of such an institute? What is the process and timeframe for making a decision and developing a plan?

Answer. The NIH is actively considering the formation of a single Institute that will focus on substance use, abuse, and addiction-related research. After receiving the SMRB recommendations, Dr. Collins formed a Task Force of scientific experts to begin a comprehensive review of the NIH substance use, abuse, and addiction research portfolio. The Task Force has met with subject matter experts from across the NIH to gain a better understanding of the breadth and diversity of NIH's substance use, abuse, and addiction portfolio. This review has made it clear that this portfolio is very complex and taken together with the administrative steps that would be required to implement a reorganization of this magnitude, we determined that additional time would be advantageous. Additionally, during the last few months, many stakeholders have requested additional input into the development of the scientific plan for the new Institute.

The NIH will continue to analyze our substance use, abuse, and addiction portfolio to provide a framework for a new proposed Institute. We will also develop a new scientific strategic plan to provide a framework for substance, use, abuse, and addiction-related research at NIH. This scientific strategic plan will be directed by the relevant Institute or Center Directors and will include extensive consultation with stakeholders, including scientists, patients, and the community, in addition to soliciting information from the Advisory Councils of the potentially affected Institutes and Centers. It is our intent to release the portfolio integration plan and the scientific strategic plan in the fall of 2012 for public comment, obtaining the Secretary's formal approval in December 2012 with the ultimate goal of notifying Congress through inclusion in the proposed reorganization in the fiscal year 2014 President's budget and standing up the new Institute at the beginning of fiscal year 2014 (October 1, 2013).

USE OF CHIMPANZEES IN BIOMEDICAL RESEARCH

*Question.* In response to a request from the NIH, the Institute of Medicine (IOM) is conducting a study on the use of chimpanzees in biomedical and behavioral research. The study will assess the current and anticipated uses of chimpanzees in the NIH research and determine whether chimpanzees are and will be necessary for

research needed to advance public health. The IOM is expected to release the report by the end of this year, in December 2011. Some interest groups have suggested that a moratorium be put in place on new funding for invasive research using chimpanzees pending the release of the IOM report. What would be the impacts of this type of temporary moratorium on the NIH research?

Answer. NIH appreciates the Senator's continued interest in the use of chimpanzees in research. As you know, chimpanzees have been used in important research such as key studies on hepatitis, malaria, and vaccine research. The Senator wisely requested that NIH initiate an in-depth analysis to be performed by the Institute of Medicine (IOM) to assess the scientific need for the continued use of chimpanzees in biomedical research. The NIH has followed this advice and anticipates a thoughtful analysis and rigorous review that will be a valuable input as NIH charts the future course for the use of chimpanzees in research.

In the interim, while the IOM study is ongoing, we believe it would be unwise to make any abrupt changes in our primate research programs.μ Therefore, we think it best to await the IOM report before making decisions that could have potentially far reaching implications.

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## QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

### THE NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH SUPPORT TO HAWAII ACADEMIC INSTITUTIONS

*Question.* Over the years the subcommittee has urged the NIH to pay particular attention to developing a cadre of scientific investigators from rural America and in the case of Hawaii, from the neighbor islands. This month the College of Pharmacy at the University of Hawaii at Hilo will graduate its first class and I appreciate the ongoing efforts by the leadership of several of your Institutes to ensure that basic research infrastructure will be made available for their faculty and students. In order to attract the next generation of scientists, it is absolutely necessary that they be exposed to caring mentors and the joy of scientific inquiry in their early academic years. Those of us who represent rural America appreciate how difficult it can be to provide this critical nurturing experience, especially when bright high school students and undergraduate students have to face significant transportation barriers, such as exist in an island State. At this time, I would appreciate receiving a report detailing the extent to which your Institutes have been able to provide scientific resources to Hawaii, and particularly to the educational campuses on the various islands.

Answer. The NIH has provided considerable support to Hawaii in an effort to ensure that Native Hawaiian and other Pacific Islanders have access to the clinical benefits of the NIH research. While research and training investments represent the majority of the NIH support to institutions in Hawaii, technical assistance to Hawaiian institutions has also been important. Periodically over the past decade, the NIH through the Office of Policy for Extramural Research Administration (OPERA) has provided workshops in Hawaii on the topics of the NIH policies, grant writing skills, and human subjects research issues including adverse event reporting, vulnerabilities of pediatric populations, and cultural issues involving Native Hawaiians participating in research studies. Also, the Office of Laboratory Animal Welfare (OLAW) presented several comprehensive overviews of the laws, regulations, and policies that govern the humane care and use of laboratory animals.

The breadth of the research enterprise in Hawaii is quite impressive. In fiscal year 2010, more than 17 of the 27 NIH Institutes and Centers have provided support for academic institutions to conduct research activities ranging from basic biomedical science to behavioral interventions. For example, Chaminade University has a National Institute on Minority Health and Health Disparities (NIMHD) Building Research Infrastructure and Capacity grant which supports renovations, research training, student academic enrichment programs, and junior faculty career development activities. The University of Hawaii Hilo has received funding from the National Institute on Drug Abuse (NIDA) for the mentoring of clinical investigators and to conduct patient-oriented mental health services research, including post-traumatic stress disorder. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is supporting a project to develop research capabilities in the area of substance use and indigenous youth populations (e.g., Native Hawaiian) at Hawaii Pacific University.

The University of Hawaii Manoa plays a pivotal role since it has the most robust research enterprise of all the Hawaiian institutions of higher education. They have received over 70 NIH awards over the past year. The NIMHD Center of Excellence,

Partnerships for Cardiometabolic Disparities in Native and Pacific Peoples, has a focus on cardiometabolic health and eliminating health disparities among Native Hawaiians and other Pacific Islanders including Filipinos, Samoans, and Tongans. The Cancer Research Center of Hawaii is an NCI-designated Clinical Cancer Center and is the only such institution in the State of Hawaii. Moreover, the University of Hawaii Manoa Research Centers in Minority Institutions (RCMI) Multidisciplinary and Translational Research Infrastructure Expansion in Hawaii serves as the integrated "home" for clinical and translational science in the State of Hawaii. In addition, Hawaiian small business concerns have received NIH support for innovative ideas to improve health through the NIH Small Business Innovative Research and Small Business Technology Transfer programs. For example, Hawaii Biotech is taking the knowledge gained through its dengue fever and West Nile virus vaccine programs and applying it to tick-borne encephalitis. This project, Recombinant Subunit Vaccine for Tick-Borne Encephalitis, addresses an important unmet biodefense need within the United States since there is no registered tick-borne encephalitis vaccine.

The NIH is pleased to be able to support biomedical research and student training programs to help further the health of Native Hawaiians and other Pacific Islanders. Recent discussions between the NIH Deputy Director and several faculty at the University of Hawaii Hilo may help identify additional gaps that could be filled through the NIH-University partnerships.

Below is a list of all the NIH awards to Hawaiian institutions in fiscal year 2010.

## FISCAL YEAR 2010 HAWAII NIH AWARDS

| Organization name | Grant number | Institute/center | Project title |
|---|---|---|---|
| CARDAX PHARMACEUTICALS, INC. | 4R44AA018922–02 | NIAAA | Heptax for Alcoholic Liver Disease |
| CHAMINADE UNIVERSITY OF HONOLULU | 1P20MD006084–01 | NIMHD | Chaminade University BRIC Project |
| EAST-WEST CENTER | 5R01HD042474–06 | NICHD | Innovations in Early Life Course Transitions |
| HAWAII BIOTECH, INC. | 5R44AI055225–04 | NIAID | Recombinant Subunit Vaccine For Tick-Borne Encephalitis |
| HAWAII PACIFIC UNIVERSITY | 3K01DA019884–04S1 | NIDA | Ecological Factors and Drug Use of Native Hawaiian Youth |
| HAWAII PACIFIC UNIVERSITY | 5K01DA019884–05 | NIDA | Ecological Factors and Drug Use of Native Hawaiian Youth |
| KUAKINI MEDICAL CENTER | 5U01AG017155–10 | NIA | Epidemiology of Aging and Dementia—Autopsy Research |
| KUAKINI MEDICAL CENTER | 5U01AG019349–09 | NIA | Epidemiology of Brain Aging in the Very Old |
| KUAKINI MEDICAL CENTER | 3R01AG027060–04S1 | NIA | Defining the Healthy Aging Phenotype |
| NEUROBEHAVIORAL RESEARCH, INC | 5R01AA013659–08 | NIAAA | Brain Morbidity in Treatment—Naive Alcoholics |
| NEUROBEHAVIORAL RESEARCH, INC | 5R01AA016944–03 | NIAAA | Long-Term Abstinence Clinical Issues and CNS Disinhibition |
| NEUROBEHAVIORAL RESEARCH, INC | 5R01AA016303–04 | NIAAA | Effects of heavy alcohol abuse on adolescent brain structure and function |
| PACIFIC HEALTH RESEARCH INSTITUTE | 5U10NS044448–08 | NINDS | Parkinson's Disease Neuroprotection Trial: Hawaii Center |
| PACIFIC HEALTH RESEARCH/EDUCATION INST | 3U10NS044448–09S1 | NINDS | Parkinson's Disease Neuroprotection Trial: Hawaii Center |
| PACIFIC HEALTH RESEARCH/EDUCATION INST | 3R01NS041265–10S1 | NINDS | Risk Factors for Pathologic Markers of Parkinson Disease |
| PACIFIC HEALTH RESEARCH/EDUCATION INST | 6U10NS044448–09 | NINDS | Parkinson's Disease Neuroprotection Trial: Hawaii Center |
| PACIFIC HEALTH RESEARCH/EDUCATION INST | 1R01DK089347–01 | NIDDK | Reducing Cost-Related Medication Nonadherence in Persons with Diabetes |
| PANTHERA BIOPHARMA, LLC | 5U01AI078067–03 | NIAID | Antidotes to Anthrax Lethal Factor Intoxication |
| PAPA OLA LOKAHI | 3U01CA114630–05S3 | NCI | IMI HALE NATIVE HAWAIIAN CANCER NETWORK |
| PAPA OLA LOKAHI | 1U54CA153459–01 | NCI | IMI HALE NATIVE HAWAIIAN CANCER NETWORK |
| PAPA OLA LOKAHI | 3U01CA114630–05S4 | NCI | IMI HALE NATIVE HAWAIIAN CANCER NETWORK |
| QUEEN'S MEDICAL CENTER | 5R01GM063954–08 | NIGMS | Molecular and functional properties of the TRPM2 catioin channel |
| QUEEN'S MEDICAL CENTER | 5R21CA139687–02 | NCI | Treatment Effects on Tumor 18F-Choline Metabolism in Advanced Prostate Cancer |
| QUEEN'S MEDICAL CENTER | 5R01GM080555–03 | NIGMS | Molecular components of the store-operated CRAC channel |
| UNIVERSITY OF HAWAII AT HILO | 5K24MH074468–05 | NIMHD | Mentoring/Career Development in PTSD Services Research |
| UNIVERSITY OF HAWAII AT MANOA | 2P20RR016467–09A1 | NCRR | INBRE II: Hawaii Statewide Research & Education Partnership (HSREP) |
| UNIVERSITY OF HAWAII AT MANOA | 3R01NS063932–03S1 | NINDS | HIV and Global Drug Therapies: Peripheral Neuropathy Complications and Mechanisms |
| UNIVERSITY OF HAWAII AT MANOA | 5R01NS053345–05 | NINDS | HIV-1 Proviral DNA and Monocyte Phenotype in Relation to Neurocognitive Function |
| UNIVERSITY OF HAWAII AT MANOA | 5U54NS056883–04 | NINDS | Imaging Studies in Neurotoxicity and Neurodevelopment |
| UNIVERSITY OF HAWAII AT MANOA | 5R01NS063932–03 | NINDS | HIV and Global Drug Therapies: Peripheral Neuropathy Complications and Mechanisms |
| UNIVERSITY OF HAWAII AT MANOA | 5R01NS053359–04 | NINDS | HIV-1 Specific Immune Responses in Thai Individuals with HIV Dementia |
| UNIVERSITY OF HAWAII AT MANOA | 5P20NR010671–04 | NINR | Center for 'Ohana Self-Management of Chronic Illnesses Hawaii (COSMCI0): Building |
| UNIVERSITY OF HAWAII AT MANOA | 5R01MH081845–02 | NIMH | The Genetic Control of Social Behavior in the Mouse |
| UNIVERSITY OF HAWAII AT MANOA | 5R01MH079717–02 | NIMH | Modeling monocyte and macrophage based gene therapy for neuroAIDS |
| UNIVERSITY OF HAWAII AT MANOA | 1R01EB011517–01 | NIBIB | Spectral Spatial RF Pulses for Gradient Echo fMRI |
| UNIVERSITY OF HAWAII AT MANOA | 5R24MD001660–06 | NIMHD | PILI 'Ohana Project: Partnerships to Overcome Obesity Disparities in Hawai'i |

FISCAL YEAR 2010 HAWAII NIH AWARDS—Continued

| Organization name | Grant number | Institute/center | Project title |
|---|---|---|---|
| UNIVERSITY OF HAWAII AT MANOA | 5R01CA115614–04 | NCI | Physical Activity in Women with Infants |
| UNIVERSITY OF HAWAII AT MANOA | 1U13HD063139–01 | NICHD | Community-Based Capacity Building: Academic-Community Partnerships Using Partici |
| UNIVERSITY OF HAWAII AT MANOA | 5G11HD054969–04 | NICHD | Office of Research Development (EARDA) |
| UNIVERSITY OF HAWAII AT MANOA | 5F32HD055000–03 | NICHD | Origins of neuronal patterning in animal development |
| UNIVERSITY OF HAWAII AT MANOA | 2T34GM007684–29A1 | NIGMS | Minority Access to Research Careers |
| UNIVERSITY OF HAWAII AT MANOA | 1R01GM093116–01 | NIGMS | Gene regulatory network evolution and the origin of biological novelties |
| UNIVERSITY OF HAWAII AT MANOA | 1P41GM094091–01 | NIGMS | Accessing Cyanobacterial Chemical Diversity: A Unique Natural Product Library |
| UNIVERSITY OF HAWAII AT MANOA | 5R01GM083158–03 | NIGMS | Transposon Based Mammalian Transgenesis and Transfection |
| UNIVERSITY OF HAWAII AT MANOA | 1R01GM088266–01A1 | NIGMS | RSK–2 regulates integrin-mediated adhesion and migration |
| UNIVERSITY OF HAWAII AT MANOA | 1K01DK090091–01 | NIDDK | Neighborhood Characteristics and Diabetes Incidence in the Multiethnic Cohort Stu |
| UNIVERSITY OF HAWAII AT MANOA | 5R25DK078386–04 | NIDDK | High School Students STEP–UP To Biomedical Research |
| UNIVERSITY OF HAWAII AT MANOA | 5R01DK079684–04 | NIDDK | Multimedia intervention to motivate ethnic teens to be designated donors |
| UNIVERSITY OF HAWAII AT MANOA | 3U10CA063844–17S1 | NCI | Hawaii Minority-Based Clinical Community Oncology Program |
| UNIVERSITY OF HAWAII AT MANOA | 5P01CA114047–05 | NCI | Pathogenesis of mesothelioma |
| UNIVERSITY OF HAWAII AT MANOA | 5R01CA058598–12 | NCI | Collaborative Genetic Study of Ovarian Cancer Risk |
| UNIVERSITY OF HAWAII AT MANOA | 5R01CA120799–04 | NCI | Testing Alternative Stage Models of Smoking Cessation: An Intervention Study |
| UNIVERSITY OF HAWAII AT MANOA | 5R37CA054281–18 | NCI | Multiethnic Cohort Study of Diet and Cancer |
| UNIVERSITY OF HAWAII AT MANOA | 1R03CA150041–01 | NCI | Urinary Estrogen Metabolites in a 2-year Soy Trial Among Premenopausal Women |
| UNIVERSITY OF HAWAII AT MANOA | 3U54CA143727–02S1 | NCI | University of Guam/Cancer Research Center of Hawaii Partnership (1 of 2) |
| UNIVERSITY OF HAWAII AT MANOA | 3P30CA071789–12S9 | NCI | Cancer Research Center of Hawaii |
| UNIVERSITY OF HAWAII AT MANOA | 3P30CA071789–12S8 | NCI | Cancer Research Center of Hawaii |
| UNIVERSITY OF HAWAII AT MANOA | 5U24CA074806–12 | NCI | The Colon Cancer Family Registry: Hawaii |
| UNIVERSITY OF HAWAII AT MANOA | 1R01CA153154–01 | NCI | Self-Control as a Moderator for Effects of Mass Media on Adolescent Substance Use |
| UNIVERSITY OF HAWAII AT MANOA | 3U24CA074806–11S1 | NCI | The Colon Cancer Family Registry: Hawaii |
| UNIVERSITY OF HAWAII AT MANOA | 7R01CA124687–03 | NCI | The Sphingolipid Pathway in Colon Cancer Chemoprevention |
| UNIVERSITY OF HAWAII AT MANOA | 2U10CA063844–17 | NCI | Hawaii Minority-Based Clinical Community Oncology Program |
| UNIVERSITY OF HAWAII AT MANOA | 5R21AT004844–02 | NCCAM | Mechanisms by which selenium influences T helper cells during immune responses |
| UNIVERSITY OF HAWAII AT MANOA | 5R21AT005139–02 | NCCAM | Exploratory Studies on the Anti-Breast Cancer Function of Bamboo Extract |
| UNIVERSITY OF HAWAII AT MANOA | 7R01AI054128–06 | NIAID | Mechansim of activation of innate immunity by ISS–DNA |
| UNIVERSITY OF HAWAII AT MANOA | 5R01AI075057–03 | NIAID | Intraspecies Transmission and Infectivity of Insectivore-Borne Hantaviruses |
| UNIVERSITY OF HAWAII AT MANOA | 5R01AI071160–04 | NIAID | Malarial Immunity in Pregnant Cameroonian Women |
| UNIVERSITY OF HAWAII AT MANOA | 1R01AI089999–01 | NIAID | Selenoprotein K modulates calcium-dependent signaling in immune cells |
| UNIVERSITY OF HAWAII AT MANOA | 5R01AI074554–03 | NIAID | Global HIV Drug Therapies and Mitochondrial Complications and Mechanisms |
| UNIVERSITY OF HAWAII AT MANOA | 5U01HG004802–03 | NHGRI | Epidemiology of Putative Causal Variants in the Multiethnic Cohort |
| UNIVERSITY OF HAWAII AT MANOA | 5R01DA021146–04 | NIDA | RGR-based motion tracking for real-time adaptive MR imaging and spectroscopy |
| UNIVERSITY OF HAWAII AT MANOA | 5R01DA021856–04 | NIDA | The Project Success Model: Evaluation of a Tiered Intervention |

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| UNIVERSITY OF HAWAII AT MANOA | 5K02DA020569–05 | NIDA | Parallel MRI for Substance Abuse Research |
| UNIVERSITY OF HAWAII AT MANOA | 5K23DA020801–05 | NIDA | Neurodevelopment of Methamphetamine Exposed Children |
| UNIVERSITY OF HAWAII AT MANOA | 5R01DA019912–04 | NIDA | Parallel MRI for High Field Neuroimaging |
| UNIVERSITY OF HAWAII AT MANOA | 5K24DA016170–07 | NIDA | Neuroimaging and Mentoring in Drug Abuse Research |
| UNIVERSITY OF HAWAII AT MANOA | 1R24DA027318–01 | NIDA | Factors for enhanced neurotoxicity in methamphetamine abuse in HIV infection |
| UNIVERSITY OF HAWAII AT MANOA | 5K01DA021203–04 | NIDA | Impact of Marijuana Exposure on Brain Maturation |
| UNIVERSITY OF HAWAII AT MANOA | 3R25RR024281–03S1 | NCRR | Pacific Education and Research for Leadership in Science (PEARLS) |
| UNIVERSITY OF HAWAII AT MANOA | 5P20RR024206–03 | NCRR | Institute for Biogenesis Research: COBRE |
| UNIVERSITY OF HAWAII AT MANOA | 5P20RR016453–09 | NCRR | COBRE: Center for Cardiovascular Research |
| UNIVERSITY OF HAWAII AT MANOA | 5R25CA090956–08 | NCI | Nutritional & Behavioral Cancer Prevention in a Multiethnic Population |
| UNIVERSITY OF HAWAII AT MANOA | 5R01CA126895–03 | NCI | Whole Genome Scan for Modifier Genes in Colorectal Cancer |
| UNIVERSITY OF HAWAII AT MANOA | 5R01CA129063–03 | NCI | Inflammation and Innate Immunity Genes and Colorectal Cancer Risk |
| UNIVERSITY OF HAWAII AT MANOA | 5R03CA135699–02 | NCI | A pooled analysis of mammographic density and breast cancer risk |
| UNIVERSITY OF HAWAII AT MANOA | 5R01CA140636–02 | NCI | Characterizing Mitochondrial DNA Susceptibility to Breast, Colorectal, and Prosta |
| UNIVERSITY OF HAWAII AT MANOA | 5R01CA080843–09 | NCI | Effects of Soy on Estrogens in Breast Fluid and Urine |
| UNIVERSITY OF HAWAII AT MANOA | 5U54CA143727–02 | NCI | University of Guam/Cancer Research Center of Hawaii Partnership (1 of 2) |
| UNIVERSITY OF HAWAII AT MANOA | 5K23HL088981–03 | NHLBI | Cardiovascular autonomic function in HIV virologic failure |
| UNIVERSITY OF HAWAII AT MANOA | 5R01HL095135–03 | NHLBI | Role of Oxidative Stress and Inflammation in HIV Cardiovascular Risk |
| UNIVERSITY OF HAWAII AT MANOA | 1R01HL098423–01A1 | NHLBI | Role of mTOR in the diabetic heart |
| UNIVERSITY OF HAWAII AT MANOA | 5UH1HL073449–07 | NHLBI | University of Hawaii Research Scientist Award in Molecular Cardiology |
| UNIVERSITY OF HAWAII AT MANOA | 5R21HL087289–02 | NHLBI | Pseudoxanthoma elasticum: Elastic fibers alterations and characterization of seru |
| UNIVERSITY OF HAWAII AT MANOA | 5R01HL081863–05 | NHLBI | Rho kinase in immune-mediated atherosclerosis |
| UNIVERSITY OF HAWAII AT MANOA | 5R01AI068525–05 | NIAID | Role of macrophages in HIV Lipoatrophy |
| UNIVERSITY OF HAWAII AT MANOA | 5G12RR003061–25 | NCRR | Research Outcomes Accelerating Discoveries for Medical Applications and Practice |
| UNIVERSITY OF HAWAII AT MANOA | 1R01HD060722–01A1 | NICHD | Contribution of Sperm Nucleus to Paternal DNA Replication |
| UNIVERSITY OF HAWAII AT MANOA | 5R21AG032405–02 | NIA | A Needle in a Haystack: New approaches to Alzheimer's Drug Discovery from Natural |
| UNIVERSITY OF HAWAII AT MANOA | 2P20RR018727–06A1 | NCRR | Pacific Center for Emerging Infectious Diseases Research |
| UNIVERSITY OF HAWAII AT MANOA | 5P20MD000173–09 | NIMHD | Partnerships for Cardiometabolic Disparities in Native and Pacific Peoples |
| UNIVERSITY OF HAWAII AT MANOA | 5R01GM057873–11 | NIGMS | Cyclopentannelation in Total Synthesis |
| UNIVERSITY OF HAWAII AT MANOA | 1U54RR026136–01A1 | NCRR | RCMI Multidisciplinary And Translational Research Infrastructure EXpansion Hawaii |
| UNIVERSITY OF HAWAII AT MANOA | 5R25RR024281–03 | NCRR | Pacific Education and Research for Leadership in Science (PEARLS) |

THE NATIONAL INSTITUTE OF NURSING RESEARCH (NINR) SUPPORT FOR END-OF-LIFE CARE AND HEALTH DISPARITIES RESEARCH

*Question.* The NINR will soon be celebrating its 25th anniversary. The late Senator Quentin Burdick and I were active in establishing the original Center and I am confident he would share my enthusiasm for how nicely it has matured over the years. At this time I would appreciate an update on the extent to which the NINR has been able to co-fund various initiatives with other NIH Institutes, particularly in the areas of end-of-life issues and racial and geographical disparities.

Answer. Improving palliative and end-of-life care and eliminating health disparities are critical components of the NINR's research mission. Consistent with this mission, as well as the Institute's longstanding practice of extensive collaboration with other NIH ICs, the NINR co-funds numerous scientific efforts with other ICs focused on these two important topics.

As the lead NIH Institute on issues related to end-of-life care research, the NINR, with support from partners across the NIH, will convene a forum on August 10–12, 2011, entitled "The Science of Compassion: Future Directions in End-of-Life and Palliative Care." A part of the NINR's 25th Anniversary commemoration, this forum is intended to energize and mobilize palliative and end-of-life care research and to draw attention to palliative and end-of-life care processes, options available to patients and their families, and the healthcare community's obligation to address these complex needs. This event is co-sponsored by the following NIH partners: National Institute on Aging (NIA), Office of Rare Diseases Research, Office of Research on Women's Health, National Center for Complementary and Alternative Medicine, and the NIH Clinical Center Department of Bioethics.

In addition, the NINR and the NIH Common Fund recently awarded $7.1 million in funding provided by the American Recovery and Reinvestment Act to support a Palliative Care Research Cooperative (PCRC), a multi-institution effort to conduct collaborative research on palliative and end-of-life care. The PCRC will bring together experienced, multidisciplinary investigators to facilitate innovative, high-impact, clinically useful palliative care research to inform practice and health policy. The PCRC will address challenges associated with conducting research with individuals with life-limiting conditions, and could lead to significant improvements in the evidence base for palliative and end-of-life care.

NINR also collaborates with other ICs to support basic, clinical, and translational research to address health disparities across the life span. The NINR currently co-funds an initiative focused on reducing health disparities in minority and underserved children, including children from: racial/ethnic minority groups; rural and low-income populations; and geographically isolated locations. The NINR, and other Institutes, have supported various important projects under this initiative. For example, the NINR-supported investigators are testing interventions to improve the well-being of African American, Hispanic, and White families where grandmothers are raising grandchildren. These custodial grand-families are at high risk for psychological difficulties and limited access to needed services. This initiative is co-funded with the following NIH Institutes: National Institute of Child Health and Human Development; National Heart, Lung, and Blood Institute; National Institute on Alcohol Abuse and Alcoholism; and the National Institute on Deafness and Other Communication Disorders.

Additionally, researchers funded by the NINR and the NIA developed the Resources for Enhancing Alzheimer's Caregivers Health (REACH) II program which teaches caregivers about Alzheimer's disease, managing stress, and maintaining their own health. In a large sample of African American and White caregivers for Alzheimer's patients, those in the REACH II intervention reported better physical, emotional, and overall health and had lower scores for depression which contributed to reducing caregiving burden. To address the need for support of caregivers, particularly in racially/ethnically diverse families, multiple efforts across the Federal Government are currently underway to implement REACH in the community.

HEALTH MESSAGES FOR THE NATIVE HAWAIIAN POPULATION

*Question.* According to the fiscal year 2012 NIH CJ, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) "supports a robust information dissemination and outreach program to distribute research-based information to the public, patients, and their healthcare providers." The NIAMS supported National Multicultural Outreach Initiative "is creating a sustainable network of partners to assist in the development and dissemination of health messages and materials for racial and ethnic minority populations." The Initiative will focus its efforts on reaching many different minority/ethnic populations including Native Hawaiians. "Working with existing NIAMS partners, the Institute will develop research-based

self-care messages and products, and ensure their distribution through trusted health and multicultural community channels. The NIAMS implemented critical phases of the Initiative in fiscal year 2011, namely, the development and pretesting of culturally and linguistically appropriate health messages and materials through audience research."

The NIAMS and its National Multicultural Outreach Initiative are supporting the development of health messages for racial and ethnic minority populations. What types of health messages are being developed and tested for the Native Hawaiian population?

Answer. In fiscal year 2011, the NIAMS completed qualitative research with members of multicultural communities, including Native Hawaiians, to help inform the development of culturally appropriate and useful health education products for adults with medical conditions affecting the bones, joints, muscles, and skin. The NIAMS conducted a total of 18 focus groups (2 with Native Hawaiians), and 20 in-depth interviews (2 with Native Hawaiians) to gather feedback from individuals on preferences for different message concepts and formats for communicating health messages. The information gleaned from this audience research will enable the development of tailored products that raise awareness about the availability of reliable, research-based health information and resources from the NIAMS and partner organizations to help patients and their families manage their conditions.

The NIAMS National Multicultural Outreach Initiative relies on the guidance and input from its working groups for the development and dissemination of health messages and products. These groups are comprised of national experts from multicultural communities, and include representation from the Native Hawaiian community.

### THE NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES (NIMHD) CENTERS OF EXCELLENCE (COE) IN HAWAII

*Question.* The fiscal year 2012 congressional justification states that the NIMHD has supported 91 COE sites in 35 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. According to the CJ, the "types of institutions are diverse and include Historically Black Colleges and Universities, Hispanic-Serving Institutions, Tribal Colleges and Universities, Alaskan Native, and Native Hawaiian Serving Institutions." In fiscal year 2010, the 51 active COEs conducted transdisciplinary research on high priority diseases/conditions including "cardiovascular disease, stroke, cancer, diabetes, HIV/AIDS, infant mortality, mental health, and obesity that disproportionately affect racial/ethnic minority and other health disparity populations."

Is the NIMHD currently supporting a COE at a Native Hawaiian Serving Institution? What high priority diseases or conditions are the focus of research at a COE in a Native Hawaiian Serving Institution?

Answer. The NIMHD COE represent a scientific platform for innovative research projects, research training, and effective community engagement to address the health status of health disparity populations. The NIMHD has provided funding for a COE at the University of Hawaii Manoa since September 2002. This COE, Partnerships for Cardiometabolic Disparities in Native and Pacific Peoples, is a regional focal point for improving cardiometabolic health and eliminating health disparities among Native Hawaiians and other Pacific Islanders, including Filipinos, Samoans, and Tongans.

The primary focus of the COE is obesity and diabetes which are known risk factors for cardiovascular disease. Eighty-two percent of Native Hawaiians are overweight or obese, which is considerably higher than the national average of 53 percent. Pacific Islander women with diabetes have a higher risk of myocardial infarction. Through dedicated efforts over the years, Partnerships for Cardiometabolic Disparities in Native and Pacific Peoples has made significant contributions to the improvements in the health of Native Hawaiians and other Pacific Islanders.

In addition, supplemental funding was provided in July 2010 to support the establishment of the Comparative Effectiveness Research Approaches to Eliminate Cardiometabolic Disparities initiative as part of the COE. The intent of the project is to train researchers in comparative effectiveness research, to conduct innovative research, to establish diabetes and cardiometabolic disease registries, and to disseminate research results to communities with health disparities in Hawaii.

### HEREDITARY ANGIODEMA RESEARCH SUPPORT

*Question.* Dr. Collins, I would like to thank you for your leadership of the National Institutes of Health, including its continuing emphasis on rare diseases. As you are aware, the NIH provides critical opportunities for research surrounding or-

phan conditions which otherwise may not have an opportunity for significant research. Recently, constituents and members of the U.S. Hereditary Angioedema Association (USHAEA), based in Honolulu, brought to my attention the absence of Federal support since 2009 for hereditary angioedema (HAE) research. I would appreciate receiving a report on why funding for this disease was eliminated and what your efforts are toward reinvigorating hereditary angioedema research support.

Answer. HAE is a rare genetic disorder. HAE patients suffer from swelling of the hands, feet, abdomen, face and/or throat. Especially the latter is a major medical emergency that may be fatal. Estimates for the prevalence of HAE range from 1 in 10,000 to 1 in 50,000 people in the United States.

In 2009, a number of research projects focusing on hereditary angioedema came to a natural end. For example, the most extensive project, sponsored by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, C1 Inhibitor Gene and Hereditary Angioneurotic Edema, was last funded in 2008 after 23 years of research and concluded in 2010. The Principal Investigator did not apply for renewed funding for this project.

The National Center of Research Resources (NCRR) funded Mount Sinai General Clinical Research Center project: CHANGE Trial (C1-Inhibitor in Hereditary Angioedema Nanofiltration Generation Evaluating Efficacy): Open-Label Safety/Efficacy Repeat Exposure Study of C1 Esterase Inhibitor (Human) in the Treatment of Acute Hereditary Angioedema (HAE) Attacks participant visits ended in March 2009 and closed in September 2009. The results were published in the NEJM in August 2010 (PMID 20818886). Currently, the NCRR-funded Mount Sinai Clinical and Translational Science Award supports the Phase III Randomized Double Blind, Placebo controlled Multicenter Study of Icatibant for Subcutaneous Injection in Patients with Acute Attacks of Hereditary Angioedema.

The NCRR General Clinical Research Center at the University of Texas Medical Branch at Galveston (UTMB) conducted the Randomized, Placebo-Controlled, Double-blind Phase II Study of the Safety and Efficacy of Recombinant Human C1 Inhibitor for the Treatments of Acute Attacks in Patients with Hereditary Angioedema. The study ended in May 2009.

The NCRR-funded University of Texas Medical Branch at Galveston (UTMB) Clinical and Translational Science Award represents an additional site which conducted the Phase III Randomized Double-Blind, Placebo-Controlled Multicenter Study of Icatibant for Subcutaneous Injection in Patients with Acute Attacks of Hereditary Angioedema (HAE). This study was completed in May 2011.

Currently, we also are supporting three training grants with projects investigating HAE, two from National Institute of Allergies and Infectious Diseases and one from the National Heart, Lung, and Blood Institute. These training grants are critical since they train the next generation of investigators. The trainees are expected to continue their careers with a research emphasis on HAE. The NIH would welcome the opportunity to support meritorious research studies focusing on hereditary angioedema (HAE).

To stimulate future research activities and applications we would encourage investigators and advocates of HAE research to submit an application for a scientific conference grant. In addition to helping to identify research opportunities and needs and develop a research agenda and research priorities for HAE, such a conference could create significant research interest in this particular rare disease. The Office of Rare Diseases Research (ORDR), collaborating with other NIH research institutes, would be pleased to confer with the U.S. Hereditary Angioedema Association (U.S. HAEA) and interested research investigators about your concerns.

CANCER PREVELANCE AND RESEARCH IN HAWAII

*Question.* Over the years the NCI has systematically invested in research activities targeting the unfortunately high incidence of cancer among my State's Native Hawaiian population. At one point the NCI researchers reported that Native Hawaiian women had the highest incidence of breast cancer in the world. I am confident that progress has been made and would appreciate a report describing the NCI's future plans for targeting the special needs of these indigenous people.

Answer. The NCI funds research that focuses on Native Hawaiian, other Pacific Islander, and Asian American populations. These studies are supported to illuminate the causes of cancer in these populations; to improve screening rates so that when cancer appears, it can be treated at an early stage; to increase knowledge about treatment options so that patients and their physicians can make more informed choices about their care; to fund registries, surveys, and reports that generate the latest statistics and inform researchers, policy makers, and the public; to

support cohorts that provide a population base from which to conduct important future research, and ultimately to prevent cancers in these populations.

*Current Efforts*

The NCI's Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO) and National Lung Screening Trial (NLST) studies, with more than 200,000 participants, include programs in Hawaii and from diverse ethnic populations. At the Pacific Health Research and Education Institute in Honolulu, of the 13,200 study participants in Hawaii, approximately half were Asians (5,553) and Native Hawaiians and other Pacific Islanders (1,053).

In the area of clinical trial recruitment of minorities, the University of Hawaii Minority-Based Community Clinical Oncology Program (MB–CCOP), funded since 1994, provides access to the NCI clinical trials in cancer prevention, treatment, and control to both children and adults.

The NCI Community Network Program (CNP) Centers address disparities at the community level with outreach, research, and training. Two CNPs are oriented to Pacific Islanders (Imi Hale and Weaving an Islander Network for Cancer Awareness, Research and Training, or WINCART) and two other CNPs are focused on underserved Asians (Asian American Network for Cancer Awareness, Research, and Training, or AANCART, and the Asian Community Cancer Health Disparities Center, or ACCHD).

National Outreach Program (NOP) supported by the Imi Hale Native Hawaiian Cancer Network is designed to reduce cancer incidence and mortality among Native Hawaiians by maintaining and expanding an infrastructure that:

—Promotes cancer awareness within Native Hawaiian communities;
—Provides education and training to develop Native Hawaiian researchers; and
—Facilitates research that aims to reduce cancer health disparities experienced by Native Hawaiians.

The Imi Hale Native Hawaiian Cancer Network made progress toward reducing cancer incidence and mortality among Native Hawaiians through a project, "Woman to Woman-Micronesians United Lay Educator Program" for Native Hawaiians focused on increasing breast and cervical cancer screening. Six months of outreach activities resulted in screening of 150 women. CNP-Southern California developed culturally tailored educational resources specifically for Native Hawaiians and the Marshallese, in colorectal cancer screening, which resulted in a library of culturally relevant resources. In addition to these primary efforts, the CNP Native Hawaiian trainees have submitted 40 grant applications and a total of 12 were ranked high enough for funding.

Imi Hale has a dedicated Community Health Educator, who seeks to bridge the gap between the community and the research community by developing culturally tailored cancer information. For instance, to help women learn to do self-breast exams to detect lumps early, Imi published Breast Health Shower Cards in nine languages. In terms of breast cancer education, Imi Hale has produced a DVD entitled "A Journey of Hope: When a Young Woman Gets Cancer." Seeking creative ways to educate women about breast cancer, Imi Hale created a breast cancer computer game (http://imihale.org/game/click__to__start.html). In addition, a series of brochures for Native Hawaiian breast cancer survivors called "Talking Story Booklets" has been developed. The outreach component works closely with such partners as the five Native Hawaiian healthcare Systems positioned on five islands.

—Imi Hale Clinical partners include: Community Health Centers serving Native Hawaiian clients, the Queen's Cancer Center and other hospitals, and the State-contracted Breast and Cervical Cancer Control Programs; and
—Imi Hale Community partners include: Association of Hawaiian Civic Clubs, Hawaii State Tobacco Coalition, Office of Hawaiian Affairs, and other community agencies.

A Comprehensive Partnership to Reduce Cancer Health Disparities Program between the University of Hawaii Cancer Center (UHCC) and the University of Guam (UOG) have an NCI-funded partnership with the aim of enhancing the awareness of cancer and cancer prevention and ultimately reducing the impact of cancer on the population in Hawaii, the Territory of Guam and the other U.S.-associated Pacific Island territories. The partnership supports projects designed to develop culturally appropriate guidelines for tobacco use prevention and cessation in youth with the underlying hypothesis that interventions to prevent tobacco use are more likely to succeed if they conform to culturally relevant guidelines developed with the active participation of the target youth themselves. The long-term goal of the community-based participatory outreach program is to engage the community as equal partners in tobacco control and cancer prevention research. The partnership also supports investigator-initiated cancer research projects that address different aspects of cancers

in Hawaii and Guam including the development of protocols for studying oral precancerous lesions and other health risks among betel nut users in Hawaii, the Territory of Guam and the other U.S.-associated Pacific Island territories.

The NCI Community Cancer Centers Program (NCCCP) is designed to create a community-based cancer center network to support basic, clinical and population-based research initiatives, addressing the full cancer care continuum—from prevention, screening, diagnosis, treatment, and survivorship through end-of-life care. The NCCCP pilot has added the Queen's Medical Center, Honolulu, Hawaii (The Queen's Cancer Center) to its 30 hospital network.

*Future Research*

The NCI will be launching a program to foster evidence-based research, data collection, and analysis within Asian American and Pacific Islander (AAPI) populations and subpopulations through a unique collaboration with the University of Guam, the University of Hawaii, the Pacific Regional Central Cancer Registry, and the Pacific Island Cancer Council. The NCI developed the Health Information National Trends Survey (HINTS) to monitor changes in the rapidly evolving field of health communication by collecting data across the Nation. The HINTS-Guam program will pilot test a localized survey instrument geared specifically to AAPI populations and subpopulations, including Chamorros and other Pacific Islanders living on Guam. Data collected from this survey will increase understanding of cancer information seeking, experiences, and behaviors (prevention, screening, treatment, etc.) among AAPI populations. Discussions have also begun on a HINTS pilot project to be conducted in Hawaii.

KIDNEY DISEASE AND DIABETES RESEARCH IN HAWAII

*Question.* It has recently come to my attention that my State's Filipino population has an extraordinarily high incidence of kidney disease. Similarly, several ethnic groups in Hawaii (including Native Hawaiians) have been found to have high incidences of diabetes. Accordingly, I would appreciate receiving a report on your efforts to develop initiatives targeting these populations, and particularly those which would stress prevention and perhaps diet.

Answer. Data show that Filipinos in Hawaii seem to have a disproportionate burden of kidney disease. The NIDDK is naturally very concerned about kidney disease in Hawaiians, including the health disparity in the Filipino population, and has several initiatives in place to address the problem. First, our National Kidney Disease Education Program (NKDEP) provides materials that can be used in Hawaii's high risk populations. The NKDEP's materials aim to raise awareness of the seriousness of kidney disease, the importance of testing those at high risk (those with diabetes, high blood pressure, or a family history of kidney failure), and the availability of treatment to prevent or slow kidney failure. NKDEP's extensive new offerings on dietary intervention in chronic kidney disease for providers and patients would be particularly useful.

The National Diabetes Education Program (NDEP) is sponsored by the NIDDK and Centers for Disease Control and Prevention (CDC) and includes more than 200 partners working together to improve the treatment and outcomes for people with diabetes, promote early diagnosis, and prevent or delay the onset of type 2 diabetes, a leading cause of kidney disease. The NDEP has a major focus on Asian Pacific Islanders; it has translated educational materials into Tagalog, one of the languages spoken in the Fillipino population. These materials address both prevention of diabetes and prevention of complications such as kidney disease. The University of Hawaii is a site for the Diabetes Prevention Program Outcomes Study, which recently reported data showing durability of effect of lifestyle intervention and the drug metformin at preventing or delaying onset of type 2 diabetes at 10 years follow-up.

People whose disease progresses to kidney failure can be treated with a kidney transplant, though limitations on available donor organs is a chronic problem. The NIDDK's "Minority Organ Donation Program" initiative supports an investigator at the University of Hawaii, Dr. Cheryl Albright, whose research focuses on educating Filipino high school students about signing up (on drivers' licenses) to donate organs. Students from Honolulu and other smaller Islands (including rural areas) are participants. The grant is in the fourth year and results are quite encouraging. The Filipino community is very interested in kidney transplants, and participated in the original National Minority Organ and Tissue Transplant Education Program (http://mottep.org/) to rally the community around kidney donation from relatives and friends.

In another initiative, the NIDDK, in collaboration with the CDC and the Indian Health Service, has funded eight Tribal Colleges and Universities in the initiative "Diabetes Education in Tribal Schools." This effort developed supplemental cur-

ricula, to be used in K–12 schools in American Indian and Alaska Native communities, about prevention and better management of diabetes, the most common cause of kidney failure. Although the cultural content is directed primarily toward American Indians, some Hawaiian schools participated in piloting the curricula. The project is completed and the curricula are being fielded in tribal schools. Also, the curricula were distributed to and currently are being used in Hawaiian schools, primarily on the Big Island of Hawaii.

STROKE DISPARITIES IN THE UNITED STATES

*Question.* I am concerned that stroke apparently remains the number two killer in the United States and a major cause of disability. In addition, stroke affects some segments and regions of our population more than others. I understand that the State of Hawaii ranks 20 out of 52 highest in our Nation for age-adjusted stroke deaths. Death rates from a certain type of stroke (intracerebral hemorrhage) are higher among Asians/Pacific Islanders than among Whites. More than 20 percent of Native Hawaiians or other Pacific Islanders have high blood pressure, a leading risk factor for stroke. Yet, the NIH invests only 1 percent of its budget on stroke research. What is your Institute doing to address the disparities that exist in stroke burden among different cultural and racial populations in the United States?

Answer. Stroke research at the NIH is comprehensive and includes research on basic disease mechanisms; epidemiology studies to assess stroke risk, occurrence and outcomes in the population; clinical research to develop effective prevention and acute treatment approaches; and development of strategies for improving recovery and rehabilitation in stroke patients. Clinical research in stroke is particularly a high priority at the National Institute of Neurological Disorders and Stroke (NINDS)—approximately 50 percent of its large Phase III trials are on stroke.

The NINDS also supports major research initiatives aimed at better defining stroke risk, incidence and outcomes in the United States and among different subpopulations. Collections of population-based data help identify and explain health disparities in stroke, and inform the development of preventive interventions that target high risk populations.

—In the Reasons for Geographic and Racial Differences in Stroke (REGARDS) study, investigators are exploring the geographical and racial influences on stroke risk in a cohort of about 30,000 individuals, about half of whom live in the "stroke belt" region of the Southeastern United States. This large study has produced over 70 publications that have led to a better understanding of disparities in stroke in the United States. Data generated from this study continue to help researchers pinpoint why the stroke rate is higher in this region, and among African Americans, and to develop targeted strategies for intervention. Recent data from REGARDS indicated that overall time spent in the stroke belt is more predictive of hypertension—a powerful risk factor for stroke—than is current residence in the stroke belt. Data from the REGARDS study have also revealed that stroke survivors were more likely to have unrecognized hypertension and diabetes.

—The Stroke Disparities Program is a multi-component program to address major stroke challenges in the African American community. The three projects in this program include:

  —an intervention strategy to increase stroke knowledge and reduce the time from symptom onset to hospital arrival (ASPIRE);

  —an intervention utilizing navigators for secondary stroke prevention that targets adherence to poststroke care (PROTECT DC); and

  —an observational imaging study to better understand racial and ethnic differences in risk, occurrence and outcomes of small brain hemorrhages (DECIPHER).

—The NOrthern MAnhattan Study (NOMAS) investigators have been following a cohort of stroke-free adults, including whites, African Americans and Caribbean Hispanics in a Northern Manhattan community. Researchers are collecting imaging, biological and neuropsychological data to evaluate the relationship between biological and imaging predictors for stroke, heart attack and death, as well as cognitive decline. Using these markers in combination with other factors such as diet, alcohol use, smoking, and history of peripheral vessel disease, investigators are developing risk factor and cognitive ability assessment tools. Genetic studies involving this and other cohorts, have suggested that there may be genetic susceptibilities underlying left atrium size and atherosclerosis of the carotid arteries that contribute to stroke.

—BASIC (Brain Attack Surveillance in Corpus Christi) investigators are comparing trends in recurrent stroke, as well as functional and cognitive outcomes

following stroke, in 5,000 non-Hispanic whites and Mexican Americans in Corpus Christi, Texas. Data from this study have shown that Mexican Americans with atrial fibrillation are more likely to have recurrent strokes than whites, and the strokes are more likely to be severe. The investigators are also exploring associations between biological and social stroke risk factors, and recently found, for example, that the density of fast food restaurants was associated with neighborhood stroke risk.

—Ethnic and Racial variation in Intracerebral Hemorrhage (ERICH), a study that was initiated in 2010, will identify differences in intracerebral hemorrhage (ICH) risk factor distribution and outcomes by race and ethnicity. This project will compare 3,000 cases of ICH, among African Americans, Hispanics and non-Hispanic whites, to 3,000 demographically matched controls in order to identify differences in risk factor distribution and ICH outcome by race, ethnicity and location of ICH and to determine differences in imaging characteristics among African Americans and Hispanics compared to whites. The investigators will also collect DNA in order to combine with other cohorts to perform a genome-wide association study (GWAS) to identify genes that affect risk of ICH in whites, African Americans and Hispanics.

—The Alaska Native Stroke Registry (ANSR) is a population-based surveillance study on the epidemiology of stroke in Alaska Natives. Comprehensive assessment of the stroke epidemiology, vascular risk factors, cultural understandings of vascular health and lifestyle, and structural barriers to risk reduction strategies has informed the development of a community level prevention intervention pilot program that aims to reduce the burden of stroke in the Alaska Native population.

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## QUESTIONS SUBMITTED BY SENATOR HERB KOHL

### COMPARISON OF AGE-RELATED MACULAR DEGENERATION TREATMENTS TRIALS

*Question.* The National Institutes of Health (NIH) recently released results of the Comparison of Age-Related Macular Degeneration Treatments Trials (CATT), which found that Lucentis and off-label Avastin are similarly efficacious at treating neovascular age-related macular degeneration (wet AMD). Now that the CATT study is released, what is the NIH going to do with the results? The taxpayers spent millions of dollars on the CATT study to determine the comparative effectiveness of the drugs. I believe the trial results ought to be actionable.

Answer. The National Eye Institute (NEI) recognizes its responsibility to fund and conduct scientifically valid clinical research and to disseminate the study results to the professional clinical community and the public.

We collaborate extensively with ophthalmic organizations to apprise their members of CATT results. In particular, outreach to professional groups was the most effective and efficient means of reaching the clinical ophthalmic community regarding CATT findings. For example, the American Academy of Ophthalmology (AAO) has 30,000 member ophthalmologists who are the primary eye care professionals that treat wet AMD. The NEI worked with AAO to disseminate CATT results through the AAO's Website, newsletters, press releases, and its upcoming annual meeting. Additionally, the AAO Executive Director has written extensively to the membership in support of CATT. We will continue to work with AAO as they develop "preferred practice plans" for the treatment of wet AMD. The Association for Research in Vision and Ophthalmology (ARVO) is a 12,500 member eye research organization comprised of clinicians and investigators. CATT investigators presented their results at ARVO's annual meeting in May 2011. These two organizations will continue to provide information and guidance to their members about CATT so that the results can inform clinical care decisions.

The NEI is also working to inform the public about the CATT findings. The release of the study was accompanied by an extensive media outreach campaign. For example, the NEI hosted a news briefing for journalists where the NEI Director and CATT investigators presented study findings and fielded questions from more than 60 media outlets. Supplemental background video footage was made available to broadcast outlets. A press release was also distributed widely to media outlets. The NEI generated robust media coverage for CATT, coverage that has been intense and more widespread than for other recent studies (see accompanying table), despite media competition from the royal wedding and the death of Osama Bin Laden. As follow-up to the initial media coverage, the NEI distributed CATT results to members of the National Eye Health Education Program (NEHEP), a partnership of 60 public and private organizations dedicated to eye health education. This program

provides the NEI with direct access to community-based public health education efforts, and we are preparing an NEI webpage devoted to CATT along with a brochure including public health information about CATT.

Of note, the May publication of CATT reported on first year results. The second year results will be published in the spring of 2012. At that time, the NEI will repeat its efforts with professional organizations and the media to disseminate CATT results.

NEI CLINICAL TRIAL MEDIA COVERAGE

| Study name | Impressions (millions) [1] | Number of original news stories | Pick-up of original news stories [2] |
|---|---|---|---|
| *CATT.*—Comparison of AMD Treatment Trials (2011) | 296 | 157 | 234 |
| *ETROP.*—Early Treatment for Retinopathy of Prematurity Study (2010) | 257 | 20 | 138 |
| *DRCR–DME.*—Ranibizumab plus laser therapy for diabetic macular edema (2010) | 232 | 42 | 29 |
| *ACCORD.*—Action to Control Cardiovascular Risk in Diabetes Eye Study (2010) | 8 | 9 | ([3]) |
| *GWAS–AMD.*—Genome-wide association study genes associated with AMD (2010) | 16 | 13 | 6 |
| *LALES.*—Los Angeles Latino Eye Study (2010) | 3 | 7 | ([3]) |
| *Myopia.*—Increased pevalence of myopia in United States (2009) | 158 | 76 | ([3]) |
| *SCORE.*—Standard Care vs. Corticosteroid for Retinal Vein Occlusion (2009) | 150 | 27 | 79 |
| *LCA.*—Leber Congenital Amaurosis (2009) | 155 | 32 | 37 |
| *CITT.*—Convergence Insufficiency Treatment Trial (2008) | 44 | 117 | 183 |
| *CDS.*—Cornea Donor Study (2008) | 63 | 118 | 74 |
| *AREDS2.*—Age Related Eye Disease Study 2 (2006) | 17 | 92 | ([3]) |

[1] *Impressions.*—Number of people exposed to the news story in print, online, or on television based on expected readership or viewers.

[2] *Pick-up.*—When an original story is reprinted in another outlet (i.e., an Associated Press article is printed in The Washington Post), it is counted as a pick-up.

[3] Not applicable.

*Question.* How does the NIH share this information with other agencies within the Federal Government?

Answer. In the preparation for the release of CATT, the NEI held a teleconference with relevant Department of Health and Human Services (HHS) agencies (FDA, CMS, CDC, and AHRQ) to inform them of CATT results and to coordinate the HHS response to media. In accordance with standard HHS and NIH operating procedures, the NEI distributed a draft press release for clearance within DHHS and responded to various issues prior to approval for release. This effort helped ensure a coordinated HHS response to CATT. Since this initial interaction, both the NEI staff and CATT leadership have been contacted by CMS staff to discuss the implications of the CATT study results.

*Question.* Has the NIH's National Eye Institute considered what effect, if any, the CATT study might have on future physician prescribing behavior regarding Lucentis vs. off-label Avastin to treat wet AMD?

Answer. Avastin, which inhibits the formation of new blood vessels, was approved by the FDA in 2004 for the treatment of colon cancer. Avastin is effective as an anticancer agent because inhibiting the blood supply to tumors inhibits their growth. Since wet AMD is due to leakage from new, abnormal blood vessels, ophthalmologists began trying Avastin off-label to treat this form of AMD in 2006 on the basis of both the cancer data and clinical trial results for Lucentis during the FDA approval process. At that time, Avastin off-label was the only available treatment for wet AMD that led to improvement in vision.

The vast majority of patients treated for wet AMD participate in Medicare. After Lucentis was FDA-approved in 2007, most ophthalmologists continued to use Avastin because the cost was significantly lower than for Lucentis and because a number of reported cases demonstrated Avastin efficacy that appeared similar to that reported in the Lucentis clinical trials. Last May, Dr. Ross Brechner and colleagues (Centers for Medicare and Medicaid Services) and Dr. Phillip Rosenfeld (Bascom Palmer Eye Institute, University of Miami) published an analysis of Medi-

care claims for wet AMD during 2008.[1] They found that 64.4 percent of patients received Avastin and 35.6 percent received Lucentis and concluded that despite its off-label designation, intravitreal Avastin is currently standard-of-care treatment for wet AMD. Medicare payments totaled $536.6 million for Lucentis and $20.3 million for Avastin.

CATT was a very tightly controlled, well-designed study, which compared the two drugs in more than 1,100 patients. The exceptionally wide dissemination of CATT results means that the retinal specialists who treat AMD and the patients they care for are undoubtedly well aware of the equivalence. As such, an increase in the number of patients receiving Avastin as first line therapy is to be expected. Careful monitoring of use of the drugs by CMS is expected.

Importantly, some patients with wet AMD respond better to Avastin, while others to Lucentis. In practice, if one is ineffective, the other may be tried. The fact that more than one drug is available is beneficial and allows ophthalmologists and patients treatment choices.

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## QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

### INTERIM STATUS OF IDeA PROGRAM

*Question.* Scientists have expressed their concern about programs that have been placed before under "interim" status and tend to lose direction and in some cases have disappeared. I am particularly concerned about the Institutional Development Award (IDeA) Program, which is so important to Louisiana. What is the reason for placing a program that serves 23 States and Puerto Rico on an interim status?

Answer. The IDeA Program has not been placed in an interim status. Under the proposed creation of the National Center for Advancing Translational Sciences (NCATS), we considered moving the program to a new unit called the Office of Research Infrastructure Programs within the Office of the Director, Division of Program Coordination, Planning, and Strategic Initiatives. However, following extensive consultation and feedback from multiple stakeholders, including grantees, professional organizations, and the public, we concluded that the IDeA program is most closely aligned scientifically and programmatically with the mission and goals of the National Institute of General Medical Sciences (NIGMS). Therefore, the National Institutes of Health (NIH) intends on moving the IDeA program and the IDeA program staff to the NIGMS. We are confident the program will flourish as a vital component of the NIGMS.

### PLACEMENT OF NATIONAL CENTER FOR RESEARCH RESOURCES (NCRR) PROGRAMS

*Question.* For many years the programs housed at the NCRR have worked synergistically to serve the IDeA community. Can this synergy continue by placing these programs under a single NIH institute?

Answer. There is no reason why synergies established between IDeA and other NCRR programs will not continue to flourish at both the national level through programmatic communication and collaboration across institutes and centers and at the local level through institutional collaborations and interactions. Fostering collaborative research networks is an inherent part of the IDeA mission, and it excels at establishing connections and linkages. IDeA institutions currently collaborate with grantees of the Research Centers in Minority Institutions (RCMI) program as well as the Science Education Partnership Award Program (SEPA). The NIH encourages such collaborations, and they will continue.

### PLACEMENT OF IDeA WITHIN THE NATIONAL INSTITUTE OF MINORITY HEALTH DISPARITIES (NIMHD)

*Question.* It has been made public that some institute directors who have been approached to house IDeA programs have voiced reservations about housing these programs in their institutes based on their programmatic mission and staffing needs. We also know that the Advisory Council for the NIMHD has enthusiastically endorsed the idea of placing these programs in the NIMHD. Have you considered the possibility of placing these programs under the management of the NIMHD?

Answer. An NIH National Center for Research Resources (NCRR) Task Force, charged with identifying the optimal new home for the IDeA program, considered a range of options, including its placement within the NIMHD. After careful anal-

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[1] Brechner, R. J, P. J. Rosenfeld, J. D. Babish, and S. Caplan. Pharmacotherapy for Neovascular Age-Related Macular Degeneration: An Analysis of the 100 percent Medicare Fee-For-Service Part B Claims File. *American Journal Ophthalmology 151:887–895, 2011.*

ysis, fact-finding, and consultation, the Task Force recommended that this program be transferred to the National Institute of General Medical Sciences (NIGMS). The IDeA program fosters health-related research and enhances competitiveness of investigators at institutions located in States in which the aggregate success rate for applications to the NIH has been historically low. By its nature, the program extends beyond traditional capacity building in supporting research projects that are designed to strengthen future investigator-initiated research applications, most of which are focused on addressing basic science questions. The NIGMS has a basic science focus as well as a longstanding focus on institutional capacity building and career development. Given these synergies, the Task Force determined that the mission of the IDeA program is most closely aligned with the mission of the NIGMS and that the NIGMS would be the optimal new home for the IDeA Program.

THE CLINICAL AND TRANSLATIONAL SCIENCE AWARDS (CTSAS) AND THE NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

*Question.* With the final five CTSAs expected to be announced in the near future, I have a couple of questions for Dr. Collins on this program's future direction now that it is being moved to the new NCATS.

Because the NCATS is primarily focused on drug development, what will become of the community research and integration aspect of the CTSAs' mission? Will community involvement continue to be a central focus of this program?

The CTSAs represent translational research across the country, but there are no centers in the gulf south—an area with significant health needs that would benefit greatly from a CTSA and could contribute much to the network of centers. Is geographic distribution considered as CTSA sites are being selected?

Answer. The mission of the NCATS will be to catalyze the development of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. In addition to strengthening and streamlining the therapeutics development process, the NCATS will support research aimed at accelerating the development, testing, and implementation of products and techniques, including diagnostics, drugs, biologics, medical devices, and behavioral interventions, for the diagnosis, treatment, and prevention of disease. The CTSAs possess the requisite expertise across the full spectrum of translational research, and they will be integral to the success of the NCATS. The involvement of research sites across the Nation and the study of the integration of research findings at the community level will continue to be an important focus of the CTSA program.

Institutions with CTSAs that are either close to or interact with communities and populations along the Gulf include the University of Texas Medical Branch in Galveston and the University of Alabama in Birmingham. The CTSA at the University of Texas Health Sciences Center at Houston serves gulf communities through its strong connections to UT's Brownsville campus.

With regard to the selection of the CTSA sites, NCRR has used the peer review process to establish priority scores to guide funding decisions. All applications, together with their priority scores, were then reviewed by the National Advisory Research Resources Council, which is able to make recommendations, where needed, concerning geographic distribution. Going forward, scientific merit will continue to be the principal selection criterion, and considerations of program relevance and public health need will be factored in at subsequent levels of review.

GEOGRAPHIC DISTRIBUTION OF SMALL BUSINESS INNOVATIVE RESEARCH (SBIR) GRANTS

*Question.* As one of the largest funders of SBIR grants, can you tell me what the NIH is doing to ensure that there is a more balanced portfolio and increased participation from States that have traditionally received a small number of SBIR grants?

Answer. The NIH prioritizes SBIR and Small Business Technology Transfer (STTR) outreach to States that historically have submitted a small number of SBIR applications and/or have lower success rates than the overall SBIR/STTR success rates. Each year, we hold an annual SBIR/STTR conference, this year on the NIH's campus in Maryland, but in past years in Ohio, Nebraska, Nevada, Georgia, and North Carolina. We also participate in direct one-on-one contact with current and potential applicants/grantees in several national, State, and regional SBIR events per year. Currently in fiscal year 2011, the NIH staff have already attended, presented, or participated on the SBIR program in Arizona, California, Florida, Kansas (via webinar), Kentucky, Maine, Maryland, Michigan, Missouri, Nebraska, New York, Virginia, Washington, DC, and Wisconsin. On the horizon is an event in Louisiana. These conferences attract attendees from across the country, and offers attendees an opportunity for one-on-one consultations with the NIH SBIR/STTR

program, review and grants management staff. In addition, there are a number of other conferences/meetings in which the NIH offers consultation to SBIR/STTR applicants and similar outreach is conducted by the individual NIH Institutes and Centers. In all venues, the NIH educates as many current and potential applicants/grantees as possible about the SBIR program.

In addition to these in-person opportunities, the NIH staff are available to provide assistance to all applicants from concept development through grant life-cycle by phone, email, webinars, and our Web sites. SBIR funding decisions ultimately are made at the NIH Institute level and are based on scientific merit (as determined by our two level peer-review system), available funding, and programmatic priority. Information about all NIH grant awards, including State location, can be accessed through our RePORTER Web site at http://projectreporter.nih.gov/reporter.cfm.

ANTIVIRAL DEVELOPMENT FOR FLU

*Question.* Discussions regarding the prevention of a flu pandemic frequently focus on vaccine development, but it is my understanding that effective management of influenza will require the continued development of new antiviral drugs. I was pleased to learn that the National Institute of Allergy and Infectious Diseases (NIAID) recently held a workshop on the influenza antiviral research pipeline. Are we making progress in the development of antiviral drugs for influenza and does the NIAID have plans for any new initiatives in this area?

Answer. In March 2011, the NIAID held the Influenza Antiviral Research Pipeline Workshop, which brought together stakeholders from a variety of sectors including academia, business, and government. Discussions focused on the state of influenza antiviral research and spanned all aspects from discovery to advanced clinical development. Workshop proceedings will be posted on the NIAID Web site in the near future.

Currently, there are four drugs licensed to treat influenza: oseltamivir (Tamiflu®), zanamivir (Relenza®), rimantadine (Flumadine®), and amantadine (Symmetrel®). Ongoing NIAID efforts in influenza drug development include combination studies with licensed and experimental drugs, studies of the safety of antiviral drugs in infants and children, studies of broad-spectrum antivirals, studies of antibody therapeutics, and evaluation of novel drug targets. For example, the NIAID also supports in vitro and in vivo antiviral screening and other preclinical services to identify new antiviral candidates. In fiscal year 2010, more than 100,000 compounds were evaluated by high-throughput screening assays against multiple influenza A strains, and several hundred compounds were tested for their efficacy against influenza in animal models. Also, the NIAID is supporting the preclinical and clinical development of a novel antiviral drug candidate; a safety study has been completed and a Phase II clinical trial is ongoing.

To meet the need for effective influenza management strategies, the NIAID will continue to support a robust influenza antiviral research portfolio, including discovery of drug targets, identification of compounds with novel mechanisms of action, and clinical studies to evaluate promising drug candidates.

STROKE IN WOMEN

*Question.* My State of Louisiana lays in the Stroke Belt, a group of Southeastern States where stroke death rates are the highest in our Nation. I am concerned about the seriousness of stroke, particularly among women who account for 61 percent of stroke fatalities. Please tell this subcommittee what studies the NIH is conducting to combat stroke in women, including prevention and rehabilitation efforts. In addition, please highlight planned activities in these areas.

Answer. The National Institute of Neurological Disorders and Stroke (NINDS) supports a large and broad portfolio of stroke research that includes numerous efforts to better understand and address the substantial burden that stroke places on women.

The NINDS supports multiple research studies on the physiological basis for gender-related differences in stroke risk and outcomes. One study funded by the NINDS and the National Heart, Lung, and Blood Institute (NHLBI) will follow a cohort of women to identify biological and physiological markers associated with ischemic stroke, and to establish which of those are influenced by sex hormones or menopausal status. This study will inform future development of gender-specific predictors for stroke risk. In another study, investigators will explore how biological functions programmed by sex-specific chromosomes are related to gender differences observed in cell death pathways activated by a stroke. The NINDS also funds a study to investigate the role of estrogen receptors in gender-related differences in incidence of stroke associated with cardiovascular surgical procedures.

The NINDS supports a number of surveillance studies that aim to illuminate differences in stroke knowledge, risk and outcomes among different sub-populations, including women, in order to inform development of tailored prevention intervention strategies. For example, the Reasons for Geographical and Racial Differences in Stroke Study (REGARDS) is a large cohort of more than 30,000 participants, more than half of whom are women. This comprehensive assessment of disparities in stroke risk and incidence is one of the largest longitudinal cohort studies of African Americans and the only national study of the epidemiology of cognitive change. The large representation of women in this important population-based study is significant as it allows for data analyses of gender-specific differences, as well as among different racial populations. For example, a recent publication from this study revealed that markers for inflammation led to more accurate vascular disease risk stratification, particularly in blacks and women, since they are at higher risk for increased levels of this marker. Studies from REGARDS will continue to improve our understanding of differences in stroke risk among a diverse U.S. population.

The NINDS supports a large number of clinical studies to improve acute management and long-term outcomes in stroke. All of the NIH-funded clinical trials are required to set and justify target enrollment by race, ethnicity, and gender and to report on enrollment progress. Approximately half of the participants in all of the NINDS-supported stroke clinical trials are women so that data can be analyzed for gender-specific differences. These trials are investigating new approaches to treat acute stroke and brain hemorrhage, to reduce brain damage due to stroke and to improve rehabilitation strategies, which will provide all patients, including women, and their physicians with more therapy options and a better chance of survival and recovery after a stroke.

The NINDS is embarking on a new stroke planning effort in 2011 to update research progress and activities in response to prior research recommendations, and to identify a specific set of high priority areas for advancing stroke research over the next 5–10 years. The planning effort will specifically address stroke prevention, treatment, and recovery in subpopulations, with a special emphasis on women and gender differences. Recommendations from this planning effort will inform future NINDS research investment and activities related to stroke in women.

NCI PRIORITIES

*Question.* Dr. Varmus, you have stated a desire for the NCI to continue to fund as many grants as in previous years, even if this means cuts in other areas, such as the Cancer Center program. Could you tell us a bit more about your plans and priorities for the institute and possible changes on the horizon?

Answer. Cancer is a complex disease requiring many approaches to make progress. It is important to fund as many meritorious grants as we possibly can within the resources we are given, because individual grants allow us to pursue new ideas effectively. We will be finding savings across the Institute by taking money away from routine administrative expenses, making cuts to the intramural and Cancer Centers programs, and by conducting reviews of large programs and cutting where possible. This will allow us to achieve acceptable grant levels and to protect certain imperatives.

In addition, realignment of the clinical trial cooperative groups, as recommended by the Institute of Medicine report in 2010, will improve the efficiency of the overall system and enable the cooperative groups to conduct state of the art oncology research more consistently. Funding for this effort is a priority for the NCI. A second imperative is maintaining the pace of work on cancer genomics. The Cancer Genome Atlas (TCGA), a project undertaken by the National Cancer Institute and the National Human Genome Research Institute to gain an understanding of the molecular basis of cancer, has already produced results in brain cancer and ovarian cancer. The rate of discovery is dependent on the level of funding. Therefore, we place a high priority on protecting funding for this project and other meritorious efforts in cancer genomics. As TCGA is expanded to include many cancer types, the ultimate goal is to ensure that genetic information is applied to prevention, diagnosis, and treatment of cancer in clinical practice.

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## QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

ECONOMIC BENEFITS OF BIOMEDICAL RESEARCH

*Question.* According to a recent Families USA report, every $1 investment in medical research stimulates $2.43 in business activity—such as support staff, supplies, food services, and building development. Are you aware of other studies that at-

tempt to quantify the local impact of the Federal investment in medical research? Are there any efforts underway at the NIH to capture the return-on-investment that taxpayers receive as a result of the Federal commitment to research?

Answer. To the best of our knowledge, there are two comprehensive published studies that attempt a quantification of the economic effects of the NIH spending at the State level, both supported by research advocacy groups. Both studies rely on the Regional Input-Output Modeling System (RIMS II), developed by the Bureau of Economic Analysis at the Department of Commerce. RIMS II measures, at a State level, the economic multiplier effect generated by local demand. National aggregate averages are extrapolated from State data.

The first report was released in June 2008 by Families USA and was titled "In your own backyard."[1] The report found, among other things, that in fiscal year 2007, the NIH funding supported more than 350,000 jobs that generated wages in excess of $18 billion in the 50 States. The average wage for these jobs was $52,000. It also found that $1 spent by the NIH funding generates $2.21 of business activity at the State level. This $2.21 figure is an average; individual States may vary (e.g., in Illinois, the figure is $2.43.)

More recently, in May 2011, the organization "United for Medical Research" released a report, titled: "An Economic Engine. NIH Research, Employment and the Future of the Medical Innovation Sector."[2] The report draws three conclusions: the NIH extramural research is an important source of income and employment around the country; the complementary relationship between public NIH investment and private industry development is critical to the health and well-being of our Nation; and the U.S. medical innovation sector is facing increasing challenges in maintaining America's competitiveness and position as the world leader in medical research. The report found that in fiscal year 2010, the NIH directly and indirectly supported nearly 488,000 jobs and produced $68 billion in new economic activity and that $1 of the NIH investments generated, on average, $2.60 of business activity, at the national level.

The NIH has worked closely with experts in the field of labor and health economics and R&D evaluation on several projects. One of the studies found that a one dollar increase in the NIH funding leverages an additional 35 cents in funding from non-Federal sources.[3]

Another study determined that 33 percent of all drugs approved by FDA and 58 percent of approved priority review new molecular entities (which tend to be the most innovative drugs) cite an NIH-funded publication or an NIH patent.[4]

Another study showed that multinational companies in the pharmaceutical sector tend to locate their R&D facilities next to hubs of skilled workers. This finding underscores the importance of the NIH investments in sustaining a strong research infrastructure system in the United States and avoiding the loss of private sector investments in R&D that could be moved abroad.[5]

Another study, Economic Impact of the Human Genome Project (http://www.battelle.org/publications/humangenomeproject.pdf), which was commissioned by the Life Technologies Foundation and prepared by the Battelle Technology Practice Foundation, assessed the benefits of the Federal investment of the Human Genome Project (HGP). Finding that the benefits are widespread and increasing over time, the report cites among other factors, the production of 3.8 million job-years of employment (one job-year for each $1,000 invested) and the generation of personal income (wages and benefits) exceeding $244 billion over the last 7 years, an average of $63,700 per job-year.

With regard to whether there are other efforts underway at the NIH to capture the return-on-investment that taxpayers receive as a result of the Federal commit-

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[1] FamiliesUSA. (2008). *In Your Own Backyard: How NIH Funding Helps Your State's Economy*. Washington, DC. Retrieved December, 2008 from http://www.familiesusa.org/issues/global-health/publications/in-your-own-backyard.html.

[2] Ehrlich, E. (2011). United for Medical Research from http://www.unitedformedicalresearch.com/wp-content/uploads/2011/05/UMR__Economic-Engine.pdf.

[3] Blume-Kohut, M., Kumar, K. B., & Sood, N. (2008). *The Impact of Federal Funding on University R&D*. Retrieved November 7, 2009 from http://www.rand.org/labor/seminars/brown__bag/pdfs/2008__sood.pdf

[4] Lichtenberg, F. R., & Sampat, B. (2011). What are the respective roles of the public and private sectors in pharmaceutical innovation? *Health Affairs, 30*(2), 332–338.

[5] Thursby, J. G., & Thursby, M. C. (2009). *Is the US a Target of R&D Globalization? Location, Type and Purpose of Biomedical Industry R&D in New Locations*: NBER. Report prepared for the NIH Office of Science Policy Analysis.

ment to research, the NIH is also participating in the STAR METRICS Project.[6] [7] STAR METRICS is a collaboration between Federal science agencies and research institutions to document how Federal science investments support knowledge creation, economic growth, workforce development and a broad range of societal outcomes. The program's goal is to build a data infrastructure that will bring together inputs, outputs, and outcomes from a variety of sources in as open a fashion as possible.

STAR METRICS has two levels and the NIH participates in both. Level I documents the initial effect of S&T investments on employment using administrative records from research institutions. This approach goes beyond the RIMSII model, capturing the actual, rather than estimated, number of jobs supported. Level II builds on Level I by connecting sources of funding, recipients of funding, interactions among scientists (in both the public and private sector) and the products of research over time ranging from the most proximal (such as meeting presentations and publications) to more distal (such as the development of a new drug).

CONGENITAL HEART DISEASE (CHD)

*Question.* Congenital Heart Disease (CHD) is one of the most prevalent birth defects in the United States and a leading cause of birth defect-associated infant mortality. Due to medical advancements more individuals with congenital heart defects are living into adulthood. Please provide an update of research within the NIH, particularly the National Heart, Lung, and Blood Institute (NHLBI) related to congenital heart defects across the life-span. The healthcare reform law included a provision, which I authored, that authorizes the CDC to track the epidemiology of congenital heart disease, with an emphasis on adults with CHD and expanding surveillance. If adequately funded, how could a population-surveillance system for adults with CHD support the NIH's ability to investigate CHD across the life-course and across subgroups?

Answer. The NIH supports research on CHD across the lifespan. For example, as part of its Pediatric Heart Network, the NHLBI is following participants in an earlier study of the Fontan surgical procedure to assess functional health status, neurocognitive performance, and transitions from pediatric care to adult care for CHD. Through its Bench-to-Bassinet program, the NHLBI is examining the genetic causes of CHD and the effects of genetic variation on the long-term clinical outcomes of affected children as they grow older. The NHLBI also funds a research partnership between the Adult Congenital Heart Association and the Alliance of Adult Research in Congenital Cardiology that seeks to improve care delivery and long-term outcomes for adults with CHD and also to inform research designs for studies in adults. Through its Pumps for Kids, Infants, and Neonates (PumpKIN) program the NHLBI supports development of pediatric devices for congenital heart disease. In addition, an investigator-initiated project seeks to develop a blood pump for patients who have undergone the Fontan surgery. Patients who have had the surgery experience significant morbidity due to diminished blood flow, especially as they grow into adulthood, and a device to assist blood flow could dramatically improve care.

An adequately funded population-surveillance system for adults with CHD could facilitate the NIH research. The surveillance data would help the NIH ensure that its research efforts address the full range of heart conditions, risk factors, and complications across the lifespan; provide the potential to link genetic and other biological information; permit monitoring of the effectiveness of new preventive and therapeutic strategies; and identify a potential pool of patients who could benefit from participation in various research activities. However, funding was not provided for this provision in the Affordable Care Act, and no funds have been requested within the budget for the Centers for Disease Control and Prevention to implement it.

THE CANCER GENOME ATLAS

*Question.* The National Cancer Institute is making tremendous progress with the Cancer Genome Atlas (TCGA) in sequencing cancer genomes and then using scientific discoveries to further specific fields of cancer research. What is the status of the TCGA gastric cancer project? Specifically, the pilot project to utilize contiguous biopsies to sequence the genome for the diffuse gastric cancer subtype? How will the NCI utilize these groundbreaking discoveries to further the field of gastric

[6] https://www.starmetrics.nih.gov/.

[7] Lane, J., & Bertuzzi, S. (2011). Research funding. Measuring the results of science investments. *Science, 331*(6018), 678–680.

cancer research? What other initiatives and steps is the NCI taking to investigate gastric cancer?

Answer. TCGA staff and extramural researchers have been steadily working on identifying, collecting, and assessing the quality of gastric cancer biospecimens for inclusion into TCGA's genotyping and molecular characterization pipeline. However, due to the difficulty in obtaining qualifying biospecimens from patients with diffuse gastric cancer, the NCI began to explore a pilot project for collection of diffuse gastric cancer biospecimens. The challenges involved in this pilot project of multiple gastric biopsies was discussed in detail in May 2011 when the NCI hosted a workshop on gastric and esophageal cancer, bringing together a group of international experts to explore and discuss the basic biology, epidemiology, and clinical research aspects of these cancers across the world. There was tremendous interest in the pilot study from the gastric cancer researchers, and in June 2011 the NCI approved TCGA to proceed with the pilot study to collect biospecimens on a small number of diffuse gastric cancers from the United States. The extent of the project will depend on the cost per case and the number of centers willing to participate. We are hopeful that analysis of these biospecimens will yield valuable information that will stimulate novel research approaches for this challenging disease and will lead to advances in the prevention, diagnosis, and treatment of diffuse gastric cancer.

In addition to the TCGA-related efforts, an NCI Genome-Wide Association Study (GWAS) on gastric adenocarcinoma and esophageal squamous cell carcinoma has already revealed a common cancer susceptibility region at PLCE1, and the NCI is funding follow-up mechanistic studies on the effect of the gene variations in this location. A second GWAS will be conducted in a mostly Caucasian cohort to provide further clues about susceptibility regions and whether they differ between populations that experience different rates of gastric cancer. The NCI also funds broad based research at four Gastrointestinal Cancer Specialized Programs of Research Excellence (SPOREs), two of which include a focus on esophageal cancers.

EOSINOPHILIC-ASSOCIATED DISORDERS RESEARCH

*Question.* Eosinophilic-associated disorders were identified in the last decade. Consequently many people go undiagnosed for years, due to lack of information and awareness about these diseases. Please describe current efforts at the NIH, particularly the National Institute for Allergy and Infectious Diseases (NIAID) to investigate eosinophilic-associated disorders. Last year, the Senate budget included report language urging the NIAID to convene a working group to develop a research agenda aimed at improving the diagnosis and treatment of eosinophilic-associated disorders. What strides are the NIH and the NIAID making to develop a research agenda focused on these conditions?

Answer. As the lead institute at the NIH responsible for research on immunologic and allergic disorders, the NIAID is committed to research to better understand the mechanisms that mediate tissue injury when eosinophils accumulate, including eosinophilic gastrointestinal disorders, a group of recently recognized allergic diseases associated with the production of IgE antibodies and other immune responses to food. The NIAID works closely with other NIH Institutes and Centers supporting research on eosinophilic disorders. Although these collaborations and communications do not occur through a formal working group or a predetermined research agenda, they have led to jointly sponsored workshops and research initiatives on eosinophilic disorders. In fiscal year 2012, the NIH, with the NIAID as the lead, will establish a working group with participation by relevant NIH Institutes and Centers, to develop a trans-NIH strategy to improve the diagnosis and treatment of eosinophilic disorders.

As part of its overall research agenda on immunologic and allergic diseases, the NIAID pursues research on eosinophilic disorders through a variety of efforts and collaborations. For example, the Consortium of Food Allergy Research (CoFAR), cofunded with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and renewed in fiscal year 2010, develops new approaches to treat and prevent food allergy. A new CoFAR project is examining the genetic aspects of eosinophilic esophagitis. The NIAID Asthma and Allergic Diseases Cooperative Research Centers (AADCRC) support basic and clinical research on the mechanisms, diagnosis, treatment, and prevention of asthma and allergic diseases, including food allergy and anaphylaxis. Many of these disorders are associated with eosinophilia. In addition, the NIAID-supported investigators are conducting a pilot clinical trial to determine the efficacy of swallowed glucocorticoids for the treatment of eosinophilic esophagitis, and developing novel noninvasive diagnostic tools for eosinophilic gastrointestinal diseases to reduce the number of endoscopies and biopsies that are currently performed. Also, on behalf of more than 30 professional orga-

nizations, Federal agencies, and patient advocacy groups, including the American Partnership for Eosinophilic Disorders, the NIAID coordinated the development of Guidelines for the Diagnosis and Treatment of Food Allergy in the United States. This document includes clinical practice guidelines for the diagnosis and management of eosinophilic esophagitis associated with food allergy. The guidelines were published in the December 2010 issue of the Journal of Allergy and Clinical Immunology and can be accessed at: http://www.ncbi.nlm.nih.gov/pubmed/21134576.

The NIAID will continue its commitment to research and trans-NIH research collaborations on eosinophilic disorders to understand the mechanisms that mediate tissue injury when eosinophils accumulate. As part of this effort, in fiscal year 2011, the NIAID will recompete the AADCRC program.

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## QUESTIONS SUBMITTED BY SENATOR MARK PRYOR

### EXTRAMURAL RESEARCH BUDGET

*Question.* What percentage of the NIH's funding leaves the greater Washington, DC area and goes to medical research in States and local communities?

Answer. In fiscal year 2010, the NIH awarded 82 percent ($25.6 billion of $31.2 billion) of its budget to more than 3,000 institutions and organizations across the United States, as well as several other countries throughout the world, 71 percent ($22.1 billion) in grants and 11 percent ($3.5 billion) in research and development contracts. The percentage of the fiscal year 2011 budget devoted to extramural research is also expected to be approximately 82 percent. An overview of the NIH funding allocations by Institute and Center in fiscal year 2010, fiscal year 2011, and the fiscal year 2012 budget is available at: http://officeofbudget.od.nih.gov/pdfs/FY12/COPY%20of%20NIH%20BIB%20Chapter%202-9-11-%20FINAL.PDF.

### PERSONALIZED MEDICINE AS A PRIORITY

*Question.* As you well know, we are currently in a very difficult economic time. The Congress is in the process of making many decisions related to addressing the Nation's budget problems. We are considering many ways to control our costs and minimize additional debt, but at the same time, we have to prioritize and ensure that important programs are adequately funded. Having said that, do you believe advances in personalized medicine could be threatened should the Congress enact cuts to the NIH's budget?

Answer. Through the application of genomic research and high-throughput technologies, breakthroughs in our understanding of the causes of many diseases and the identification of new targets and pathways for the development of new therapeutics are within reach. For example, a decade ago, diagnosis of cancer was based on the organ involved and treatment depended on broadly aimed therapies that often greatly diminished a patient's quality of life. Today, research in cancer biology is moving treatment toward more effective and less toxic therapies tailored to the genetic profile of each patient's cancer. The NIH research is also identifying genetic markers that can predict whether an individual will respond well to a particular medication or will be at risk of having an adverse reaction. The NIH-funded researchers are also uncovering information about genes and the environment that will help point the way toward more personalized, targeted treatments for other diseases. The new National Center for Advancing Translational Sciences (NCATS) will provide the infrastructure and technologies to bring these critical basic discoveries to fruition through new diagnostics and therapeutics. Significant budget cuts could threaten the NIH's ability to continue to support these advances. However, the specific research areas that would be affected in the event that budget cuts materialize cannot be determined now since the NIH would need to re-evaluate its research priorities.

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## QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

### REORGANIZATION OF NCRR PROGRAMS

*Question.* There remain concerns within the Congress and the research community with the decision to eliminate the National Center for Research Resources (NCRR). Can you explain the rationale behind this decision and where the National Center for Research Resources' assets will be moved?

Answer. With the decision to move the Clinical And Translational Science Awards (CTSAs) into the proposed National Center for Advancing Translational Sciences (NCATS), it was necessary to consider the impact of its transfer on NCRR and

whether there were long-range benefits that could be achieved by relocating its remaining programs within other NIH components. A task force was formed to determine if the remaining programs should be kept in a separate organization or if there was an opportunity for greater scientific synergies by moving the remaining programs to other NIH components. The task force was guided by the following considerations and principles in developing its recommendations:

—The scientific synergies that could be achieved by placing the NCRR program in adjacency to existing (or in the case of the NCATS, proposed) portfolio/mission of the recipient IC versus the existing synergies among the NCRR programs.

—The "goodness of fit" for the NCRR program within the recipient IC versus the negative effects of adding a program that is disproportionately large and/or not well aligned to the recipient IC's current (or in the case of the NCATS, proposed) mission.

—The level of disruption to long-standing NCRR programs led by dedicated NCRR staff versus the disruptive innovation from reassigning NCRR staff to enable interactions with new colleagues and/or new programs.

The Task Force agreed with the SMRB recommendation that the CTSAs be placed in the proposed Center. The Task Force then determined that the greatest scientific synergies could be achieved by placement of the remaining programs to other components of the NIH. The Research Centers in Minority Institutions (RCMI) program was proposed for placement in the National Institute for Minority Health and Health Disparities; the Institutional Development Award (IDeA) program was proposed for placement in the National Institute for General Medical Sciences (NIGMS); the Imaging and Point-of-Care Biomedical Technology Research Center (BTRC) grants, and Biomedical Imaging, and Point-of-Care research grants for Technology Research and Development were proposed for placement in the National Institute of Biomedical Imaging and Bioengineering; the remaining BTRCs and all other research grants for Technology Research and Development, and the BIRN network grants were proposed for placement in the NIGMS; the Gene Vector Repository was proposed for placement in the National Heart, Lung, and Blood Institute; and the Comparative Medicine Program, Extramural Construction and Animal Facilities Improvement, Shared and High-End Instrumentation, and Science Education Partnership Awards (SEPA) were proposed for placement in a new Office of Research Infrastructure Programs in the Division of Program Coordination, Planning, and Strategic Initiatives in the Office of the Director.

The Task Force implemented a transparent process to collect and consider input from a wide range of internal and external experts, as well as stakeholders ranging from members of the public to members of the extramural research community. As the deliberations progressed, the NIH made information available to the public through a feedback page available on its website. The final Task Force recommendations were accepted by the NIH Director and the Secretary, and transmitted to the House and Senate Appropriations Committees in a letter dated June 6, 2011. Additional budget details on the reorganization were provided to the subcommittees on June 23, 2011.

### BASIC AND APPLIED RESEARCH BALANCE

*Question.* How do you balance the NIH's goals in research aimed at knowledge generation (basic research) versus translation of that knowledge toward cures and improving human health (applied research)? Will the NCATS help to achieve a better balance?

Answer. Basic research advances knowledge of fundamental biological processes and elucidates the molecular underpinnings of human health and disease. Basic research makes it possible to understand the causes of disease onset and progression and opens up new avenues for developing new and improved diagnostics, therapeutics, and preventive strategies. Realizing the benefits of fundamental biomedical discoveries depends on the translation of that knowledge into strategies and products that treat disease and sustain and improve health. It is important to understand that "basic" and "translational" research are inherently interrelated and comprise a cyclical process. There are important feedback loops between the fields so that advances in one ultimately yield new avenues for scientific inquiry and discovery in the other. Breakthroughs in our understanding of therapeutic targets and pathways also stimulate new avenues for basic scientific inquiry. By studying the process of developing new therapeutics and diagnostics in an open access environment, the NCATS will ultimately catalyze the cycle of discovery in order to advance public health.

From a funding standpoint, 54 percent of the NIH budget is devoted to basic research and 46 percent to applied research, a ratio that has not varied appreciably for decades. The NIH does not intend to shift resources currently devoted to basic research to fund translational research. The NCATS will be formed through the realignment of existing translational research programs and, as such, will not affect the balance of basic and applied research supported by the NIH. It will certainly use discoveries made through basic research to advance its work while also providing important insights for basic scientists to pursue.

MOLECULAR LIBRARIES PROGRAM AS PART OF THE NCATS

*Question.* Dr. Collins, can you discuss the NIH Roadmap Molecular Libraries Probe Production Center Network component of the NCATS. I understand that this national network of centers provides for the first time a sophisticated infrastructure for drug discovery to the academic and nonprofit research community. What role will this program play in the NCATS going forward?

Answer. The NIH Molecular Libraries Probe Production Center Network (MLPCN), a component of the NIH Molecular Libraries Program (MLP), is a collaborative research network that enables the generation of effective and useful small molecule chemical probes for the entire biomedical research community. Through support from the NIH Common Fund, the MLPCN offers biomedical researchers access to large-scale screening capacity, along with medicinal chemistry and informatics needed to convert the large number of active compounds identified by high-throughput screening into useful probes for studying the functions of genes, cells, and biochemical pathways. Traditionally, these resources and associated expertise have resided exclusively within the private sector.

By providing early stage chemical compounds to the biomedical research community, the NIH anticipates that the components of the MLP can further enable researchers in both the public and private sectors to validate new drug targets, which could then move into the drug-development pipeline. This is particularly true for rare diseases, which may not be attractive for development by the private sector. For this reason, several components of the Common Fund's MLP are transitioning to be funded and managed through the NCATS. These include the Small Molecule Repository, Cheminformatics/PubChem, and the NIH Chemical Genomics Center (NCGC), an intramural high-throughput screening Center. The Common Fund will continue to provide support for the Chemical Diversity technology development program, the Imaging Probe Database, and the extramural Specialized Screening Centers.

THE NIH, ACADEMIA, AND INDUSTY RELATIONSHIP

*Question.* Much of the country's translational research has been within the pharmaceutical industry and the biotechnology community. Can you elaborate on the relationship between the NCATS and these entities? Is there a change in roles in academia and the commercial world?

Answer. The process of translating fundamental knowledge into new or better clinical applications is an exceedingly complex, costly, and risk-laden endeavor. Moreover, the average length of time from target discovery to FDA approval of a new drug is 14 years and the failure rate exceeds 95 percent, i.e., fewer than one out of twenty projects that enter the drug development pipeline will result in a new FDA-approved product. At the same time, recent progress in genomics, biotechnology, and other fields of biomedical research has advanced the potential for development of new diagnostics and treatments for a wide range of diseases, opening a wide door of opportunity in translational science.

There is a growing recognition on the part of all those involved in translational medicine that the current model for development is not sustainable and that novel partnerships and collaborations are critical to progress. The NIH is uniquely positioned to help bring about the changes by complementing the translational efforts of each sector. To achieve this goal, the NCATS will bring together resources and skilled scientists to study the steps in the therapeutics development and implementation process, consult with experts in academia and the biotechnology and pharmaceutical industries to identify bottlenecks in the processes that are amenable to reengineering, and develop new technologies and innovative methods for streamlining the processes. Cross-sector collaborations will be an essential part of how the NCATS operates.

FUTURE OF R01 FUNDS

*Question.* Will the establishment of the NCATS result in the loss of R01 funds?

Answer. No. Funds for research project grants will not be affected by the establishment of the NCATS, which is being created by realigning several existing NIH translational research programs. The NCATS will stimulate the pursuit of new avenues of scientific inquiry by facilitating and complementing translational research efforts carried out elsewhere at the NIH. It will not diminish the agency's commitment to basic science. Moreover, the NIH requested an additional $100 million for the operation of the Cures Acceleration Network within the NCATS, some of which would be used for research project grants.

PROCESS INNOVATION AND THE NCATS

*Question.* Dr. Collins, you have stated that "process innovation" is an important component of the NCATS. Can you explain what this is and why it is important? How will process innovation relate to individual disease-focused projects the NCATS may do?

Answer. Process innovation involves studying the therapeutics development process with the goal of developing new approaches and technologies that can strengthen and streamline the development pipeline itself. By approaching the development pipeline as a scientific question, the NCATS will identify bottlenecks in the processes that are amenable to re-engineering and develop new technologies and innovative methods for improving and advancing the discovery, testing, and implementation of new therapeutics. Among the specific developmental steps that may be addressed are target validation, preclinical toxicology testing, clinical trial design, and drug rescue and repurposing. In order to evaluate these innovations and new approaches, the NCATS will undertake targeted therapeutics development and implementation projects that may have relevance to individual disease-focused projects.

REORGANIZATION OF THE COMPARATIVE MEDICINE PROGRAM

*Question.* I have heard from several elite schools of medicine, including Stanford, MIT, UAB, and Auburn that splitting the components of the National Center for Research Resources' Comparative Medicine program into different administrative entities would have a negative impact on the NIH's critical scientific infrastructure. Dr. Collins, can you address their concerns and share with the subcommittee a solution to ensure components of the Comparative Medicine program remains intact and together within the new organizational structure?

Answer. Initially, we had considered a number of options with regard to the placement of the programs within the Division of Comparative Medicine, including dividing them among relevant institutes and centers. However, following extensive consultation with multiple stakeholders, including grantees, professional organizations, and the public, we concluded that it was important to keep the programs within the Division of Comparative Medicine together because of their intrinsic uniqueness and synergies. As such, the Division of Comparative Medicine is to be transferred in its entirety to the new Office of Research Infrastructure Programs in the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director.

BROADENING THE IDeA PROGRAM

*Question.* The National Center for Research Resources' Institutional Development Award program broadens the geographic distribution of the NIH funding for biomedical and behavioral research. It is my understanding that the goal of the program is to expand biomedical research capabilities to areas that currently lack it through research and infrastructure funding opportunities and faculty development.

In its entirety, Alabama is a significant recipient of the NIH funding, mainly due to the research funding received by its two medical schools. While they provide great benefit to my State and Nation through medical breakthroughs and economic investment, I am concerned that their success puts other Alabama institutions at a competitive disadvantage with similar institutions in IDeA-eligible States.

Has the NIH considered ways to include institutions in this program from non-IDeA eligible States? If not, are there other avenues within the NIH that could serve a similar role to IDeA for schools in States where one or two universities' significant NIH funding limits their access to preliminary support?

Answer. The current authorization language for the IDeA program limits participation in the program to institutions located in States with low aggregate success rates for obtaining NIH funding or States that do not attain a particular level of support from the NIH. It does not allow for participation by institutions from States with high success rates or States that receive substantial support from the NIH. In 2008, a working group of NCRR's advisory council, which was formed to review the eligibility criteria for the IDeA program, explored whether it would be possible to

base eligibility on institutional or regional success rates. The group was unable to identify an alterative approach that met the intent of the law.

In States that are not eligible for IDeA, institutions with limited NIH funding are encouraged to participate in are encouraged to apply for Academic Research Enhancement Awards (AREA) http://grants.nih.gov/grants/funding/area.htm which supports projects in the biomedical and behavioral sciences conducted by faculty and students in health professional schools, and other academic components that have not been major recipients of the NIH research grant funds. In addition, institutions could try to increase the NIH grant support by partnering with institutions with more significant NIH funding. Such partnerships can help build the experience and capacity necessary to successfully compete independently for the NIH funding in the future.

GULF OIL SPILL HEALTH EFFECTS RESEARCH

*Question.* According to the NIH press statement, of the 40 known oil spills in the past 50 years, the health effects have been studied from only eight of those spills. I am pleased to see the NIH will begin to review health effects of people impacted by the Deepwater Horizon oil spill in the Gulf of Mexico. It is critical to understand how being exposed to the oil and the dispersants may have affected the health of cleanup workers and volunteers. Could you discuss how this study will be conducted and what you are hoping the GULF Study will help us learn?

Answer. The Gulf Long-term Follow-up Study (GuLF STUDY) will help determine if oil spills and exposure to crude oil and dispersants affect physical and mental health. The National Institute of Environmental Health Sciences (NIEHS) is leading this research. A major facet of the study is to compare the health of clean-up workers and others who did not do clean-up work to learn if health problems are more common in workers. GuLF STUDY researchers will also examine other factors that may explain why some people are more likely than others to get sick and how stress affects health. The NIEHS will send approximately 90,000 invitation letters to people to be included in the study. Of this group it is expected that 55,000 will be enrolled and complete telephone interviews. Participants will be interviewed about their oil-spill clean-up jobs, demographic and socioeconomic factors, occupation and health histories, and current health, including stress and mental health. About half of the cohort will be asked to complete a brief clinical examination in their home. The home exam will include additional health questionnaires and collection of biological samples, such as blood and urine, and environmental samples, e.g., house dust. The exam will include basic clinical measurements such as height, weight, blood pressure and tests of lung function. The home exams will largely target workers residing in the four most affected Gulf States—Louisiana, Mississippi, Alabama, and Florida). All cohort members will be followed for development of a range of health outcomes. Follow-up of the entire cohort is initially planned for 10 years, with extended follow-up possible depending upon scientific and public health needs and the availability of funds.

GuLF STUDY researchers are hoping to learn if exposure to constituents of oil, dispersants, and oil-dispersant mixtures during oil spill clean-up is associated with adverse health effects, particularly respiratory, neurological, hematologic, and mental health. In addition, this research is anticipated to reveal biomarkers of potentially adverse biologic effects associated with oil spill-related exposures. Results of the study will provide further insight into how stress and job loss can affect health, including mental health. Overall, the findings may influence long-term public health responses in Gulf communities or responses to other oil spills in the future.

CYSTIC FIBROSIS RESEARCH

*Question.* In February, the NIH announced that federally funded research led to the development of a very promising therapy that targets the genetic defect that causes Cystic Fibrosis. How will the fiscal year 2012 NIH budget request support additional research on Cystic Fibrosis?

Answer. Cystic fibrosis (CF) research continues to be a high-priority area. The NIH estimates the fiscal year 2012 budget request would support about $88 million for CF research, ranging from basic science studies through clinical trials. The results of our prior investments have provided enormous benefit to affected patients. Whereas years of life expectancy for children born with CF could once be counted on the fingers of one hand, today average survival is 37 years and some patients live into their 50s and beyond. Evidence-based improvements in nutrition, infection control, and symptom management have substantially enhanced the quality of life of affected persons. Newborn screening for cystic fibrosis, now universal in the United States, is not only enabling early interventions but also providing unprece-

dented opportunities for effective translation of new research advances into clinical practice.

With improved understanding of CF biology, advances in experimental methods, and growing availability of new targets for interventions, we anticipate that CF research will be especially productive in the next few years and that tangible improvement in patient outcomes will follow. The recent NHLBI workshop "Future Research Directions in the Pathogenesis, Treatment, and Prevention of Early Cystic Fibrosis Lung Disease" identified a number of important topics for future research that can be pursued as funding permits. They include work with animal models to understand how early lung disease develops, identification of genetic and environmental factors that modify the manifestations and course of CF, examination of the role of mutant CFTR (the defective gene product in CF) in airway growth and development, and exploration of the mechanisms that underlie CF-related diabetes and liver disease. The NIH will continue to adjust its research portfolio in CF to ensure that needs and opportunities for advancing research are addressed.

THE NIH–FDA COLLABORATIONS

*Question.* The development of treatments for diseases, especially rare diseases, is an expensive and lengthy process. A very small percentage of potential medicines even make it to the clinical research stage, let alone to FDA review. What can the NIH do to reduce some of the regulatory requirements that both slow the pace and increase the cost of medical research, but that add little meaningful accountability?

Answer. The NIH is taking a multi-pronged approach to promote efforts to address unnecessary, inconsistent, and duplicative regulatory requirements. We work closely with FDA and the Office for Human Research Protections to enhance the consistency of regulations governing clinical research. Through the NIH–FDA Joint Leadership Council, we are working with FDA to help ensure that regulatory considerations are a component of scientific research at all phases of development and they are informed by the most current science and technologies. Such efficiencies along with targeted support for the development of novel technologies including new and improved preclinical toxicology approaches for testing safety should quicken the pace and reduce the human-related costs of medical research. The proposed National Center for Advancing Translational Sciences will be focused on studying diagnostics and therapeutics development, testing, and implementation; identifying bottlenecks amenable to re-engineering; and formulating innovative methods to streamline the process.

CLINICAL TRIAL PROCESS

*Question.* One of the priorities of the Joint NIH–FDA Leadership Council is to optimize and maximize data from clinical trials. Would you consider working with the FDA to grant greater flexibility regarding the approval of orphan drug therapies on the basis of a single, well-designed trial?

Answer. The FDA and the NIH have complementary roles and functions—the NIH supports and conducts biomedical and behavioral research and the FDA ensures the safety and effectiveness of medical and other products. The NIH does not share regulatory authorities with the FDA, i.e., we do not make decisions about regulatory pathways or the approvability of investigational products. However, we certainly have common goals and are working closely in a number of ways to address issues related to therapeutics development and regulatory science. As you noted, the agencies are working at the leadership level through the NIH–FDA Leadership Council, formed in 2010, to help ensure that regulatory considerations form an integral component of biomedical research planning and that the latest science is integrated into the regulatory review process. The challenges associated with the development and review of therapies for rare and neglected diseases, such as the availability of alternative regulatory pathways for trials of rare diseases and the level of scientific evidence needed for approval of a new orphan therapy, are among the specific topics of mutual interest. We also collaborate closely on issues associated with the development of new cancer diagnostics and therapeutics through an interagency oncology task force and, in accord with the provisions the Best Pharmaceuticals for Children Act, to advance the development of preclinical and clinical methodologies that provide optimal approaches for treating diseases in childhood. We believe all of these efforts can go a long way toward achieving our common goal of advancing public health by promoting the translation of basic and clinical research findings into medical products and therapies.

## QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

### TRANSFER OF THE IDeA PROGRAM TO THE NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

*Question.* The NIH has proposed the elimination of the National Center for Research Resources (NCRR). I am particularly concerned that this elimination will affect the Institutional Development Award (IDeA), which has benefitted my home State of Mississippi. Under the proposal, the IDeA program will be moved to the National Institute of General Medical Sciences. There have been concerns expressed that the IDeA program should not be placed in an Institute with a defined constituency. Dr. Collins, can you elaborate on the decision process for moving IDeA to the National Institute of General Medical Sciences? Why do you think this is the best Institute to house the IDeA program?

Answer. The IDeA program fosters research and enhances the competitiveness of investigators at institutions located in States in which the aggregate success rate for applications to the NIH has historically been low. By its nature, the IDeA program extends beyond traditional capacity building in supporting research projects that are designed to strengthen future investigator-initiated research applications, most of which are aimed at addressing basic science questions. The National Institute of General Medical Sciences (NIGMS) has a basic science mission as well as a longstanding focus on institutional capacity building and career development. Given these synergies, the NIGMS was determined to be the optimal new home for the IDeA program. The NIH reached this conclusion based on a careful analysis of existing NCRR programs as well as extensive consultation with stakeholders across the scientific community and input from the NIH Institutes and Centers, including NCRR leadership and staff.

### JACKSON HEART STUDY IMPACTS

*Question.* African Americans are more likely to be diagnosed with coronary heart disease, and they are more likely to die from heart disease. Due to this greater prevalence, the Jackson Heart Study is exploring the reasons for this disparity and uncovering new approaches to reduce it. Can you discuss the impacts this study will have?

Answer. The goals of the Jackson Heart Study (JHS) are to determine the roles of established risk factors such as obesity, dyslipidemia, and high blood pressure in the development and progression of cardiovascular disease (CVD) and to identify factors related to the emergence of such risk factors. Moreover, the study seeks to shed light on the contributions of sociocultural factors (e.g., stress, racism, discrimination, and coping strategies) and familial/hereditary factors, genetic variants, and gene—environment interactions to the development of CVD and its risk factors. Based on our experience with other NHLBI-funded epidemiological studies of CVD such as the Framingham Heart study, we expect the JHS to provide important information that will help researchers to generate new hypotheses and design studies to test interventions to prevent CVD. Ultimately, we expect the results of the JHS to benefit not only Mississippians but also African Americans beyond the participants in the study.

The JHS also seeks to build research capabilities in minority institutions, address the critical shortage of minority investigators in epidemiology and prevention, and reduce barriers to dissemination and use of health information in a minority population. The JHS educational and community outreach components are very strong; consequently, the research findings will be efficiently disseminated among participants. The JHS training component continues to provide outstanding opportunities to inspire, motivate, and educate students to become research leaders and to study and disseminate important findings on prevention of CHD.

### STAFFING THE JACKSON HEART STUDY

*Question.* The Jackson Heart Study is the largest epidemiologic investigation of Cardiovascular Disease among African Americans in the United States. The National Heart Lung and Blood Institute opened a field office in Jackson to provide scientific investigators and support staff to the study. It is my understanding that this one-person office will soon have no staff due to the staffer leaving Jackson. I am concerned that the National Heart Lung and Blood Institute may not fill the position quickly which would result in an adverse effect on the Jackson Heart Study. It is vital that the field site maintain strength to support scientific research at the Jackson Heart Study. Dr. Collins, can I have your assurance that the National Heart Lung and Blood Institute will replace this position in a timely manner?

Answer. At present, the National Heart, Lung, and Blood Institute (NHLBI) medical officer stationed at the Jackson Heart Study site plans to remain there indefinitely. Should the position become vacant in the future, the NHLBI would promptly pursue recruitment via standard competitive procedures.

GEOGRAPHIC HEALTH DISPARITIES FOR STROKE AND OBESITY

*Question.* Health disparities are persistent across ethnic populations as well as geographically. Geographic isolation, socioeconomic status, and health risk behaviors contribute to health disparities in these rural communities. Mississippi is part of the "Stroke Belt" and has the highest rate of obesity in the Nation. Both of these issues are persistent problems in the rural South, with 10 out of 11 States with the highest rates of obesity being in the South. Dr. Collins, how is the NIH addressing the geographic issues associated with many of the most serious diseases affecting our Nation?

Answer. The NIH supports a broad portfolio of research to understand the complex factors that contribute to obesity, stroke, and related health problems, and to develop and evaluate prevention and treatment strategies for diverse populations.

The Look AHEAD clinical trial, supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and other NIH components, is determining whether lifestyle intervention improves health in overweight/obese people with type 2 diabetes, and in particular the impact of the intervention on the incidence of cardiovascular events, including stroke, heart attack, hospitalized angina, and cardiovascular-related death. For the first four years of this long-term study, participants in the lifestyle intervention group lost more weight and improved their blood pressure, fitness, glucose control, and good cholesterol, with less use of medication, compared with those in the control group. Look AHEAD includes sites across the country, including in Alabama, Louisiana, and Tennessee.

A major National Institute of Neurological Disorders and Stroke (NINDS)-funded epidemiological study related to the "Stroke Belt" is the REGARDS study (REasons for Geographic and Racial Differences in Stroke) in which investigators are exploring the geographical and racial differences in stroke risk in a cohort of about 30,000 individuals, about half of whom reside in the Stroke Belt region of the United States. This study also includes measures of functional cognitive decline, which may be a risk factor for stroke as well as a marker for unrecognized stroke. Data generated from this study has led to more than 70 publications, and will continue to help researchers pinpoint the reasons that the stroke death rate is higher in this region, and among African Americans, and to develop targeted strategies for intervention. Recent data from REGARDS indicated that overall time spent in the Stroke Belt is more predictive of hypertension—a powerful risk factor for stroke—than is current residence in the Stroke Belt. Data from the REGARDS study have also revealed that stroke survivors were more likely to have unrecognized hypertension and diabetes.

To improve stroke care utilization and patient outcomes among vulnerable populations, the NINDS also invests in research to increase stroke awareness and reduce the time from symptom onset to hospital arrival, so that patients can be evaluated and treated in a timely manner.

In one such study, a novel behavioral intervention will be tested in which children in high risk, minority communities are taught through Hip Hop Stroke (stroke rap songs and animated musical cartoons) to recognize and act on the five cardinal stroke symptoms and the importance of early treatment, with the hopes that they will communicate this information to their parents. Preliminary pilot data indicated that 74 percent of children communicated the material to their parents, which significantly improved their stroke knowledge.

In the SWIFT (Stroke Warning Information and Faster Treatment) study, a culturally sensitive educational intervention focused on improving knowledge retention and time of arrival to the emergency department has been tested in minority communities. The outcome and results of this study are currently under review in a major medical journal.

The ASPIRE program (Acute Stroke Program of Interventions addressing Racial and Ethnic disparities) is currently testing strategies to overcome community/sociocultural and system barriers to stroke treatment with the goal of increasing the number of stroke patients treated with the clot-busting drug, tissue plasminogen activator (tPA), in six Washington, DC, hospitals.

Ten years ago, the NINDS convened a Stroke Progress Review Group (SPRG) to identify and prioritize scientific opportunities in stroke research. In 2011, the NINDS will embark on a new stroke planning and evaluation effort, which will identify a specific set of high priority areas for advancing stroke research over the

next 5–10 years. The topic of health disparities in stroke will be included as a cross cutting topic in this effort.

CARDIOVASCULAR DISEASE RESEARCH

*Question.* Cardiovascular Disease is the leading cause of death in Mississippi, accounting for more than 40 percent of all deaths. In 2004, the State of Mississippi implemented a 10-year plan to address Cardiovascular Disease risk factors in a two-fold approach: prevention of potential risk factors and management of existing risk factors. In addition, the Jackson Heart Study is the largest investigation of causes of Cardiovascular Disease in an African-American population. While both initiatives are good starts to addressing this health issue in my home State, Cardiovascular Disease is the number one killer in the United States and we need comprehensive research to fight the disease nationwide. What plans do you have to increase research in the area of Cardiovascular Disease?

Answer. The NHLBI is committed to supporting a comprehensive research program on the causes, prevention, diagnosis, treatment, monitoring, and management of cardiovascular disease (CVD). We invest 63 percent of the NHLBI extramural budget in CVD research, and we intend to continue that high level of support. This year, the Institute has launched a number of new projects, including two major clinical trials:

—The International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) addresses management of patients with stable coronary heart disease who have substantial ischemia on a cardiac stress test. The trial will evaluate whether an invasive approach (performing an angiogram and then opening or bypassing any blockages with stents or surgery) plus optimal medical therapy is better than optimal medical therapy alone in forestalling CVD events. Quality of life and cost-effectiveness will also be assessed.

—The Cardiovascular Inflammation Reduction Trial (CIRT) addresses cardiovascular disease risk reduction in heart-attack survivors with persistently high levels of C-reactive protein, an indicator of inflammation. The trial will evaluate whether a very low dose of the anti-inflammatory drug methotrexate reduces rates of recurrent heart attack, stroke, and cardiovascular death. Several other conditions that have an inflammatory basis, such as diabetes, venous thromboembolism, and atrial fibrillation, will also be assessed.

The NHLBI has responsibility for cardiovascular, lung, and blood diseases that affect millions of people worldwide. We will continue our longstanding emphasis on the support of a balanced research portfolio that addresses the many public health needs and scientific opportunities that fall within our mandate.

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QUESTIONS SUBMITTED BY SENATOR LAMAR ALEXANDER

REORGANIZATION OF NATIONAL CENTER FOR RESEARCH RESOURCES (NCRR) PROGRAMS

*Question.* In my State of Tennessee, the largest single Federal grant at one of the State's largest medical research institutions is a Clinical and Translational Science Award (CTSA), for $40 million. How will this program and others like it be affected by the dissolution of the NCRR, and the creation of the National Center for Advancing Translational Sciences (NCATS)?

Answer. The NIH is committed to supporting each program currently housed within the NCRR; the proposed reorganization will not adversely affect the individual programs. Indeed, a careful programmatic evaluation concluded that important scientific synergies could be gained by moving NCRR programs to other NIH components with adjacent scientific missions. Staff responsible for administering and directing these programs will transfer with their respective programs to ensure continuity and oversight. With regard to the Clinical and Translation Science Awards (CTSA) program specifically, it is to be transferred to the proposed National Center for Advancing Translational Sciences (NCATS). The transfer was recommended by the NIH Scientific Management Review Board, a congressionally-mandated advisory committee to the NIH Director, and further supported by an internal NIH task force charged with assessing the optimal location for NCRR programs. The task force's analysis confirmed that the goals of the CTSA program were in close alignment with those of the new center. Decisions regarding the selection of individual CTSAs will continue to be made based upon each proposal's scientific merit and program relevance.

CTSA PROGRAM MISSION

*Question.* Given the established focus of the NCATS on drug development, will the CTSA's continue to be able to build on the programs of training, career development for young investigators, research informatics, community engagement and clinical research infrastructure?

Answer. The focus of the NCATS is to develop new and innovative approaches to conducting research across the therapeutic development pipeline, in the context of strengthening and streamlining the process itself. The CTSAs have the infrastructure and diverse expertise that supports translational research, including training and career development for the next generation of clinical investigators, informatics, and community engagement, and they will be integral to fulfilling the NCATS mission. The CTSAs are making important contributions in transforming translational research across the country, and the NIH is committed to building upon the program's successful efforts. Ensuring that the pipeline of new investigators is sufficiently equipped to tackle the challenges associated with translational science through training and mentoring is an inherent part of the NCATS mission and will continue to be an essential component of the CTSAs.

PERSONALIZED MEDICINE

*Question.* Physicians and researchers in Tennessee are investing a great deal in the science of personalized medicine. Can you tell us what the term "personalized medicine" means to you, and what role you see for the NIH?

Answer. The concept of "personalized medicine" is based on the idea that one size does not fit all when it comes to the practice of medicine. Knowledge gathered from basic research and clinical studies have demonstrated that individuals are highly unique in their susceptibility to disease, reaction to medical treatments, and response to environmental and social factors. More than ever before, and largely thanks to research supported by the NIH, we now have the tools to understand, describe, and quantify these biological differences as well as the power to better predict which available treatments are optimal for certain patients and to design rationale-based new targeted-based therapies.

The NIH will continue to play a pivotal role in the advancement of personalized medicine. For example, our support for pharmacogenomics research will advance understanding of the predictive roles and influences of genes in drug response. Findings from such research can help identify the right drug for the right patient at the right time. Increasingly, this information will help doctors calculate dosages that match a person's unique physiology. Pharmacogenomic information already is contained in approximately 10 percent of FDA-approved drug labels, helping to prevent the inappropriate use of diagnostics and therapies. Pharmacogenomic knowledge can also reduce the financial, emotional, and physical costs associated with the current trial-and-error based approach to treatment. Knowing each patient's DNA sequence is expected to add efficiencies and new research capabilities to current endeavors. As such, we are also fostering technological advances that are expected to bring down the cost of sequencing an individual genome to under $1,000. These advances will help make genetic analysis a routine part of medical care and a revolutionary factor in approaches to basic research and practice.

DNA DATABANKS

*Question.* Several major research institutions are creating databanks that allows researchers to access a large collection of human DNA. How does the NIH also plan to build on the mapping of the human genome by optimizing unique resources such as this?

Answer. In support of its mission to improve public health through research, the NIH has a longstanding policy of making data publicly available from the research that it funds. The NIH recognizes that data sets are not only valuable for addressing the questions that the experiments that generated them were designed to ask, but also can be powerful resources when combined with other data sets or used to answer other scientific questions. This is particularly true of DNA data sets that consist of information across the full sequence of the human genome. Consequently, building on the data sharing practices that characterized the Human Genome Project, the NIH launched research programs to stimulate the creation of genomic resources and created policies and tools for facilitating the sharing of genomic data to capitalize on the databanks created by other institutions with or without the NIH funding.

For example, under the leadership of the National Human Genome Research Institute (NHGRI) the International HapMap Project used the reference human ge-

nome sequence to build a comprehensive map (database) of the variation within human DNA sequences, so that "spelling" differences in the DNA code of those with disease and those without disease could be identified and studied. The 1000 Genomes Project is now capitalizing on technological advances to extend and deepen the HapMap data. All data from each of these projects are publicly available to any investigator through the web with regular updates as new data are generated.

In addition, to leverage the infrastructure and databank resources created at other research institutions, the NIH has introduced funding programs, such as the NHGRI-supported Electronic Medical Records and Genomics (eMERGE) Network. This consortium of U.S. medical research institutions has the primary goal of developing, disseminating, and applying approaches to research that combine existing DNA biorepositories with electronic medical record (EMR) systems for large-scale, high-throughput genomic research. eMERGE Network institutions use their own databanks (e.g., Vanderbilt University's BioVU DNA databank) for this program, but all data are shared through an NIH database, the database of Genotypes and Phenotypes (dbGaP), which provides centralized and consistent access to researchers around the globe. Importantly, dbGaP includes not only eMERGE data, but data from studies across the disease spectrum. Extremely rich databanks from studies such as the Framingham Heart Study, The Cancer Genome Atlas, and many other projects reside within dbGaP, enabling many more investigators to analyze the data as independent or combined data sets. The standardization of access supported by the NIH facilitates cross-study analyses, enables expansion of the study design beyond the initial research focus of the individual databanks, and increases the statistical power to identify the genetic contributors to common diseases that create substantial public health burden. And, importantly, all of these benefits are achieved through robust data sharing policies intended to protect the interests of the research participants who contribute their personal information to the individual databanks.

INDUSTRY INVESTMENT IN GENOME SEQUENCING

*Question.* How does private investment in genome sequencing help to leverage the Federal investment of genomic research through the NIH funding?

Answer. The sequencing of the human genome has rightly been regarded as one of the most important scientific undertakings of the modern era. The NIH's investment in genomics has been, and continues to be wide-ranging, from basic research to uncover and understand the structure of our genome to translational science aimed at using a patient's DNA code to tailor treatment. Enabling all of this research are innovative new tools for DNA sequencing that have precipitated a drop in the cost of sequencing an individual genome from hundreds of millions of dollars to $15,000 or less.[2] In the process, an entire industry of genomics-focused companies has been created, one that, according to a recent study conducted by Battelle Technology Partnership Practice, has generated an economic contribution of almost $800 billion since the start of the Human Genome Project.[3] [4]

The field of genomics has benefited from a combination of public and private investment. During the course of the last 10 years, the National Human Genome Research Institute's Genome Technology Program has provided support for the development of almost all of the currently commercialized, as well as several yet-to-be-commercialized or emerging, sequencing technologies. Private investment during and since that initial period of the NIH support has and will continue to bring these innovative advances to the market. Newer and increasingly cheaper sequencing machines and reagents have increased both capacity and productivity, enabling the NIH grantees to answer more research questions in the same period of time and for the same cost as previously. Illumina and Life Technologies, for example, have now developed smaller and less expensive sequencing machines that are bringing DNA sequencing within reach of single-investigator research labs. Affordable access to these technologies will greatly amplify the number of researchers that can employ genomic sequencing within their research plans, expanding the benefit of the Federal investment in genomic sequencing into yet more basic, translational, and clinical research domains. Companies like Illumina and Complete Genomics are also offering sequencing services that the NIH-funded researchers have used to great ef-

[2] Additional information on sequencing costs is available at http://www.genome.gov/27541954.
[3] http://www.battelle.org/publications/humangenomeproject.pdf.
[4] Additional information on the economic impact of the human genome project is available at http://www.genome.gov/27544383.

fect, such as the discovery last year of the causative genes behind rare disorders like Miller syndrome, something that had eluded science until now.[5]

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## QUESTIONS SUBMITTED BY SENATOR LINDSEY GRAHAM

### EOSINOPHILIC DISORDERS WORKING GROUP

*Question.* I have heard from individuals in my State about the enormous challenges to children with eosinophilic disorders and their families. I understand that these conditions are often misdiagnosed and there is no cure for these children, many of whom suffer from extreme pain and are unable to eat normal food. This subcommittee has asked that the NIH convene a working group on this topic. When will this group meet and when can we expect to have a report of the group's recommendations?

Answer. Eosinophilic gastrointestinal disorders (EGID) are a group of diseases characterized by a wide variety of gastrointestinal symptoms including abdominal pain, swallowing problems, food impaction (food lodged or wedged in the esophagus), vomiting, diarrhea, growth impairment and bleeding. EGIDs are associated with increased numbers of eosinophils, a type of white blood cell, in the gastrointestinal lining. The most common EGID, eosinophilic esophagitis, is characterized by inflammation and accumulation of eosinophils in the lining of the esophagus. This disease and other EGIDs are diagnosed by a patient's clinical history plus endoscopy with biopsy.

As the lead Institute at the National Institutes of Health (NIH) responsible for research on immunologic and allergic disorders, the National Institute of Allergy and Infectious Diseases (NIAID) works closely with other NIH Institutes and Centers supporting research on eosinophilic disorders. Although these collaborations and communications do not occur through a formal working group or a predetermined research agenda, they have led to jointly sponsored workshops and research initiatives on eosinophilic disorders. In fiscal year 2012, the NIH, with the NIAID as the lead, will establish a working group with participation by relevant NIH Institutes and Centers, to develop a trans-NIH strategy to improve the diagnosis and treatment of eosinophilic disorders.

As part of its overall research agenda on immunologic and allergic diseases, the NIAID pursues research on eosinophilic disorders through a variety of efforts and collaborations. For example, the Consortium of Food Allergy Research (CoFAR), cofunded with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and renewed in fiscal year 2010, develops new approaches to treat and prevent food allergy. A new CoFAR project is examining the genetic aspects of eosinophilic esophagitis. The NIAID Asthma and Allergic Diseases Cooperative Research Centers (AADCRC) support basic and clinical research on the mechanisms, diagnosis, treatment, and prevention of asthma and allergic diseases, including food allergy and anaphylaxis. Many of these disorders are associated with eosinophilia. In addition, the NIAID-supported investigators are conducting a pilot clinical trial to determine the efficacy of swallowed glucocorticoids for the treatment of eosinophilic esophagitis, and developing novel noninvasive diagnostic tools for eosinophilic gastrointestinal diseases to reduce the number of endoscopies and biopsies that are currently performed. Also, on behalf of more than 30 professional organizations, Federal agencies, and patient advocacy groups, including the American Partnership for Eosinophilic Disorders, the NIAID coordinated the development of Guidelines for the Diagnosis and Treatment of Food Allergy in the United States. This document includes clinical practice guidelines for the diagnosis and management of eosinophilic esophagitis associated with food allergy. The guidelines were published in the December 2010 issue of the Journal of Allergy and Clinical Immunology and can be accessed at: http://www.ncbi.nlm.nih.gov/pubmed/21134576.

The NIAID will continue its commitment to research and trans-NIH research collaborations on eosinophilic disorders to understand the mechanisms that mediate tissue injury when eosinophils accumulate. As part of this effort, in fiscal year 2011, the NIAID will recompete the AADCRC program.

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[5] http://www.sciencemag.org/content/328/5978/636.

QUESTION SUBMITTED BY SENATOR JERRY MORAN

BUDGETARY EFFECTS ON THE NCI PROGRAMS

*Question.* Dr. Collins, I recently visited the University of Kansas and was given a tour of the University's drug discovery, delivery, and development operation. This visit helped demonstrate to me not only the many elements that will become part of the application by the University for National Cancer Institute (NCI) comprehensive cancer center designation, but also the impressive role that the NCI's cancer centers play across the Nation. This network of centers drives basic research, brings individuals into clinical trials, and, most importantly, leads to the development of new treatment advances that will change the course of cancer for all Americans and individuals across the globe.

While I understand that the University of Kansas' application for the NCI designation will be determined on its scientific merits, can you please explain how the NCI cancer center program will be affected by the proposed budgets of the NIH and the NCI?

Additionally, considering possible scenarios for the fiscal year 2012 budget, what will the effects of such scenarios be on current NCI programs and on the prospect for funding the review of new applications?

Answer. The the NCI-designated Cancer Centers are an important part of the NCI's research portfolio, and they play a unique and valuable role in providing cutting-edge cancer care and access to the NCI-sponsored clinical trials across the country. The final fiscal year 2011 appropriation has already necessitated a 5 percent reduction in funding below fiscal year 2010 for the cancer centers, and it is difficult to predict how they will be affected by the resolution of the fiscal year 2012 budget.

The NCI's first priority must be to preserve funding for Research Project Grants (RPGs). Ensuring support for as many new RPGs as possible will enable investigators, especially new investigators, to pursue novel ideas that will preserve the pipeline of innovative cancer research. This year, nearly every NCI program budget has had to be trimmed in order to award adequate, though reduced, number of new RPGs.

SUBCOMMITTEE RECESS

Senator HARKIN. Is there anything else that any one of you would like to state for the record now? If not—Yes.

Dr. COLLINS. Well, Senator, I'd just like to thank you and this subcommittee for your steadfast support for biomedical research.

All of us involved in this enterprise sitting here at this table, and many others who are not at the table, but who are engaged every day in this effort to try to find interventions for people with disease appreciate your support and your strong voice that, even in difficult times, medical research is basically a societal good.

I think a society ultimately will be judged by the ways in which, even in difficult times, priorities are chosen.

We think, in terms of alleviating suffering as well as encouraging our American competitiveness and our economic growth, that what we are able to do through NIH is a very good story indeed, but we appreciate the fact that you have convened this hearing and given us a chance to tell some of that story.

Senator HARKIN. Well, thank you very much, Dr. Collins, and I can just reciprocate then I'll join all my colleagues in thanking you and all of you and all your colleagues at the NIH, all the Directors, the people who work there, and through you the whole network of researchers, young and old, some of who have just come on, some who have been there for many years, to thank you for your outstanding public service. All of you, every single person engaged in NIH, thank you.

The subcommittee will stand recessed.

[Whereupon, at 11:45 a.m., Wednesday, May 11, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2012

**WEDNESDAY, JULY 27, 2011**

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 10:05 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Durbin, Landrieu, Reed, Pryor, Brown, Shelby, Cochran, Alexander, Moran, and Kirk.

## DEPARTMENT OF EDUCATION

### OFFICE OF THE SECRETARY

**STATEMENT OF HON. ARNE DUNCAN, SECRETARY**

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education will please come to order.

Secretary Duncan, welcome back to the subcommittee. This is obviously a critical moment to be talking about education funding. The Nation will default on its loans in just 6 days unless Congress raises the debt ceiling; we all know that. I believe that to bring Federal deficits under control, we must be willing to make some tough, but necessary, budget choices. But we must be just as willing to say no to foolish and destructive choices. And this is especially true when it comes to funding for the education of our children.

2011 CONTINUING RESOLUTION IMPACT ON EDUCATION BUDGET

The fiscal year 2011 continuing resolution eliminated 37 education programs totaling more than $900 million. Those cuts included the successful Striving Readers initiative, the Federal Government's only comprehensive literacy program. Meanwhile, cash strapped State and local governments are slashing school budgets and firing tens of thousands of teachers. Los Angeles public schools cut their budget for summer classes from $18 million last year to $3 million this year. Philadelphia recently issued layoff notices to more than 1,500 of its 11,000 teachers. Many districts are short-

ening their academic calendar despite growing evidence that students should be spending more time in school, not less.

From my perspective, as chairman of both this subcommittee and also the authorizing committee, I believe the combined Federal, State, and local budget cuts pose a grave threat—let me repeat that—pose a grave threat to education reform efforts across the country just as those efforts are reaching critical mass.

Forty-eight States and the District of Columbia have collaborated to create high-quality, common education standards. Mr. Secretary, your Race to the Top initiative has jump started ambitious State-level reforms on teacher accountability, academic standards, and the better use of data in tracking student performance.

In the HELP Committee, the authorizing committee, we hope to mark up the reauthorization of the Elementary and Secondary Education Act this year. However, it is wishful thinking—wishful thinking—to expect improvements in school quality when we are laying off teachers, increasing class sizes, and reducing instructional time. To demand reform without resources is to set up students and teachers to fail.

INVESTING IN EDUCATION

Other countries understand this. China, for example, has tripled its investment in education. It is building hundreds of new universities. Even in times of austerity and shrinking budgets, smart countries do not just turn a chainsaw on themselves. They continue to invest in the future.

A good case in point is early childhood education. Experts agree that high quality pre-kindergarten education gives a critical boost to students' long-term academic success. But the quality of early childhood education programs varies widely. Many States lack any coordination.

The fiscal year 2011 appropriations bill addresses these challenges head on. And, Mr. Secretary, I applaud your efforts on this. We have provided $700 million for your Race to the Top initiative, and working together, you very wisely, I believe, have put $500 million of that into an early learning challenge grant program, in a competition. Studies have shown that high quality pre-school returns $7 for every $1 invested, but we will not be able to continue that investment if overall funding for domestic discretionary spending is slashed.

At the other end of the learning continuum, we must do everything we can to preserve the fiscal integrity of the Pell Grant program. The 9 million students who rely on Pell grants to earn a postsecondary education each year need to be assured that this aid will not vanish in the middle of their college careers. So, I was very pleased that Senator Reid's plan would virtually close the Pell shortfall for the next 2 years. I want to engage with you on that aspect also in the question period. This will greatly improve our prospects of maintaining the maximum Pell grant at its current level of $5,550 per year.

Mr. Secretary, I appreciate the work that you are doing not only to protect our Nation's investments in education, but to challenge the States to do better, and to make sure the money is spent in ways that will truly improve student learning.

I also want to thank you for coming out to Iowa this last weekend, both for an event on Sunday regarding early childhood learning and also for Governor Branstad's education summit for Iowa. I could not be there because I had to come back here, but I read your remarks, and from all I hear, your presentation was both well received and challenging to the lawmakers and the policymakers in the State of Iowa.

With that, I will yield to my ranking member, Senator Shelby.

STATEMENT OF SENATOR RICHARD C. SHELBY

Senator SHELBY. Thank you, Mr. Chairman. Thank you for calling this hearing.

Mr. Secretary, I look forward to hearing your testimony today on the fiscal year 2012 budget request for the Department of Education.

BUDGET SAVINGS

But as we convene today's hearing, I am gravely concerned that the Department of Education has delayed some of the tough choices that are necessary to ensure national economic stability. We all understand the critical role of education in our society and its impact on our Nation's ability to compete in a global economic environment. However, our Nation is $14 trillion in debt, and I think we must rein in spending.

FISCAL YEAR 2012 DEPARTMENT OF EDUCATION BUDGET REQUEST

In times of economic uncertainty, while every Department should be looking for savings and efficiencies within the budget, the Department of Education has requested a 13.3 percent increase from 2011. In comparison to 2010, the 2012 budget request is a 20.7 percent increase. Let me repeat that—20.7 percent increase since 2010.

The Department of Education has requested 20.7 percent more funding in 2012 than it received 2 years ago. However, in your written statement, Mr. Secretary, you state, and I quote, "Our request is a responsible budget that emphasizes both fiscal constraint and investment in education reforms that will deliver results." Mr. Secretary, how can you consider an over 20 percent increase since 2010 a responsible budget that emphasizes fiscal restraints?

RACE TO THE TOP BUDGET REQUEST

One of the key investments proposed by the Department of Education in 2012 is Race to the Top. The budget includes $900 million for the program, an increase of $200 million or 28.6 percent above 2011. According to the Department, Race to the Top funds are awarded to States that are leading education reform with ambitious, yet achievable plans. Specifically, Race to the Top creates incentives for State and local reforms that produce improvements in student achievement, while reducing achievement gaps.

ALABAMA AND RACE TO THE TOP COMPETITION

I understand that education reform is never easy. However, it is made significantly more difficult when States must meet prescrip-

tive requirements, in this case a de facto requirement for charter school legislation, to even compete for available funding. My State of Alabama has been a leader in innovative science, technology, engineering, and mathematics (STEM) initiatives. The Alabama math, science, and technology initiative has earned nationwide recognition as a model for increasing the math and science achievements of students, the very achievement that Race to the Top states it supports. Yet, Race to the Top only awarded STEM programming 15 points out of 500. That is troubling, Mr. Secretary.

Instead, the Department chose only States with charter schools as awardees. Despite its nationally recognized STEM program, a key component to our future workforce competing in a global economy, Alabama finished dead last in the latest round for Race to the Top funding. And although the Department of Education often states its objectives to be loose on means and tight on ends, the experience of the State—my State—clearly illustrates this is not the case.

STATE FLEXIBILITY TO INNOVATE

As the United States continues to fall behind other developed countries in reading, math, and science, States should be given the flexibility, I believe, to implement critical reforms as identified on the State and local level. The Federal Government should not mandate initiatives, but assist States in implementing programs that they deem most important to improving their students' achievement.

PELL GRANTS—GROWTH IN COST

A key component to this achievement is improving access to education. As a Nation, we are on the brink of breaking our commitment to students who wish to attend college because the Pell Grant program is on a fiscally unsustainable path. Since 2008, the cost of the Pell Grant program more than doubled. Legislative changes that expanded eligibility, combined with the dramatic rise in the number of students seeking further education due to the economic recession, have caused costs to skyrocket.

And while the 2012 budget request offers proposals to address the growth in costs, the administration also proposes a $5.6 billion increase in discretionary Pell Grant funding. We cannot continue to throw money at this problem. Access to higher education must be protected and immediate reforms are necessary to ensure the Pell Grant program continues as the basis of our commitment to helping low income students attend college.

DISTANCE LEARNING AND STATE AUTHORIZATIONS

Finally, Mr. Secretary, I am concerned about State authorization provisions related to distance learning under the proposed program integrity regulations. While I understand the Department of Education has delayed the enforcement date related to distance learning until July 2014, as long as an institution is making a good faith effort to obtain the necessary State authorizations, I do not believe that this adequately addresses the underlying issue. Simply ex-

tending the deadline does not take into account the burdensome impact of these regulations on colleges and universities.

In addition, the definition of what "good faith" means—good faith effort is vague, and the Department's proposed guidelines will prove costly and time-consuming.

I hope, Mr. Chairman, that we can work together to find the appropriate balance between fiscal responsibility and meaningful education investments because we need this in America.

Senator HARKIN. Thank you very much.

OPENING STATEMENT OF SECRETARY DUNCAN

Again, Mr. Secretary, welcome, and your statement will be made a part of the record in its entirety. Please proceed as you so desire.

Secretary DUNCAN. Thank you so much, and good morning, Chairman Harkin and Ranking Member Shelby. Thank you very much for having me here today to talk about education, the economy, and the need to continue investing in our future, even as Congress and the administration work together to reduce overall spending and manage our Nation's deficit.

KEY INVESTMENTS IN FISCAL YEAR 2012 BUDGET REQUEST

Our Department of Education has submitted a formal statement on our 2012 budget proposal outlining our request to boost investments in education in order to secure America's future. Key investments include closing the Pell Grant shortfall both through efficiencies and more resources, protecting desperately needed title I and Individuals with Disabilities Education Act (IDEA) formula funds for students most at risk, expanding reform programs, including Race to the Top and Investing in Innovation, or i3, and our early learning and college completion programs. These programs support State and local policies to accelerate achievement for all students, particularly for students most at risk, and provide adequate funding for student aid administration, now that all Federal student loans are originated through the direct loan program.

BUDGET REQUEST IN CURRENT ECONOMIC CONDITIONS

Recognizing the real fiscal challenges facing the country, we also propose efficiencies, consolidations, and cuts in programs that are not as effective as they should be. We understand that just as every family is doing more with less, so should we. But like America's hardworking families, we also understand that you cannot sacrifice the future to pay for the present, and nothing is more important to a family's future and to our future as a Nation than education.

INVESTING IN PROGRAMS THAT WORK

Mr. Chairman, I was in Iowa earlier this week where I talked about the fact that your State had gone from being a national leader in education to being frankly in the middle of the pack. I know that was a difficult message for citizens in Iowa to hear, but I didn't want to sugarcoat the message because that would not be doing any favors to Iowa's children.

And your State is not unique. In fact, America as a whole has gone from being a world leader in education to being in the middle of the pack. In this new century, the middle of the pack is simply not what we want for our children or for our country. We all have to get better, and in order to get better, we must continue to invest in programs that are working.

PELL GRANT PROGRAM

The Pell Grant program is helping millions of young people and adults get new skills for the jobs of tomorrow. Demand has skyrocketed from 6 million to 9 million grants in 4 years. College has never been more necessary for success in the global economy, but it has also never been more expensive and out of reach for an increasing number of Americans. We cannot afford to go backward. We must once again lead the world in college graduates.

WELL-ROUNDED CLASSROOM AND AFTER SCHOOL PROGRAMS

We must continue to invest in programs like title I and IDEA, and programs that help support literacy, science, and mathematics, and other subjects necessary for a well-rounded education, and provide a rich offering of high quality after-school activities. They give struggling students the extra help they need to succeed. They promote equity and safety in schools, strengthen the teaching profession, and support English language learners, students with disabilities, rural students, and other special populations.

TEACHER PREPARATION AND CLASSROOM INNOVATION

We also have to give States and districts the flexible dollars that allow for innovation and reform. Today in America, thanks to programs like Race to the Top and Investing in Innovation, States and districts are preparing teachers to teach to higher standards. They are integrating technology into classrooms, expanding arts programs for students with disabilities, and producing a new generation of teachers in science, technology, engineering, and math, the STEM fields.

SCHOOL TURNAROUND PROGRAM

Today, thanks to our School Turnaround Program, low-performing schools across the country are undergoing dramatic changes—new leadership, new staff, new curriculum, longer school days, and fresh approaches to educating students at risk of failure.

NEED TO KEEP EDUCATION SUPPORT IN TOUGH ECONOMY

From big cities like New Orleans and Chicago to small towns in Tennessee and Kansas, educators are tackling our toughest challenges, exploring new approaches to education, and building new partnerships that are making a difference in the lives of our children. At the same time, we all know States and districts are facing more fiscal pressure than ever before. Recovery Act funding has largely dried up, and local and State revenues have yet to recover from the recession. The harsh result is that too many students are losing out—losing out on music, drama, sports, science, field trips, exchange programs, summer school, and many other unique and

wonderful things that make education so worthwhile. Their generation, our children, are being cheated out of a world-class education because our generation is unable or unwilling to make the tough choices necessary to protect them.

The current debate about the debt ceiling and the deficit is not just about budgets and numbers. It is really about the fundamental promise at the heart of the middle class American dream. For much of the last century, America was a country where if you worked hard, you and your family could enjoy the basic benefits of a secure and comfortable life—a job, a home, affordable healthcare, quality education, and a secure retirement. Today, for too many Americans, these building blocks of middle class life are increasingly beyond their reach, and that is creating uncertainty and anxiety. This is not good for the country, it is not good for our families, it is not good for children and for education.

PREPARED STATEMENT

So, while I absolutely appreciate the hard work underway to cut spending and get our debt under control, I want all of us to work together to do this in a way that does not undermine the education of our Nation and the education of our children. They are counting—our children are counting on us to prepare them for the future. Business owners are counting on us to produce the workforce they need to compete in the new economy. Families are counting on us to open the doors to opportunity for every child, regardless of background, income, ability or disability. We cannot let them down. We cannot let ourselves down. The path to a strong future starts in our Nation's classrooms.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF ARNE DUNCAN

Chairman Harkin, Ranking Member Shelby, and Members of the Committee: Thank you for this opportunity to talk about President Obama's fiscal year 2012 budget to help America out-educate the rest of the world. While the President's overall request for 2012 reflects broad agreement that the Federal Government has to start living within its means, we believe it is absolutely essential to keep investing in education so that, as the President put it, "every American is equipped to compete with any worker, anywhere in the world."

FINAL FISCAL YEAR 2011 APPROPRIATION

I want to begin by thanking the Chairman, the Ranking Member, and other Members of this Subcommittee for your work on the fiscal year 2011 appropriation for education. I know that you faced some tough decisions in reaching agreement on the 2011 budget, but I believe the final appropriation reflected a responsible mix of continued investment in high-priority activities as well as reductions in programs and activities based in large part on the recommendations in the President's 2012 budget.

In particular, I want to thank you for your renewed support of the Race to the Top program, which now includes the Early Learning Challenge competition. In May, I was pleased to share the podium with Secretary of Health and Human Services Kathleen Sebelius to announce a $500 million competition that will reward States that create comprehensive plans to transform their early learning systems by coordinating services, raising standards, and increasing the effectiveness of pre-K teachers. I also announced separately that we will use the remaining $200 million in fiscal year 2011 Race to the Top funding to support a competition involving the nine States that were high-scoring finalists but did not receive funding in the first two rounds of Race to the Top.

I'm also grateful that Congress provided $150 million for a second Investing in Innovation (i3) competition, as well as $30 million to keep moving forward with our Promise Neighborhoods initiative. In addition, Congress did the right thing by providing the significant funding and programmatic changes needed to maintain the $5,550 maximum Pell Grant award, as well as essential funding for the continued effective and efficient administration of the Department's postsecondary student financial aid programs.

PRESIDENT OBAMA'S 2012 BUDGET REQUEST

Turning to 2012, we recognize that the final 2011 appropriations bill will have an impact on the levels provided in fiscal year 2012, and we are aware of the ongoing bicameral, bipartisan discussions between the Administration and congressional leadership on the Nation's long-term fiscal picture, which may result in further adjustments to funding levels for 2012. Nonetheless, the 2012 budget request for the Department of Education reflects the Administration's policy priorities and remains a good starting point for developing these funding levels. The request represents both fiscal constraint and investment in education reforms that will deliver results. The overall discretionary request for the Department of Education, excluding Pell Grants, is $48.8 billion.

As you know, financing the Pell Grant program, which is funded through a combination of discretionary and mandatory appropriations and has faced growing demand in recent years as more and more students and working adults seek to improve their knowledge and skills, has been a real challenge for the Department and for the Congress. The President's budget responds to this challenge by proposing a combination of tough choices to generate savings from Pell Grants and student loan programs and increased discretionary funding. The overall goal of our Pell Grant proposals is to protect the $5,550 maximum Pell Grant award, put the program on more sustainable financial footing in 2012 and beyond, and ensure that more than 9 million low-income students can continue to rely on Pell Grants to enter and complete a college education.

Our 2012 request included a Pell Grant Protection Act that was designed to rein in Pell costs and place the program on more solid financial footing by eliminating the extra Pell Grant, ending the interest subsidy for graduate student loans, and allowing the conversion of guaranteed student loans to the Department. This proposal, combined with administrative action to implement enhanced income verification procedures for Pell Grant applicants as part of improvements in the processing of the Free Application for Federal Student Aid (FAFSA), would have produced an estimated $100 billion in discretionary Pell Grant savings over the next 10 years. The final 2011 appropriations act ended the extra Pell Grant, achieving a significant portion of the savings proposed in our 2012 request, and we will be working with the Subcommittee to build on those savings in negotiations over the 2012 appropriation.

MAKING TOUGH CHOICES

Before I describe some of the key investments we are proposing for 2012, I want to emphasize that our overall strategy for supporting effective education reform is fully consistent with the current fiscal environment. From the beginning, this Administration has envisioned a smaller Federal role focused on key priorities and structured to ensure the most productive use of the resources entrusted to us by taxpayers and the Congress. This is why, for example, our reauthorization proposal for the Elementary and Secondary Education Act (ESEA) would consolidate 38 existing programs into 11 more flexible authorities that would give communities more choices to implement their own research-based reform strategies.

We also have worked hard to identify and eliminate duplicative, unnecessary, or ineffective programs, and Congress accepted many of these recommendations in its final action on the fiscal year 2011 appropriation. Key eliminations included Even Start, Smaller Learning Communities, Educational Technology State Grants, Tech Prep Education State Grants, and Leveraging Educational Assistance Partnerships, as well as a number of smaller programs. While each of these programs undoubtedly provided meaningful benefits to students and schools over the years, we recognize that all levels of government are challenged to do more with less in these times of financial constraint. That's why our 2012 budget places a priority on spending smarter through cost-effective reforms that improve student outcomes, including by consolidating and, where appropriate, eliminating programs.

But make no mistake; the President's request for education is about investing in our Nation's future. President Obama has said that to win the future, we have to win the education race, and his 2012 budget reflects what is needed to educate our

way to a better economy. More specifically, the 2012 request for education is designed to promote reform, reward success, and support innovation at the State and local levels while maintaining strong support for students most at risk of educational failure. To meet these goals, our 2012 investments in education are divided into four significant priorities.

SUSTAINING REFORM MOMENTUM

First, our request includes an additional $900 million for Race to the Top, which already has demonstrated how competitive rewards create powerful incentives for State and local leaders to make groundbreaking education reforms. In the first two RTT competitions, 46 States created bold comprehensive reform plans that have buy-in from Governors, legislators, local educators, union leaders, business leaders and parents. As noted earlier, we will use 2011 Race to the Top funds to make awards to high-scoring but unfunded finalists from the first two rounds of Race to the Top. The 2012 request would focus on supporting district-level reform plans while also emphasizing cost-effective strategies that improve student achievement in a time of tight budgets. The Department would also carve out a portion of funds for rural school districts to ensure that communities of all sizes and from all geographic areas are able to compete for a fair share of Race to the Top funds.

While we are very pleased that we will be able to launch the Early Learning Challenge Fund with fiscal year 2011 Race to the Top funds, we are seeking additional funding in 2012 to continue critical investments in early learning that will support model systems of high-quality early learning supports and services for children from birth to kindergarten entry. These investments would complement proposed 2012 increases for programs in the Department of Health and Human Services, including increases for Head Start and for quality child care.

The 2012 request also would encourage reform and innovation through a $300 million request for the Investing in Innovation (i3) program to develop, evaluate, and scale up promising and effective models and interventions with the potential to improve educational outcomes for hundreds of thousands of students. The request includes priorities for science, technology, engineering, and mathematics (STEM) education and early learning, as well as an overall focus on increasing productivity to achieve better student outcomes more cost-effectively. The Department would include a refined rural priority in the i3 competition to ensure geographic diversity in the communities served by recipients, and would fund applications from providers and other entities proposing evidence-based approaches to address the unique needs and priorities of rural districts and schools. We also would take a page from the Department of Defense by creating a new Advanced Research Projects Agency: Education (ARPA–ED) that would use both discretionary and mandatory funds to pursue breakthrough developments in educational technology and learning systems, support systems for educators, and tools that improve outcomes from early learning through postsecondary education. We see this as a natural complement to the innovations found in the field through the i3 program.

In addition, our request would significantly boost funding for the Promise Neighborhoods program to $150 million to support comprehensive, innovative and cost effective approaches to meeting the full range of student needs, drawing on the contributions of schools, community-based organizations, local agencies, foundations, and private businesses. Also, the request would maintain funding for safe school programming designed to reduce substance use, violence, and bullying while providing States with greater ability to adapt interventions to school needs and drive resources to the most unsafe schools.

GREAT TEACHERS AND LEADERS

Our second priority is teachers and school leaders. I think we can all agree that nothing is more important, or more likely to improve student achievement and other key educational outcomes, than putting a great teacher in every classroom and a great principal in every school. Our 2012 request, together with a proposed restructuring of teacher and leader recruitment and preparation programs as part of our ESEA reauthorization plan, is designed to support State and local reforms of systems for recruiting, preparing, supporting, rewarding, and retaining effective teachers and school leaders. For example, the budget includes funding for a Teacher and Leader Innovation Fund to support ambitious reforms, including innovative teacher evaluation and compensation systems, to encourage effective teachers, principals, and school leadership teams to work in high-need schools. We also are seeking funds for Teacher and Leader Pathways to expand high-quality traditional and alternative pathways into teaching, with an emphasis on recruiting, preparing, placing, and supporting promising teacher candidates for high-need (including rural) schools,

subject areas, and fields. Included in this request is a set-aside to help prepare 10,000 new STEM teachers over the next 2 years, as part of the President's plan to prepare 100,000 new STEM teachers over the next decade. In addition, the Presidential Teaching Fellows program (formerly the TEACH program), paid for with mandatory funds, would award $10,000 scholarships to the best students attending our most effective teacher preparation programs who agree to work in high-need schools.

COLLEGE COMPLETION

Our third priority is college completion. I've already talked about the Pell Grant program, which is the foundation of Federal efforts to support both increased college access and completion for low-income students. Unfortunately, we know that far too many students who enroll in college drop out and never earn a degree. Currently, one-third of postsecondary students leave school without earning a degree and only one-half finish after 6 years. Clearly, access isn't enough, and we need a much stronger emphasis on attainment in postsecondary education. Through the $123 million "First in the World" competition, we'll provide venture capital to develop innovative approaches to increase college completion rates and improve educational outcomes while lowering costs and time to degree for students in higher education. And through our proposed College Completion Incentive Grants program, we would provide mandatory funding over the next 5 years in grants to States to reward institutions with exemplary college completion outcomes.

The President's budget also would continue support for key existing programs supporting college access and completion, particularly for minority and disadvantaged students. The request includes funding for the Federal TRIO programs and the GEAR UP program, which helps an estimated 756,000 middle and high school students prepare for and enroll in college. The 2012 budget also provides discretionary and mandatory funding for the Aid for Institutional Development programs, which support institutions that enroll a large proportion of minority and disadvantaged students, and discretionary and mandatory funding for the Aid for Hispanic-Serving Institutions programs, which help ensure that Hispanic students have access to high-quality postsecondary education opportunities.

We also look forward to working with Congress to strengthen the Perkins Act, which shapes the Career and Technical Education program, and improve its alignment with the education reform efforts at the core of our ESEA reauthorization proposal, so that the Perkins Act is a stronger vehicle for supporting the President's 2020 college completion goal and the Department's efforts to improve secondary schools.

SUPPORT FOR AT-RISK STUDENTS AND ADULTS

Finally, the President's 2012 budget for education would maintain, and in some cases expand, the Federal Government's commitment to formula programs for students most at risk of educational failure. For example, our request for the reauthorized Title I College- and Career-Ready Students program (currently Title I Grants to Local Educational Agencies) includes increased funding to recognize and reward high-poverty districts and schools where disadvantaged students are making the most progress. The $600 million request for a reauthorized School Turnaround Grants program would expand support for school districts undertaking fundamental reforms in their persistently lowest-achieving schools, while the budget also provides funding to help English Learners meet the same college- and career-ready standards as other students.

In Special Education, our request for Individuals with Disabilities Education Act Grants to States would help States and school districts pay the additional costs of educating students with disabilities, while our request for Grants for Infants and Families program would complement the proposed Early Learning Challenge Fund.

The 2012 request also provides significant resources to help adults pursue educational and employment opportunities, including funding for Adult Basic and Literacy Education State Grants to help adults without a high school diploma or equivalent to become literate and obtain the knowledge and skills necessary for postsecondary education, employment, and self-sufficiency, and mandatory and discretionary funds for Vocational Rehabilitation (VR) State Grants to help States and tribal governments to increase the participation of individuals with disabilities in the workforce.

We are looking forward to the reauthorization of the Workforce Investment Act (WIA) so that low-skilled adults and individuals with disabilities have access to the education and training they need to be successful in the 21st century economy. A reauthorized WIA would provide opportunities to upgrade the skills of our Nation's

workers so that they are able to compete in this new economy. One of those opportunities includes a new Workforce Investment Fund, which we are proposing in partnership with the Department of Labor, to help provide flexibility for the connections necessary to get people into good jobs or the education needed for a better job. The Fund will also provide resources to evaluate and replicate best practices so that we better serve those who have the hardest time finding work—those with limited basic skills and individuals with disabilities.

CONCLUSION

In conclusion, President Obama's 2012 budget for education is part of a comprehensive and responsible plan that will put us on the path toward fiscal sustainability in the next few years. Like every other agency across the Government, we are working hard to more efficiently steward the Department's resources. At the same time, education remains a priority for the Administration due to the critical importance of our education system for our continued economic prosperity. The Department's budget includes a responsible mix of savings and investments that will promote reform and innovation, support a comprehensive ESEA reauthorization, and encourage improved postsecondary outcomes. I look forward to working with the Committee to build support for the President's 2012 budget for education and to secure the best possible future for America by providing the best possible education for all of our children.

Thank you. I would be happy to answer any questions you may have.

PELL GRANTS AND TOTAL EDUCATION BUDGET REQUEST

Senator HARKIN. Thank you very much, Mr. Secretary. We will start a round of 5-minute questions.

Mr. Secretary, I want to talk about this 20 percent increase. I was quite surprised to hear that this budget had gone up 20 percent since 2010. So, I started looking at it, and when you look at the figures, excluding Pell grants, in fiscal year 2010, it was $46.64 billion, fiscal year 2012, the President's budget is $48.8 billion, which is about a 4 percent increase. So, why do we have a 20 percent increase that I heard my ranking member talk about? Is that not because of the increase in the Pell grants—the number of Pell grant money? Is that right, Mr. Secretary?

Secretary DUNCAN. Yes, sir.

UNEMPLOYMENT IMPACT ON PELL GRANT PROGRAM

Senator HARKIN. Well, I would point out, of the $77.4 billion request for fiscal year 2012, $28.6 billion is for Pell grants. Now, we might say, well, gee, what is going on here? Maybe we have got to cut back on Pell grants. What is going on is we have got over 20 million out of work. We've got an 18 percent—not 9—almost 18 percent unemployment rate in this country.

So, I guess what we are going to do is penalize the kids because their parents are out of work, and they have now fallen into the classification where they qualify for Pell grants, where before they probably would not have qualified for Pell grants.

INCREASED DEMAND FOR PELL GRANTS

So, I hope we keep our eye on exactly what is happening here. Most of this increase is because of the increased use of Pell grants. We have an increased use of Pell grants because we have more poor people in this country, and we have more poor people because 18 percent of people are out of work and they are not working.

So, I guess we have a choice to make. Do we cut these kids off at the knees?—Say, no, you qualify, but you are not going to get the money because we have to keep our budget down, you see, and

our spending down. Well, as I said in my opening statement, that is like turning a chainsaw on yourself. Or up my way, we say, it is like eating your seed corn, when you are cutting education.

PELL MAXIMUM GRANT

I can tell you, Mr. Secretary, this subcommittee and our committee, and I hope the Congress, will continue to be fully supportive of the maximum Pell grant.

PELL SHORTFALL AFTER ELIMINATION OF YEAR ROUND PELL

Now, again, we in the fiscal year 2011 continuing resolution, in order to free up money to make sure we had money for the basic Pell grant, we—Congress ended the year-round Pell Grant program known as "two Pells", which allowed students to receive two Pell grants in a single year. Well, that cut into some students, but it brought down the costs of the Pell Grant program. But even with that change, the shortfall for fiscal year 2012 is about $11 billion.

MAXIMUM PELL GRANT

So, the other proposal that Senator Reid came up with—that we worked with him on—was to eliminate the in-school interest subsidy for graduate loans as another way of making sure we could keep the maximum Pell grant for the poorest students. This proposal was also in the President's budget.

So, when you look at the options, why, Mr. Secretary, do we choose this one? Why do we choose eliminating the in-school interest subsidy for graduate loans? Why—could you just enlighten us why that is better than other options we might have?

Secretary DUNCAN. Yes, Mr. Chairman. These are all very tough choices. In an ideal world, you know, better economic times, maybe you would not make any of these choices. But at the end of the day, we desperately want to preserve that maximum Pell grant.

ELIMINATION OF TWO PELLS AND IN-SCHOOL SUBSIDIES

And I think there are two factors at work here. One, as you said, is we simply have more young people around the country who qualify, who have need. Second, what is so critically important, I think, that we all understand is that our economy is changing. And to get the jobs of the future—there was a recent study that came out from the Georgetown University Center on Education and the Workforce. They estimate that going forward, we are going to be about 3 million college graduates short of what the economy needs—what the market is asking for. And so, at a time of increasing need, there is also increasing demand. And so, we have to keep that maximum Pell Grant at $5,550. We have had to make tough calls. Eliminating the two Pells in one year—in an ideal world, I would never want to do that. Eliminating in-school subsidies for graduate students, again, in an ideal world we'd never want to do that. But we are trying to be fiscally responsible and share the pain and make these tough choices. We think those are the lesser of the evils, and we want to at all costs maintain that Pell maximum award at $5,550.

Senator HARKIN. I appreciate that. And when we looked at that, the interest subsidy for graduate students, I mean, let us face it. If you are a graduate student, you are probably going to get a pretty good job when you get out. And so, in the whole spectrum of things, they could probably afford that interest payment—we hope so anyway, with all the unemployment. But hopefully our graduate students will lead us—help lead us out of this mess. But I can see where we would take on that rather than the poorer students in undergraduate school.

Secretary DUNCAN. Yes, sir.

Senator HARKIN. So, it is a tough choice, but one that we supported.

My time is up. Senator Shelby.

STRONG EDUCATION SUPPORT NEEDED DESPITE TOUGH ECONOMY

Senator SHELBY. Thank you, Mr. Chairman.

Mr. Secretary, I do not think any of us want to take a chainsaw to any program that is going to sustain our educational system and hope for our young people at all. But we are all taking a chainsaw to our budget right now to a certain extent because of our failure to act. We have a $14 trillion debt. You probably, in putting your budget together, made some tough choices.

What we have got to do, I believe, is make some wise choices, and then carry them through. And what those all are, I am not sure, but I know that we cannot, as Senator Harkin said, we cannot starve the future. We cannot starve our children of food and sustenance. We cannot starve them of an education.

JOB AND EDUCATION REQUIREMENTS OF NEXT DECADE

Where are the jobs going to be, in your judgment, in the next, say, 10 years? Where are the jobs in America going to be, and what kind of education process do we need to get there, to have our people ready for the workforce jobs that are needed? Because at the end of the day, we've got millions of people unemployed, and a lot of them are losing hope every day.

INADEQUACY OF EDUCATION FOR CURRENT HIGH SKILL JOBS

Secretary DUNCAN. Let me give you four different statistics that sort of get at this. One is that even in this tough economic climate, we have 3 million unfilled jobs in this country. Many of those are high-skilled, high-wage jobs, and we are simply not preparing the workforce for those jobs.

EDUCATION AND JOB DEMANDS OF NEXT DECADE

Going forward, up until about 2018, we are going to need to fill 2.6 million job openings in the STEM fields—science, technology, engineering, and math. Going forward, there is an estimate that by 2018, if we stay on the current course, if we do not improve, we are going to be 3 million college graduates short of what the market demands.

And then finally, by 2018, between now and then, 63 percent of job openings will require at least some college-level education. And these are not our facts; these are all facts from outside groups, the

Bureau of Labor Statistics, and the Georgetown University Center on Education and the Workforce. So, we need an increasingly educated, high-skilled workforce with this particular emphasis on the STEM fields.

PELL GRANTS—INTEGRAL TO EDUCATION BUDGET AND GOALS

Senator SHELBY. Mr. Secretary, as we think of Pell grants, do we not have to think of them in the overall budget process of the Department of Education? In other words, they are not separate from; they are part—an integral part of the budget. Is that correct?

Secretary DUNCAN. I think, again, all of our work from, you know, early childhood education, which we will talk about——

Senator SHELBY. Everything——

Secretary DUNCAN [continuing]. K to 12 reform, all of that is to what goal? The goal, as the President has laid out, is to lead the world in college graduates by 2020. We think that—we have to educate our way to a better economy. So, the Pell grants are absolutely vital, integral, critical to getting us as a country——

Senator SHELBY. But they are not the only part of the education part.

Secretary DUNCAN. No, sir.

Senator SHELBY. An important part, yes.

Secretary DUNCAN. Yes, sir.

PELL GRANTS—HOW DO WE PAY FOR THEM?

Senator SHELBY. Now, how are we going to pay for it? That is the bottom line. In other words, the growth—we have a lot of people unemployed. We know this, which we hate. But how are we going to pay for this, because that is going to be the bottom line up here this year and in the future. What are our priorities? What are our priorities in education? What are your priorities in the Department of Education? Could you list, say, the top three or four? You are going to have to make some decisions. So do we.

SAVINGS FROM ELIMINATING TWO PELLS AND IN-SCHOOL SUBSIDY

Secretary DUNCAN. So, we are making very tough decisions. We have talked about eliminating the grad school subsidies. That is going to save the country $18 billion over the next 10 years.

Senator SHELBY. Eighteen billion dollars.

Secretary DUNCAN. Over the next 10 years.

Senator SHELBY. Would that pay for the Pell Grant increase, for the, say, the undergraduates?

Secretary DUNCAN. Short term, it helps. I mean, this is $18 billion with a B, this is real money.

Senator SHELBY. Okay.

Secretary DUNCAN. So, eliminating the second Pell——

Senator SHELBY. That is $1 billion here and $8 billion there, and it is real money?

Secretary DUNCAN. Exactly. I am learning that here in Washington.

Senator SHELBY. Okay.

Secretary DUNCAN. Eliminating the second Pell Grant each year, which again was a tough, tough call, that is $5 billion every single

year. So, over 10 years that is $50 billion. So, these are very real savings. You know, tough calls, not calls we wanted to make, but we had to make, we think, to preserve that maximum funding for Pell grants.

EDUCATION PRIORITIES—CRADLE-TO-CAREER CONTINUUM

To answer your question, our priorities are continuing to strengthen early childhood education, to continue to drive K to 12 reform, and to continue to invest in—to increase access to higher education. So, this is a cradle-to-career continuum, and those are the three steps along that pathway.

Senator SHELBY. But if you cannot have it all, and you cannot—I wish you could, and I wish that I were here when we owed no money as a Nation, because I think a lot of us could get together and have a lot of good ideas including investment in education. We are going to have to make tough decisions.

And thank you. My time is up.

Senator HARKIN. Senator Reed.

EDUCATION REFORM

Senator REED. Thank you very much, Mr. Chairman, and thank you, Mr. Secretary. And certainly you have an extraordinarily challenging job, given the budget pressures. I think you rightly point out the central need to fundamentally reform our education system at the elementary and secondary level, and also support it at the higher education level.

LARGE-SCALE COMPETITIVE VS. FORMULA-BASED GRANT PROGRAMS

But let me take a moment because I am concerned that the overarching strategy at the Department has been to focus almost exclusively on these untested, large-scale competitive grant programs at the expense of some proven research-based programs that have a track record of success. Race to the Top is probably the signature program. That is a novel, and I think bold, way to sort of rethink education. But it has displaced programs, for example, like the school library program.

NEED FOR LIBRARY PROGRAMS

And the Department's own evaluation has found these library programs to be extraordinarily effective over many decades. In fact, since 1965, more than 60 educational library studies have produced clear evidence that school libraries staffed by qualified librarians have a positive impact on student achievement. And I think it just follows that someone who knows about how to use the library and wants to use the library, is probably prepared for learning the rest of his or her life.

There is no plan that I have seen or has been shared with me for the Department to replace either through Race to the Top or any other program the support that we have given to school libraries. So, frankly, those programs are not only on hold, but they very well might be lost. And I do not have to remind anyone around here, the first thing to go at the local school committee meeting is, well, we will not buy any library books this year. In fact, back in

the 1990s when I got involved in this issue, librarians would come to me with books stamped ESEA, 1965, and that was 25 years after the legislation was passed. So, I am concerned about that.

TEACHER QUALITY PARTNERSHIPS

Another example, too, is the Department has a program that is trying to develop support for teachers, but there is already a teacher quality partnership grant program that was included in the Higher Education Opportunity Act. This program has high bars for reform. You are consolidating that program into a broader, more flexible funding stream, which could water down reforms.

NEED FOR FULL RANGE OF STUDENT AID PROGRAMS

And then we all are committed to maintaining student financial aid. And the President, I must admit, and your leadership has been instrumental in increasing the maximum Pell grant. However, the strength and resilience of our Federal aid programs comes through a combination of Pell, State grants, institutional aid, and student loans. And as we try to work the Pell Grant, it seems that we have done a lot to undermine the other programs. In fact, we have eliminated some of them effectively.

And so, I do not know. They are not easy questions—with easy answers. I have specific questions I will submit to you in writing. But I would just in the remaining minute ask you to comment.

FORMULA GRANT PROGRAMS FORM MAJORITY OF ED BUDGET

Secretary DUNCAN. Sure. I will try and respond succinctly.

So, the vast majority—let me be very clear—the vast majority of our funding has been, continues to be, and will be going forward, formula-based, not competitive-based. And in fact, 84 percent of our money is formula-based funding, the large—absolute large majority being title I and IDEA.

SUPPORT FOR INNOVATION AND ACHIEVEMENT

We have asked for a small percentage of money to reward excellence and courage. And what has been so interesting to me in programs like to Race to the Top is it is not just within the States that won money, like your State, but it is in a State like Chairman Harkin's, where they did not receive a dime from us, that we have seen a massive amount of change. For the first time, States are raising standards, and that benefits disadvantaged children, and rural children more than anyone. We have dummied down standards in far too many places.

And so, at the end of the day, it was not just about who received money; it was creating a climate in this country where folks started to do the right thing, started to think about high standards, or working together on better assessments, or finally turning around chronically under-performing schools that they hesitated to do before. And so, that work is going on nationwide whether States receive money or not.

SUPPORT FOR LITERACY PROGRAMS

In terms of the literacy funding and school libraries, and you have been a strong advocate there, we were very disappointed that in our fiscal year 2011 budget, funding for literacy basically got decimated, went to zero in the continuing resolution. And so, we are asking for a very substantial increase in literacy funding because that is so fundamental, so foundational to student learning. And if students cannot read, if they cannot express their ideas verbally and on paper, frankly however much else we do does not matter. And so, we are, again, in tough economic times, asking for a significant boost in that funding.

INCREASING COLLEGE COMPLETION RATES

And then again, just finally on the need for access to higher education. We want to continue, as I have said repeatedly, we want to continue to maintain that commitment. One thing we have not talked about is we are asking for some i3-like money, some creative money, to really reward institutions and States, and nonprofits that can increase college completion rates, and increase productivity, and do a better job of helping students with disabilities to graduate. So for me, access is desperately important, but it has got to be about more than access. It has got to be about attainment. It is about getting that college diploma. And we want to really invest in places that are going to build cultures around not just access, but around completion.

Senator REED. Mr. Secretary, I have specific questions I will submit to you. But I thank you again for your presence today and for your service. Thank you.

Secretary DUNCAN. Thank you.

STRENGTHENING LITERACY IN THE EARLY GRADES

Senator COCHRAN. Mr. Chairman. Mr. Secretary, thank you very much for your cooperation and participation in this hearing. I am pleased to be a co-sponsor with my friend from Rhode Island of S. 1328, The Strengthening Kids' Interest in Learning and Libraries Act. And that question that he put to you is one that I identify with.

In our State, we have a financial problem because we do not have enough tax money coming into the State government agencies, and in county and local agencies that fund education programs to take care of all of our needs. So, we were really excited when the Elementary and Secondary Education Act was approved and funding under the various titles began coming to our State, and have provided some needed financial benefits that have been used to involve students who were not learning at the rates they should have been in innovative programs, literacy programs. And the school libraries played an active role in this.

I was just curious to know what your assessment of the Department of Education's Learning and Libraries Act is having on that challenge.

MISSISSIPPI'S GAINS IN LITERACY IN EARLY GRADES

Secretary DUNCAN. Again, we want to do everything we can to enhance literacy through libraries, the classroom, and technology. That is just fundamental. And I have to tell you, I have been recently studying, Senator Cochran, Mississippi's results on increasing literacy in the early grades. And I think Mississippi is making as fast, if not faster, progress than any State in the country. And so, I am spending a lot of time talking to folks from your State, looking at what they have done right there.

And Mississippi, as you know, historically has really been maybe 50th in so many indicators. And particularly in the early grade literacy, I think you have gone from 50th as a State to 43rd. That is remarkable progress in a short amount of time. So, I think there are a lot of lessons to be learned about what you guys are doing as a State to create a culture of literacy, to better support teachers, to raise expectations.

And, again, I am always looking not at just where you rank, but rates of progress. And the progress your State is making is very significant, very encouraging, and I think has national implications. So, I thank you for the leadership there. And I thank the State for taking on such a foundational issue and making remarkable progress in a short amount of time.

FEDERAL ROLE IN EDUCATION

Senator COCHRAN. I am very proud of the fact that my parents were both involved in education. And my father was a school superintendent, and my mother was a mathematics teacher. And they both were very strong advocates for Federal assistance to education at a time in Mississippi when some people thought there were strings attached, and there were—it would strengthen the Federal role in education—and not necessarily to the benefit of the children, but to the control of the Federal Government over local decisionmaking.

I think all of that has gotten sorted out, and there is not as much suspicion now as there used to be with Federal money coming into the State, and with it, strings being attached that might not be consistent with what was really best for the children and the atmosphere they were growing up in.

LITERACY THROUGH SCHOOL LIBRARIES

But we want to continue to monitor the use of Federal dollars. And there is one program, I think it is called the Second Evaluation of the Improving Literacy Through School Libraries Program. What effect do you think this has had on the ability of school districts that do not have adequate resources for furnishing libraries? Has that provided meaningful benefits in your opinion?

Secretary DUNCAN. I would have to look at the details of that. But, again, whatever we can do to support literacy, to support early literacy, in the classroom, after school, through print, and more and more going forward, digital resources, we want to do that, and we want to give students and communities who historically have been under-served or under-resourced—disadvantaged communities—we want to give them more opportunity.

TITLE I REWARDS PROGRAM

Senator COCHRAN. Well, one area that has been brought to my attention is the title I program and a new—under new authority called Title I Rewards. I was going to ask you if you could submit for the hearing record your assessment of how that program is working.

While Mississippi has the country's highest concentration of children in poverty, it received only $1,318 per title I eligible student. And we were looking at some comparisons with other States that had student populations about our size, and Wyoming received—and I am not fussing about the higher level, but three times as much funding for that program as our State did. I am just curious to know why is that, and if that is a disparity?

Secretary DUNCAN. We would have to look at that and look at how States are allocating title I dollars. But to answer your question directly, our Title I Rewards Program hasn't been funded yet; that is a request, so there is nothing to evaluate. But our goal is very, very clear. There are certain high poverty, often high minority districts that do an amazing job of increasing student achievement. And we want to shine a spotlight on that, we want to recognize that, we want to learn from that, and we want to incentivize that, give them more resources.

And so, I think, again, with everything we are doing, we are trying to put a spotlight on excellence. We spend billions and billions of dollars, you know, well over $10 billion a year on title I. I want to know which districts are doing an amazing job of helping disadvantaged students be successful, and give them additional resources and learn from them. That is the purpose of that program, but it has not been funded yet, so there is nothing to evaluate. That is part of our request.

Senator COCHRAN. All right. Thank you very much. Mr. Chairman.

FIRST GENERATION STUDENTS—COLLEGE DROPOUT RATE

Senator BROWN. Thank you very much, Chairman Harkin, and, Mr. Secretary, nice to see you again.

Eighty-nine percent of first generation students—89 percent leave college without a degree after 6 years, a terrible waste of human talent, a terrible waste of the future potentially, and a terrible waste of dollars.

The Gates Foundation said 54 percent of students that leave during that 6 years cite the need to work and make money; 31 percent cite an inability to afford the tuition and fees. And this is a direct result of Government not investing the way that we should. I appreciate the President's efforts there.

You came a couple of years ago to speak to an annual—I have done it four times in my 5 years now in the Senate—annual presidents' conference. We bring in 50, 55 college presidents in Ohio, 2-year, 4-year, private, public. And you spoke 1½ years ago, 1 year plus ago there. And trying to figure this whole issue out.

What—talk to me—give me 2 or 3 minutes—what the Department is doing to target and eliminate barriers faced by first-generation students, especially community colleges.

My wife was a first-generation. Her dad carried a union card for 35 years. She was one—the oldest of four children that went to college. She graduated with very little debt. It was—I guess I can say this—30 plus years ago. And she—but she talks about calling home those first 2 years, and her parents never had any real substantive useful advice for her about how to navigate their way through college.

So, give me a couple of minutes of very specific, what this Department is doing to rescue—give those young people opportunities that they need.

HELPING FIRST GENERATION STUDENTS GRADUATE

Secretary DUNCAN. First of all, thanks so much for your passionate leadership in this area. And as we become an increasingly diverse country, as the minority population becomes the majority, our ability to help those first-generation students, not just graduate from high school, but graduate from high school truly college- and career-ready, and then to graduate from college is critical. The fate of our Nation hangs on our ability to do that well, so I cannot overstate the importance.

MAINTAINING ACCESS THROUGH PELL GRANTS

Three very specific things we are trying to do. One of the big emphases today is our desperate fight to maintain access for poor students to Pell grants, which by definition are students you are talking about. And if we scale back on Pell access based upon the research that the Gateses and many others have done, we will simply have a lot less people going on to college. And they are going to be at a huge disadvantage in this knowledge-based, globally competitive economy. So, we have to maintain that commitment and help more and more people have access.

INVESTING IN COMMUNITY COLLEGES

Second, we have not talked enough today about community colleges. We think community colleges have been this unpolished gem along the education continuum. Many are doing a magnificent job, whether it is with 18-year-olds or 38-year-olds, or 58-year-olds, folks going back to retrain and retool, in areas like green energy jobs, healthcare jobs, technology jobs. We are making an unprecedented investment—$2 billion along with the Labor Department, to invest in community colleges that are building strong partnerships with the private sector. And, again, their work and their courses are leading to real jobs in the community.

It has been a great partnership with Labor. My Under Secretary of Education, Martha Kanter, is a former president of a community college. We have never had someone at that level with that background. We did that very strategically because we thought that was so important.

FIRST IN THE WORLD—BUILDING A COLLEGE COMPLETION CULTURE

Finally, we want to invest in the fiscal year 2012 budget in what we are calling the First in the World Competition, and to really again put significant money, over $100 million behind States and

universities and nonprofits that can show us what they are doing to build cultures around completion, particularly for first generation college goers, folks with disabilities, those who have been denied opportunities historically. So, those three, Pell access, a huge play in the community colleges in trying to invest in place, building cultures around completion would be the three I would give to you this morning.

Senator BROWN. Thank you, Mr. Secretary.

Two other issues, one a comment, and then a last question.

FEDERAL DIRECT STUDENT LOAN ORIGINATION FEES

It is my understanding that Speaker Boehner's latest deficit reduction plan proposes to eliminate the Department of Education's ability to offer incentives to borrowers who pay their loans on time. The Federal direct student loan program, which makes so much sense in terms of students dealing with interest rates, cost, debt all of that. I know that my colleagues do not—they think it is another big Government program. It is one that saves money and helps students, and kind of throws the middle man out, if you will, the banks, and has made such a difference. But under their deficit reduction plan, college students would have to pay a higher origination fee for their Federal direct loan. I would just like you to continue to do the right thing on the Federal direct loan program. It matters so much.

TITLE VI CULTURE AND FOREIGN LANGUAGE PROGRAMS

My last question is this. The title VI international education and foreign language studies programs are, I think, especially important for us to enhance our capacity to understand foreign languages and cultures and people—increasingly important in both a globalized economy and in an uncertain world.

For 50 years, the United States has invested in building this national capacity, which is vital to our economic and diplomatic efforts around the world. I was disappointed that fiscal year 2011 appropriations contained severe reductions to international programs.

I think we—and my question is this. I would like more specifics about how you are measuring the effectiveness of this program, because I think if you really do measure it, including implementing the recommendations made by the 2007 National Academies report, the more accurately you measure this, the less likely you are going to want to, from my experience with this, be making any cuts to this program. So, if you would give me your thoughts on that.

Secretary DUNCAN. No, I really appreciate you pushing on that. And we were disappointed those funds got cut substantially in fiscal year 2011. We are looking to restore funding for that program that we think is very important. And, again, in a smaller world and a more globalized world, in order to give young people those kinds of opportunities, we want to restore funding in fiscal year 2012. That is part of our request.

Senator BROWN. Thank you.

Thank you, Mr. Chairman.

Senator MORAN. Mr. Chairman, thank you.

TEACHER AND STUDENT CLASSROOM EXPERIENCE

Secretary, I appreciate the conversation you and I had last week, and look forward to working with you to see that good things happen in education, in our country, and particularly in Kansas.

STATE AND LOCAL FLEXIBILITY

I voted against No Child Left Behind in its early creation back when I was a member of the House of Representatives for a number of reasons. I have genuine concern about what is happening in regard to teachers. And I am concerned that education becomes more of a bureaucracy as compared to a profession. I worry that the classroom experience is being diminished with focus on in-service teachers' meetings preparation as compared to that opportunity for teachers to do what they do best, teach our students in a classroom, in my view, as students learn with a teacher who loves to teach, with a student who wants to learn, and parents who encourage that through discipline and encouragement.

And I want to make sure that the programs we create here in Washington, DC, do not impede upon that educational opportunity in the classroom.

FEDERAL FUNDS AS PERCENT OF KANSAS EDUCATION BUDGET

In Kansas, we receive just over 7 percent of our education funding from the Federal Government, and yet as I talk to educators—teachers, school administrators, superintendents, board members—the amount of time, effort, energy, and cost associated with trying to figure out what the Department of Education, what the Federal Government is doing in education consumes a much more substantive amount of their time than the 7 percent of funding that is received. And I suppose one could answer, well, let us provide more money. I doubt that that is a realistic option.

STATE FLEXIBILITY AND WAIVERS

I would love to hear from you the efforts that you are—your Department is pursuing to make sure that schools have the flexibility, that the focus is on the classroom, that it is not upon paperwork and bureaucracy. And in particular, you indicated that if we do not have ESEA reauthorized by September, that you had plans to offer waivers. And I am interested in knowing what those—what you would require—what those waivers would be and what you would require of States to actually receive a waiver. And also your thoughts about the growth model, which seems to be educators' kind of solution to AYP is changing the model, and what efforts in that regard do you see beneficial?

Secretary DUNCAN. So, lots there, and I appreciate your leadership and thoughtfulness on these issues.

IMPROVING PARTNERSHIPS WITH STATES AND LEAS

First of all, one of the biggest things I am trying to do, and I want you collectively to hold me accountable, is we want our Department to be a better partner. I was a school superintendent for 7½ years, and frankly, I often chafed at the restrictions of the Federal Government—I tell the story frequently that I had to have a

huge battle with my Department of Education here for the right to tutor poor children after school in Chicago. I won that battle, but it made no sense that we had to fight the Federal Government to do the right thing by children.

So, I am acutely aware of the history there. I cannot say we are doing it perfectly every day, but I just want to assure you we are trying. And I would encourage you to talk to supes and State school chief officers, and teachers to find out if we are being more receptive and doing a better job of listening.

INCREASED EFFICIENCY THROUGH PROGRAM CONSOLIDATION

We have tried to consolidate programs, to cut from 38 to 11, to become more efficient and effective, but also just to have less points of contact, make it simpler for folks to deal with us.

FLEXIBILITY IN EXCHANGE FOR RESULTS

And then for me, the tradeoff in all of this, whether it is in our education plans, Race to the Top, i3, Promise Neighborhoods, whether it is in, hopefully, reauthorization of ESEA, and if not, potentially waivers—to me, the real tradeoff is where States and districts are raising the bar, setting higher standards, and holding themselves accountable. I am a big believer in growth rather than absolute test scores. I want to know how much students are improving each year, not whether they are at some artificial cut point.

Where States are doing the right thing, we want to provide a lot more resources and a lot more flexibility. Where folks are backing down, reducing standards, showing an unwillingness to close the achievement gap, we are going to challenge them very, very hard.

NO CHILD LEFT BEHIND

But for me, the grand trade off philosophically in all these things is, if we can hold folks accountable to a high bar, then we should give them a lot more room to move. I think the current law, I have said repeatedly, is far too punitive. It is far too prescriptive. It led to a narrowing of the curriculum, and it led to a dumbing down of standards. None of those things are good for children or teachers or education in our country, and we want to fix the law in a common sense way. Chairman Harkin is working extraordinarily hard in a bipartisan manner. We are working very, very closely with Senator Enzi, and with the gentleman to your left, Senator Alexander, someone I have great, great respect for, who held my position. I listen very closely when he speaks.

BIPARTISANSHIP APPROACH TO EDUCATION BILL

And we just hope, despite some of the dysfunction, frankly, that we see coming from our Congress, that we can think about education, while putting politics to the side, putting ideology to the side, to come up with a common sense, bipartisan bill. It is the right thing to do. And I desperately hope that will still happen.

Senator MORAN. I thank you for your answer, and I will follow up with questions in writing.

WAIVER FOR MC PHERSON USD SCHOOL DISTRICT 418

But in that regard, as I indicated to you, I am very grateful for the waiver you provided McPherson USD School District 418. They have created their own set of tests and standards, and you granted the first waiver nationwide. It is an example of what is going on in Kansas. It is very beneficial.

Secretary DUNCAN. And let me be very clear on that. That was not a gift; that was something McPherson earned. They basically said they were raising the bar above State standards. And whenever anyone is holding themselves to a higher level of accountability and challenging both adults and students to do more, we want to do everything we can to support that, and, frankly, to get out of the way. So, I appreciate their courage. That is tough, tough work. But if we had more districts and more States doing that, today education would be in a much better place. So, that was not a gift; that was something they absolutely earned. And I appreciate the example they are setting for the country.

Senator MORAN. I do criticize you for using my time to compliment Senator Alexander.

Do that when he asks his questions, I would appreciate it.

Thank you, Mr. Secretary.

Secretary DUNCAN. I will use his time to compliment you.

Senator HARKIN. Senator Landrieu.

Senator LANDRIEU. Mr. Secretary, let me begin by using some of my time to compliment Senator Alexander. I have worked with him on many issues.

And I appreciate his continued support for our bipartisan reform efforts.

I want to thank you, Mr. Secretary, for your passionate leadership and your inspirational leadership. I think you are exactly the right Secretary for the challenges before this Nation. And I thank you for being tough and not backing up and pushing this all forward.

TEACH FOR AMERICA

But I wanted to raise just a couple of questions that are concerning to me.

First, is because of the zeroing out of several critical and, in my view, superior programs, one of which, not the only one, but one of which is Teach for America. This subcommittee rallied in a bipartisan way because that program was zeroed out both by the President's budget and by a missed definition, in my view, of earmark. This subcommittee rallied, the chairman helped us, to identify 1 percent of title II–A funds last year so that some funding could move to Teach for America and other programs that were, in my view, in a very shortsighted way zeroed out.

We have a plan—90 Members of Congress have sent a letter to you and the President, urging you to set aside 5 percent this year for these high-performing, effective programs. I am going to ask you this question in a minute. But I want to put on the record, Teach for America last year, there were 48,000 applicants. Now, these applicants are the top 1 and 2 percent of students graduating from all of our universities. From 1,500 colleges they applied. They

only selected 5,000. Again, 48,000 applied, 5,280 were selected by limits of budget.

LEVERAGING POWER OF TEACH FOR AMERICA

TFA, for every $7 in non-Federal funding, they leverage $7 in the private sector for every $1 that we fund them.

TEACH FOR AMERICA AND STEM INSTRUCTION

In addition, TFA is the largest single provider of STEM—science, technology, engineering, and math—teachers in the country, so science, technology, engineering, math, STEM. They are providing more teachers, so we cut this program out entirely. It makes no sense to me.

TEACH FOR AMERICA FUNDING

We have tried to say collectively, how do we get our best and brightest in the classroom? So, Teach for America comes up with a plan, mostly private sector driven, nonprofit driven. We put up a little money, they put up a lot of money, the public benefits.

I am very confused as to how we zero out a program like this. So, we want to solve this problem.

Are you committed to increasing 5 percent so that at least Teach for America has an opportunity to compete for decent enough money to get them back on track to continue to provide the technology, engineering, and math teachers this country desperately needs? If so, why? And if not, why not?

TEACH FOR AMERICA—LEADERSHIP DEVELOPMENT BENEFITS

Secretary DUNCAN. First of all, obviously I think Teach for America has done a remarkable job, not just at producing teachers and teachers in STEM areas and teachers in disadvantaged communities, but one of the huge residual benefits of the program is it has been an amazing leadership program. And many innovative superintendents, many leaders of nonprofits, many education entrepreneurs are Teach for America alums. And I think that is a benefit. When I ran Chicago Public Schools, I worked to bring TFA in. What I did not realize—I was not smart enough at the time, when we started opening really innovative new schools in disadvantaged communities—a wildly disproportionate number of the principals leading those efforts were Teach for America alumni. So, it was a really important lesson for me.

FUNDING INCREASE FOR TEACH FOR AMERICA

Senator LANDRIEU. So, do you support the 5 percent——

Secretary DUNCAN. So, we are adding—I am getting to that. We are right now, as you know, TFA successfully competed, again, not a gift, won, a $50 million grant to invest in innovation. Had great evidence, great data on effectiveness. We were happy to do the 1 percent set-aside. I would need to sort of sit down with my staff and think about the 5 percent set aside as we move forward. I understand the need, and to give more folks the chance to compete would be interesting to me. So, I am not willing to commit to it today, but——

Senator LANDRIEU. Well, the nine of us are going to push you very hard to do that. And there are other programs, not just Teach for America, that are superior, effective, and extraordinary in their results. We should not be eliminating them.

RACE TO THE TOP ACCOUNTABILITY

And my second question, Race to the Top——

Secretary DUNCAN. I could not agree with that more.

RACE TO THE TOP AMENDMENTS

Senator LANDRIEU. Okay. My second is, every State except Georgia that won Race to the Top in the first two rounds has now amended its State reform plan in some way, usually to push back timetables or scaling, you know, scale back initiatives. According to the list of approved amendments, there were 12 winners that changed their plans 25 times.

My question is, the administration has requested an additional $900 million for the Race to the Top, but before approving additional funding, are you going to continue to give out funding to States just to see their timelines, which they promise to meet, push back, or there are promises made, then modified, and not reach the goals that we all hope for them to do?

Secretary DUNCAN. No, we are absolutely holding them accountable for outcomes, and we are never giving waivers for material changes in applications. We have asked them to take on very, very ambitious work. If it takes a little bit longer to get that work done well, we are happy to support that. If it is bypassing that work or avoiding it, we will never grant that waiver. And to be very clear, we will withhold funding if they take that step.

I am not, frankly, seeing that. I am seeing huge amounts of courage. I am seeing extraordinarily hard work going on. Sometimes it takes a little longer, but I am interested in the outcome, in quality. And the second we see a State back away from that, we will stop funding them immediately. I want to let you know that, absolutely.

Senator LANDRIEU. Okay. And I know my time is up, Mr. Chairman, but I do have other questions. I will just submit them for the record on the TRIO program and emergency preparedness for schools. And I thank you very much.

Secretary DUNCAN. Thank you.

TEACH FOR AMERICA FUNDING

Senator HARKIN. I might just say to my friend from Louisiana that I have always been a big supporter of Teach for America. It was one of those earmarks that we used to do.

Senator LANDRIEU. But it is a federally authorized program, so I am very confused about that definition.

Senator HARKIN. Well, we put a set-aside in there for everything at 1 percent. I would be delighted to visit with you about whether that should be increased at this level or not on that set-aside.

Senator LANDRIEU. Thank you, Mr. Chairman, for your leadership.

Senator HARKIN. Well, for the competition.

Senator LANDRIEU. And it is not just for Teach for America, but there are several effective programs out there. I mean, I understand eliminating programs that do not work, but when we start eliminating the best programs that are working at even a public/private partnership, I think we have gone way off the cliff.

Senator HARKIN. Well, I could not agree more. Thank you very much.

Senator Pryor.

Senator PRYOR. Thank you, Mr. Chairman, and I want to thank the Secretary for being here today. It is great to see you. I think the last time you and I saw each other face to face was in Little Rock when you were at Little Rock Central High School doing your Courage in the Classroom kick off. I hope that was successful. We loved having you in Arkansas. Thank you very much for coming down.

PROMISE NEIGHBORHOOD PROGRAM

I want to ask about the Promise Neighborhoods program. This is a program under which the University of Arkansas at Little Rock was successful in getting a planning grant for fiscal year 2010. I am curious about your view of how the Promise Neighborhood projects are going. What kind of results you are seeing out there? What kind of end results you are looking for?

Secretary DUNCAN. This is a hugely important initiative to me, particularly in our Nation's most distressed, most disadvantaged communities. The only way we strengthen those communities is by increasing the quality of education and building community support for that work, and building the kind of wrap-around services and nonprofit partnerships that help schools to be successful in very tough communities.

PROMISE NEIGHBORHOODS FUNDING

We were fortunate to be able to fund 20 planning grants, that being one of them, around the country. We had 300 applicants, and we had many more highly creative, thoughtful proposals that I would love to have funded that we simply did not have the money for. Fiscal year 2011, we have $30 million that we are going to use for a combination of purposes—starting to fund some programs, some communities for implementation and others to develop a plan. But we would like to see a significant increase in the investment in Promise Neighborhoods for fiscal year 2012 to really start to move to implementation across the country.

And the grants are in very poor rural communities. We have one planning grant on an Indian reservation, Native American reservation, and others in distressed inner-city communities where we can get the kind of results that Geoffrey Canada has done in the Harlem children zone in New York, dramatically transforming the life chances of young people there.

NEED FOR RECOGNIZING, FUNDING MORE PROMISING PROGRAMS

We can prove, demonstrate, that communities can come together to help the most challenged children and families be very successful academically. So, we think this is the right investment. It is

early on. There is much greater need and capacity out there than we are able to fund, and that is what is heartbreaking to me. There are people doing amazingly thoughtful work, collaborating, partnering in ways that they never would have done before. We support that effort to not scale back. And so we would respectfully ask for a significant increase in funding to move toward implementation to a wide variety of communities around the country.

Senator PRYOR. I think that is great. So, you are seeing what you would hope to see out there, which is communities coming together and really getting great things done. And now you are getting to the implementation stage.

PROMISE NEIGHBORHOOD APPLICANTS AND AWARDS

Secretary DUNCAN. And we were blown away by the number of applicants, the quality of applicants. And, again, we were able to fund 20 or 21. There were probably over 100 that I would have felt great about investing in, and I was thrilled to do the ones we did. I would love to have had the chance to invest in many other communities.

SCIENCE, TECHNOLOGY, ENGINEERING AND MATHEMATICS

Senator PRYOR. Well, thank you for that answer. Now let me also ask about STEM. This is an area that is very important. You have prioritized STEM education in your budget. My view is that focusing on STEM will absolutely translate into better jobs, better opportunities for many, many, many Americans around the country. Could you comment on that and talk about your vision for STEM education and how that impacts the future workforce?

Secretary DUNCAN. So, at its heart as we go forward, we simply have to produce a lot more young people with skills, with competency, with a passion for the STEM disciplines. That is where the jobs of the future are. That is going to be the future creators, the innovators, the entrepreneurs who are going to create jobs in fields that do not even exist today.

STEM TEACHER SHORTAGE

Right now, we have a shortage of teachers who are strong in STEM. We have had that shortage in this country probably for 20, 25, 30 years, and I want to stop admitting the problem. I want to try and fix it. And we need teachers with great passion, great interest in the STEM fields, not just for AP calculus and physics, but in third, and fourth, and fifth grade where too often students start to turn away from that, lose interest because their teachers do not know the content area, and they start to back away.

So, we have to invest significantly to get that next generation of teachers to come in to the STEM fields. The President has challenged us to recruit 100,000 new teachers in the STEM areas. We have to make sure that students in elementary school, eighth grade have access to classes like algebra I. We have to make sure that students—sophomores, juniors, and seniors—in high school have access to AP classes and college-level classes in the STEM fields.

I think we—I am a little controversial on this but, I think particularly in disadvantaged communities, in rural and remote areas,

we should be thinking about where there is a scarcity of great STEM teachers, and I think we should pay those teachers more money to take on those assignments in communities that just haven't had access. And we see across the Nation far too many young people—we just did a recent data survey—data collection with the Office of Civil Rights. There are far too many—hundreds of thousands of young people who do not have access to a class like algebra I in eighth grade. And if you want them taking, you know, AP physics or calculus down the road, you have to start them in that trajectory.

So, we have a lot of hard work here. I do not want to keep admitting the problem. I want to try to fix it.

Senator PRYOR. Right. Mr. Chairman, thank you. Before I close, I would like to say to Secretary Duncan that I know we have picked on Senator Alexander today. But I know that Senator Alexander has great respect for you because the other day he was telling me that he thinks you are the second best secretary of education we have ever had.

Thank you.

Senator HARKIN. Thank you, Senator Pryor. I must just add on the STEM stuff, Mr. Secretary, you pointed out it is so important to get down to first-, second-, third-graders who have a natural instinct and interest in science, and to encourage that at that level.

Senator Kirk.

EDUCATION SUPPORT FOR CHILDREN OF MILITARY FAMILIES

Senator KIRK. Thank you. And, Mr. Secretary, it is great to see you in this job after what you did for the Chicago Public Schools.

And I want to talk to you about—Senator Durbin and I are working on making sure that we are supporting the military families, especially around Great Lakes. We have a unique arrangement there. We are working with the chairman to make sure that we do not see a couple of school districts implode that support the military families there.

CHARTER SCHOOLS

Then there is a unique charter school initiative that we are rolling, which I think will look a little bit like a DOD school, and further support military families that may be replicable throughout the rest of the country. I wonder if you could comment on those two initiatives.

Secretary DUNCAN. Yeah. I do not know the details. I think you are working in the North Chicago community.

Senator KIRK. Right.

Secretary DUNCAN. And I will just say simply, we cannot do enough to support our military families. And as I talk to troops who are serving and who have come back from service in Iraq and Afghanistan, when I ask what can we do to help you, they consistently say, take care of my children. Educate my children. That is the least we can do.

And so, I do not know the details of the proposal. Whatever I can do to support getting high quality options, strengthening education for the children of adults who are serving our country, I want to do everything I can to help that. I have tried to travel to as many

bases and schools around military communities to really understand the challenges.

COMMON STANDARDS BENEFIT MILITARY FAMILIES

This is a little bit off topic. There are huge benefits of the common standards that folks are doing, higher standards, for as you know, military families move very frequently, and they get devastated by those moves to different States doing different things, and children finding out they are far behind. So, they have been extraordinarily supportive of the work we have done to have college- and career-readiness common standards in the vast majority of States around the country. So, at the local level, nationally, whatever I can do to help support these children, please count me in.

EXPANDING CHARTER SCHOOL OPPORTUNITIES

Senator KIRK. Thank you. Senator Durbin and I are also working on the Durbin-Kirk ALL–STAR legislation to expand charter school opportunities for kids. Right now, for example, in a community you know well, Chicago, only about 10 percent of families even have the ability to send their kids to a charter school. So, we would change the Federal funding law to allow us not just to start new charter schools, which is allowed under Federal law, but to expand current ones. And I think that would allow us to pick the winning charter systems. But can you comment on that?

Secretary DUNCAN. I think, again, that is where I have been very, very clear. I am not pro-charter; I am pro great schools. And where you have great charters, giving them the chance to replicate, to serve more students, it is silly not to do that. I have also challenged the charter community, when schools are not working, we need to hold them accountable and close them down. But where you have high-performing charters, particularly in disadvantaged communities, to give them the chance to serve more children makes absolute sense to me.

And where you have now not just sort of mom and pop charter models, you have some national models. You have folks that are replicating at a pretty significant scale in many communities and demonstrating this is not one amazing principal or one charismatic teacher, but systemically they are closing achievement gaps in very significant ways.

And where we are seeing that, I just want every child in this country to have a chance to go to a great school.

ACADEMIC YEAR CALANDAR

Senator KIRK. Yeah. Can I have you talk about a big picture item? Our basic school calendar was established two centuries ago, in the 19th century, to provide a summer break to bring in the harvest, which I think is particularly inappropriate for the now 80 percent of Americans who live in an urban or suburban area.

We generally see in school performance that the summer break will set kids back at least 1 month if not more. Give me your views on all-year school in the 21st century.

LONGER SCHOOL YEAR NEEDED

Secretary DUNCAN. I usually get booed by children when I talk about this, and adults usually—most adults cheer, not everyone.

But I think we are crazy on this as a country. The fact that our school calendar is based upon an agrarian economy makes no sense to me whatsoever. And other countries that are out-educating us today—I do not think they are any smarter than us but, a lot of them are just going to school 30, 40, 50 more days a year than we are.

Senator KIRK. Right.

Secretary DUNCAN. And they are just working a little bit harder and we need to work a little bit harder. All of you guys are in your positions because you work pretty hard. And we are just denying that opportunity to our young people. So, I am advocating everywhere I can, passionately, for longer days, longer weeks, and longer years.

And let me be clear. Particularly in the summer, not that every child needs to do that. If you have a middle class child—a child that has access to libraries and summer camps and museums, that is okay. But if that child is going to be in the street or is going to sit in front of a TV all summer, that is a devastating loss. We are trying to close achievement gaps, not expand them.

And so, to not give those students those kinds of opportunities makes no sense. So we can be, you know, thoughtful, we can be creative here, you can differentiate, you know, on what students need. But to just say we are going to stop learning in June and just hope for the best, particularly in disadvantaged communities, just makes no sense to me whatsoever.

And, Senator, I have gone too long on this. But what really troubles me is you see some districts being really creative around the use of time and technology and doing some great things. You see other districts retrenching, going to 4-day weeks, shortening the school calendar. And I understand these are tough economic times, but those are horrendous decisions, and we need more time, not less. Our children need more structure, more opportunities to learn. And if we want them to compete and to compete successfully in a global economy, right now we are putting them at a competitive disadvantage from children in India and China who are going to school 30 to 50 days more each year than children in the U.S. I do not know why we would want to put our children at a competitive disadvantage.

Senator KIRK. And, Mr. Chairman, I know there are difficulties and we have to work out payer work arrangements, but the country, I think, should begin a debate on moving to all-year school. I think that would help our performance.

And I would say the very controversial thing of joining Senator Landrieu on praising Secretary Alexander and his work.

Senator HARKIN. Thank you very much.

Senator Alexander.

Senator ALEXANDER. Well, thanks. If I had known all these compliments were going to flow, I would have come on time.

That gives me a chance to restate what I have said many times. I really compliment President Obama for his appointment of Sec-

retary Duncan, who has a real heart for the job and a lot of experience, and is willing to challenge a lot of conventions. And despite the fact he is more of a basketball player than a politician, he is a better politician than most cabinet members and than most senators. So, all of us, I included, really respect your work.

EDUCATION ACCOUNTABILITY

Let me use my time to talk with you for a few minutes about what we call accountability in the education business. And I want to read a letter—not a whole letter. I want to read a sentence from a letter or two and see whether you agree with it. I think you are generally familiar with the letter. This is a letter that the chief counsel of Chief State School Officers wrote to me and cc'd Senator Harkin, and Senator Enzi, and Senator Bingaman in May, talking about the work they have been doing, which you have been very much involved with. And I have asked, Mr. Chairman, this letter be included in the record.

Senator HARKIN. It will be.

[The information follows:]

COUNCIL OF CHIEF STATE SCHOOL OFFICERS,
*Washington, DC, May 19, 2011.*

The Honorable LAMAR ALEXANDER,
*455 Dirksen Senate Office Building,*
*United State Senate, Washington, D.C. 20510.*

DEAR SENATOR ALEXANDER: In anticipation of our meeting, I wanted to share with you some information regarding the important work currently being led by the States on behalf of our Nation's students. We look forward to discussing our work with you in greater detail in hopes that we might be able to partner with you and work with the Senate Health, Education, Labor and Pensions Committee to inform reauthorization of the Elementary and Secondary Education Act (ESEA).

Over the course of the past several years, and in the face of outdated and burdensome Federal requirements, States have led in developing policies and systems designed to ensure that all students graduate from high school ready for college and career. This is evidenced by myriad State-led reforms, including:

—The development and adoption of college- and career-ready, internationally benchmarked standards, including the Common Core State Standards in reading/language arts and math that have been adopted by 45 States and territories;

—The ongoing development of robust, internationally benchmarked, assessments aligned to rigorous standards, including through the two national assessment consortia (PARCC and SMARTER Balanced);

—The design and implementation of growth models for accountability, which focus schools on ensuring that students meet the goal of college- and career-readiness; and

—The development of improved standards for teacher and principal effectiveness, and teacher and principal evaluation systems focused on student achievement.

In the light of this State leadership, CCSSO spearheaded a task force of chiefs in developing a roadmap for States in looking at next-generation accountability systems. Coming out of this task force are principles that would guide new models of school and district accountability designed to better drive school performance toward college- and career-readiness; more accurately and meaningfully identify and support the range of schools; and better provide actionable data to support districts, schools, principals, teachers, parents, students, and policymakers to dramatically improve student achievement. Beyond these core requirements, States may and will develop proposals that approach these issues in different ways. Each state's proposal would be guided by the following principles:

—Fully align accountability expectations and measures to the goal of all students graduating from high school ready for college and career;

—Make annual accountability determinations for all schools based on the performance of all students;

—Base accountability determinations on student outcomes, including but not necessarily limited to improved, rigorous statewide assessments in reading and math (grades 3–8 and high school) and accurate graduation rates;
—Base accountability determinations in part on disaggregated data of student performance across relevant subgroups;
—Provide timely, transparent, disaggregated data and reports that can meaningfully inform policy and practice;
—Include, as appropriate, deeper diagnostic reviews of school and district performance, particularly for low-performing schools, to create a tighter link between initial accountability determinations and appropriate supports and interventions;
—Focus on building district and school capacity for significant and sustained improvement in student achievement toward college- and career-ready performance goals; and
—Focus significant interventions on the lowest performing 5 percent of schools (elementary and middle, and high schools) and their districts (in addition to targeted interventions to address the lowest performing subgroups and/or schools with the greatest achievement gaps).

A critical number of States are committed to moving forward in the design of accountability systems aligned to these principles and we expect a number of additional States to join in the next couple of weeks. States seek a reauthorization that supports this State leadership and innovation, and does not remain a barrier or seek to codify a single "right" answer for national education reform. We want to work with you in this effort and hope that our work helps to inform your conversations going forward. I look forward to meeting with you to discuss these issues in greater detail.

Sincerely,

*Gene Wilhoit.*

NO CHILD LEFT BEHIND—FLEXIBILITY AND ACCOUNTABILITY

Senator ALEXANDER. Thank you. Thank you.

In this letter, it talks about the work that the different States have done in creating common core standards, in creating a test to see where children are meeting that standard, and creating what we call growth models, which have been discussed in this hearing before, and especially in working in there that you, and I, and others care a lot about, which is finding a way to measure teacher and principal effectiveness, and especially relating that to student achievement. And it is a very impressive record.

And they go on to say this. And I had a conversation about this with one of your predecessors, Secretary Dick Riley, the former Governor of South Carolina, who supports this idea. The last—this is the sentence in the letter, it says, "States seek a reauthorization of the Elementary and Secondary Education Act that supports this State leadership and innovation, and does not remain a barrier or seek to codify a single right answer for national education reform." Do you agree with that?

Secretary DUNCAN. Yes.

FEDERAL ROLE IN EDUCATION

Senator ALEXANDER. Well, good. Then as we go down through these, one of the difficult issues that we have as we think about fixing No Child Left Behind is this accountability section. And to what extent should the Federal Government write anything about tests, write anything about a growth model, write anything about how to measure teacher performance, because whenever we put it in law, then the Department of Education, which you and I know something about, then goes through a process of rulemaking, establishes "parameters," which are what people in Washington think

Chicago superintendents or Governors of Tennessee ought to be doing. And it all sounds good. By the time you get it all done, you have a superintendent flying in from Denver, Chicago, or Nashville seeking the Secretary's approval for some specific growth model, which is a big waste of everybody's time.

So, what I am trying to get at—and let us take a specific example. Let us take the idea of relating student performance to teacher pay. I am a big advocate of rewarding outstanding teaching, master teachers. I think it is the Holy Grail of education. How do we reward outstanding school leaders and teachers with more pay, more honor?

TEACHER INCENTIVE FUND

And I think many of us agree on that. But my fear is that if we put it into the law, and we write a rule about it, then suddenly we will be defining what 100,000 schools will be trying to do, and I do not think it works well that way. I think what has worked well is your teacher incentive fund where you give grants and money to local school districts who then work with their teachers or work with their community and come up with different models for rewarding outstanding teaching.

So, what would your advice be as we work on fixing No Child Left Behind about how we accomplish this goal, which there is broad bipartisan support for, without running into the problem of violating what the Chief State School Officers have told us they do not want done.

Secretary DUNCAN. Yeah. These are really, really thoughtful questions, and you and I have talked about this a multitude of times.

STATE FLEXIBILITY

There is a balance we are trying to strike and where I think we are all trying to get to the same point and trying to figure out how to do that. The last thing we want to be is to be prescriptive or top down. We think the teacher incentive fund has been very effective. We think Race to the Top, frankly, was very effective. We said that student achievement had to be a significant part of teacher evaluations, but we did not say a number, and, frankly, we do not know that number. We have seen a huge amount of very creative and very, very hard work going on at the State level because we incentivize that in the right way.

So, the Council of Chief State School Officers, Gene Wilhoit, has been an amazing profile in courage. All this work of higher standards, better assessments we talk about, that is not coming from you or I. That is coming from Governors and chief State school officers having the courage to do the right thing. And I cannot overstate what a great partner they have been.

ENSURING ACHIEVEMENT GAINS WITHIN FLEXIBILITY

I think the vast majority of States are moving in the right direction now. My only concern is I do not want to give a pass to a State that somehow goes in the wrong direction. And we have a history of Governors, both Republican and Democrat, who dummied stand-

ards under No Child Left Behind, who did exactly the wrong thing for children for their State, because it was politically expedient, because it made them look good politically, but it hurt their children, hurt their education, ultimately hurt their State's economy. And nobody said anything about it. It was like they all got a great pass.

So, I want to continue to reward courage, to incentivize that. But I also think as the Federal Government, we have an obligation to make sure if a State says, you know, we are not going to do accountability, we do not care about achievement gaps, we think poor children, black or brown children cannot learn—we have to think about what the Federal responsibility is there. And I think that is—we are trying to get that fine line worked out and, again, we continue to look to your advice and guidance of how best to do that.

Senator HARKIN. And, Senator Durbin.

Senator DURBIN. Thank you very much, Mr. Chairman. Secretary Duncan, Mr. Skelly, thank you for being with us.

Mr. Secretary, thanks for the good job you are doing.

GROWTH IN RATE OF STUDENT INDEBTEDNESS

In October of last year, we reached a milestone in America that most people did not know and did not hear about. For the first time in the history of our country, student loan debt exceeded credit card debt in America.

The rate of growth of student indebtedness in our country is alarming. The indebtedness that students are incurring to go to school is holding them back in terms of their own personal ambitions and career goals, and creating a problem for us because should they default, ultimately the taxpayers will be the losers.

I and many others have voted consistently for student assistance because that is why I am sitting here today. Were it not for the National Defense Education Act enacted by this Congress out of fear of Sputnik and the Russians, I do not know if I would have gone to college or to law school. So, I have always felt that I owed it to the next generation to give them the same chance.

PELL GRANTS VERSUS STUDENT LOANS

And I have always felt the same way about Pell grants because, rather than loans, this is money that a student does not have to repay. The Pell Grant now is in the range of $5,500. The administration believes it is important and had made it part of our budget negotiations.

And notwithstanding that, the next time I vote on Pell grants, I am going to have a very difficult time voting for them and looking at student loans the same way. And you know, because we have discussed it at length.

FOR-PROFIT SCHOOLS

And the chairman of this committee has looked at a problem that we are facing that I think many Members of Congress are ignoring; that is the growth of for-profit schools.

For-profit postsecondary education trains or educates 10 percent of the students, claims 25 percent of all Federal aid to education, and accounts for 44 percent of all student loan defaults.

What is going on is nothing short of scandalous. There are private companies that have found a way to game our system, to bring students out of high school into a so-called learning environment to burden them heavily with debt, to hand them worthless diplomas, and then watch while they fail.

We have got to do something about this, Mr. Secretary.

I cannot vote blindly for Pell grants and college student loans knowing that this Ponzi scheme is going on in the name of for-profit colleges. Now let me add, there are good ones, and I could name a few and you could, too. But there are so many bad ones, terrible schools, that are exploiting students these days.

You looked at this. You have come up with a proposal. I think it moves in the right direction, but I think it moves too slowly.

How can we in good conscience extend Pell grants and student loans knowing that this kind of predatory lending is going on, this kind of subprime mortgage pyramid is being created in the name of higher education?

WORKING TO ENSURE EFFICACY OF FEDERAL STUDENT AID

Secretary DUNCAN. Sir, your leadership in this issue and Chairman Harkin's absolute passion and leadership I think has changed the national conversation.

And what we tried to do is very simple, and I think it is a significant step in the right direction. Is it perfect? Absolutely not, and we have had those conversations. But what we want to do is where you have good actors, as you said, we think that is a good investment. We think that is good for young people and folks who have not had those kinds of opportunities before to have the chance to increase their skills, if it is leading to meaningful work, if those skills and what they are learning are real. If it is not, we simply cannot continue to invest taxpayer money anytime, but particularly in tough economic times, in those places.

So, we put in place some pretty significant rules and guidance that has been heavily challenged by many in the industry. Some of the good actors are actually supporting it, which has been interesting. But basically, trying to eliminate those programs that were not leading to good outcomes, where there is, you know, false advertising, where there are no jobs available, where you are under a mountain of debt that you cannot pay back. That is a horrendous investment. So, we have tried to move in the right direction.

I would also add, I think we have seen pretty significant changes in behavior. We have seen a number of CEOs lose jobs. You have seen institutions start to behave in some very different ways. And so, I think this is going in the right way, and I feel much more comfortable about our investment in grants and loans, more comfortable today than I did before our regulation.

ACCREDITATION AND TRANSPARENCY OF FOR-PROFIT SCHOOLS

Senator DURBIN. I have only a few seconds left. Here is what I think we have to do. You cannot expect a student or that student's family to know whether a school is worth investing in. There is no way they can tell whether the claims made by the school are true or not. It starts with the accreditation.

I have been disappointed, sadly disappointed, by the limited, if negligible, standards for accreditation. Schools that are a laughing matter end up being accredited. How is a student supposed to know? How is a family supposed to know? They assume that if they are accredited and our Federal Government will send Pell grants and college student loans through those schools, that it is a good education. Why would they not assume that?

Do we not have an additional obligation when it comes to evaluating these schools?

Secretary DUNCAN. No, I think that is a great, great point. Absolutely. And we need to look at that. You have been very, very clear on that.

I would only add one thing; what we are trying to do now is to really increase transparency so that young people and their parents can have a much better understanding of outcomes. And we think that transparency—we think there are lots of choices out there, and that transparency will hopefully drive behavior in the right way.

But your basic question about accreditation is an absolutely real one, and I will take that to heart.

REPAYMENT OF STUDENT LOAN DEBT

Senator DURBIN. And the last point I will make, if you will bear with me for 5 seconds. Student loans are different than other debts. They are not dischargeable in bankruptcy. A student loan you will carry to the grave, and that is something we ought to remember and students should be advised of before they make these decisions.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF SENATOR RICHARD J. DURBIN

I want to thank the Chairman for convening this hearing to review the fiscal year 2012 budget request for the Department of Education.

We are engaged in a debate this week about our Nation's long-term fiscal outlook as we consider proposals to raise the debt ceiling. We can deal with our debt responsibly and in a balanced way.

We have to reduce the debt and deficit. But investing in education and retraining is the best way to ensure our economic recovery now and our economic growth well into the future.

*President's Budget for Fiscal Year 2012*

The President's fiscal year 2012 budget recognizes the importance of education to sustained economic recovery by investing in key areas:

—*Early childhood education*.—The President's budget includes $8.1 billion for Head Start to serve an additional 1 million children and families.

The budget also includes an additional $1.3 billion to support 1.7 million children and families through the Child Care Development Block Grant Program.

—*High-quality schools*.—The President's budget includes $26.8 billion, an increase of 6.9 percent, for a reformed Elementary and Secondary Education Act that is focused on raising standards, encouraging innovation, and rewarding success.

—*Innovation and reform*.—The budget would invest $1.4 billion in competitive programs that leverage scarce Federal dollars to bring about systemic reform in education.

—The Early Learning Challenge Fund would spur States to improve the quality of early childhood programs.

—A new Race to the Top program would bring resources to school districts willing to make needed reforms.

—A new "First in the World" competition would encourage colleges and universities to demonstrate success in graduating more high-need students and preparing them for employment.

These are the kinds of programs that use limited resources to inspire meaningful improvements. And it's the students who win.

*Pell Grants and For-Profit Colleges*

I would like to say a word about Pell Grant funding.

The Department of Education expects demand for Pell grants to reach 9.6 million students next year, up from 6 million in 2008.

The President's budget would maintain a maximum Pell Grant award of $5,550 per year for these students.

As a beneficiary of Federal investment in higher education, I have always voted to support Pell Grants and Federal student loans.

But I have become deeply troubled by what I see happening in higher education today. The Federal financial aid system is in serious peril, largely because of the actions of many for-profit colleges.

For-profit colleges educate less than 10 percent of students, take in 25 percent of all Federal financial aid, and account for 44 percent of all student loan defaults.

We can't afford to see taxpayer dollars wasted by sending billions of dollars of Pell Grants to for-profit schools, many of which aren't providing a good return on that investment.

If we want our economy to grow, we should help low-income students attend colleges that put them on a path to success.

But it is irresponsible for us not to question whether the taxpayers are getting their money's worth at many for-profit colleges.

And as we consider increasing funding for the Pell Grant program to meet our commitments to students, I think we should also have a serious conversation about how to ensure the value of that investment.

Taxpayers deserve some assurance that a Pell Grant invested in a student is leading to a better career, a higher salary, and a greater potential to contribute to the economy—not wasted at a for-profit college that leads to little except debt.

*Conclusion*

Chairman Harkin, we can invest in education in a way that's fiscally responsible and will lead to stronger economic growth long into the future.

The Administration has provided us a good start to that conversation, and I look forward to hearing from Secretary Duncan this morning.

## MISUSE OF STUDENT AID BY FOR-PROFIT INSTITUTIONS

Senator HARKIN. Well, thank you, Senator Durbin. And, again, I thank you for your great leadership in this area. You are the one who first started getting me focused on this a year and a half ago. And as you know, our authorizing committee has had a series of hearings and investigations into this going back 18 months. And what we have uncovered is just about what you just talked about. It is an invasion into the programs that we have developed to help poor kids get a decent education to prepare them for a career.

And it has turned into almost an open spigot of taxpayers' dollars being siphoned off to hedge funds, Wall Street. You would be surprised how many of these for-profit schools are owned by Wall Street entities. And they are most interested—their interest is in the bottom line, not on education.

Well, we do not mean to get into that, but thank you for your leadership.

## SPECIAL EDUCATION MAINTENANCE OF EFFORT WAIVERS

Mr. Secretary, I do not mean to hold you any longer, but just one issue I wanted to raise with you relates to special education. Obviously you know this is a long-standing interest of mine. We have discussed this many times.

Tight budgets are leading some States to ask for waivers for their maintenance of effort requirements under IDEA. I want to thank you for your close scrutiny of those requests, which should be granted only under exceptional circumstances. I also would encourage you to continue to take a close look at any additional requests and use all of the resources available to you to make sure a free and appropriate public education is not denied students with disabilities.

SPECIAL EDUCATION—FREE, APPROPRIATE PUBLIC EDUCATION

Whenever this issue comes up, I always take the opportunity for a little teachable moment perhaps and a little history lesson. I was here at the beginning of this when we did IDEA. And many States I know and some people think that IDEA, the Individuals with Disabilities Education Act, which superseded the Education of All Handicapped Children Act, was somehow a Federal mandate on States, requiring them to give a free, appropriate education to kids with disabilities.

FAPE—A CONSTITUTIONAL REQUIREMENT

Well, that is absolutely wrong. The mandate on States to have a free, appropriate public education for kids with disabilities is a constitutional mandate—constitutional. PARC v. Board of Education, Pennsylvania Association of Retired Citizens v. Board of Education. That established the principle that if a State—first of all, as we all know, States do not have to provide free education. There is no constitutional requirement for any State—Alabama, Mississippi, or Iowa, or any other State to provide a free public education. What the Constitution does say is if a State—if a State decides to provide a free public education—or FAPE, it cannot then discriminate on the basis of race, or sex, or national origin, and PARC v. Pennsylvania—I am sorry, it was PARC v. Pennsylvania—that case said that a State cannot then discriminate either on the basis of disability.

FEDERAL ASSISTANCE TO STATES IN PROVISION OF FAPE

The Federal Government came along and said, okay, if that is the case, we will try to help States with IDEA to provide some help and support. And if you want this money, if a State wants to partake in IDEA, well, here are certain requirements. No State has to take one dime of IDEA money. But if they do, they have to meet certain requirements in terms of a free and appropriate public education.

So, this is a constitutional matter. Even if we provided not one dime of IDEA money, States would still have to provide a free, appropriate public education to every kid with a disability.

Now, I say all this, Mr. Secretary, I know you understand that, but I always like to take that time to reaffirm the fact that we have constitutional obligations to provide this kind of education to our kids. And when States ask for waivers from their constitutional obligation, that ought to be looked upon with very close scrutiny as to whether or not they need that kind of waiver.

So, again, I say this in a way of thank you because I know you have looked at that with close scrutiny, and to make sure that you have continued to look at those waivers very, very closely in the future. So, I thank you for that.

And I will turn to Senator Shelby.

Senator SHELBY. Secretary, you have been very patient, but I have three quick areas I would like to get into.

RACE TO THE TOP APPLICATION SCORING PROCESS

I am concerned that the scoring process for the Race to the Top applications essentially mandates which interventions should be used by States and local school districts to improve student achievement and reduce achievement gaps. The Federal Government, I believe, should give States the flexibility to implement critical reforms as identified on the State and local level.

If Race to the Top receives funding in 2012, can I have your commitment to review the scoring process for the Race to the Top applications, and specifically reevaluate the scoring measures on science, technology, engineering, and mathematics reform efforts? And will the Department consider changes to the Race to the Top program that allow States to be evaluated on their statewide vision and reform efforts identified at the State and local level? And if not, why not?

Secretary DUNCAN. No, absolutely happy to continue to learn every single year——

Senator SHELBY. Okay.

Secretary DUNCAN [continuing]. And to get that feedback. I thought we did a very, very good job. Did we do it perfectly? Of course not. And, you know, this is a work in progress, and I'm happy to have that conversation going forward.

Senator SHELBY. Do you disagree with some of my concerns here?

Secretary DUNCAN. I do not know if I disagree. I welcome that conversation.

Senator SHELBY. Okay.

Secretary DUNCAN. We want to continue in everything we do to emphasize STEM. We did it as a competitive priority on i3 and Promise Neighborhoods and other things. So, STEM is a consistent thing there, and I think it is a fair, you know, question, and we will look at it very closely.

Senator SHELBY. So, you would review the scoring process.

Secretary DUNCAN. Yeah, absolutely, no question, not just in that area, across the board. Again, we will take what worked and what did not, and learn from it, and try and get better.

IMPACT OF COMPETITIVE-BASED FUNDING ON RURAL AREAS

Senator SHELBY. Mr. Secretary, formula versus competitive funding. The President's budget, your budget, proposal includes a substantial increase in the amount of discretionary funding that would be competitively awarded. This is a significant policy shift from the current formula grant structure. I am concerned that replacing formula-funded programs with so-called competitive programs will result in the redirection of critical Federal funds from smaller rural States or urban areas because they will not be able to compete for funding on a level playing field.

RACE TO THE TOP COMPETITION

For example, Mr. Secretary, my State of Alabama, Iowa, and Mississippi, were all shut out from the competitive Race to the Top grants. These three States did not receive any funding in round one or in round two.

Are you concerned at all that a shift from formula funding to competitive funding may not allow many high-need States and districts to receive Federal funding as illustrated in the Race to the Top?

Secretary DUNCAN. Yeah. So, we have thought about that very, very carefully. Two answers just to think about. Again, to be very, very clear, the overwhelming majority of our money will continue to be, will always be, formula-based. So, in this budget, 84 percent is formula-based.

Senator SHELBY. You see my concern here?

Secretary DUNCAN. Yes, I do.

Senator SHELBY. And I am sure it is a concern of the two colleagues of mine.

Secretary DUNCAN. Yes, sir. And so, what we have tried to do in the Investing in Innovation fund, in the Promise Neighborhoods initiative, is to really make sure that rural States and communities could compete, and we think we did that better. So, we will continue to learn. And in all of these competitions, the goal is not a fancy PowerPoint presentation. We want to invest in places that have the courage and the capacity to do some things very, very differently.

So, I am acutely aware of that, and we want to continue to strike that balance. We think in some of the other competitions, that went very well. And we want to continue to learn across the board in this area.

MATHEMATICS AND SCIENCE PARTNERSHIPS

Senator SHELBY. In the area of mathematics and science partnerships, the United States continues to fall behind, as we know, other developed countries in reading, math, and science education.

According to the 2009 Performance Reporting Ranking, the 34 countries of the Organization for Economic Cooperation and Development, the United States ranks 25th in math, 17th in science, and 14th in reading. It is unacceptable to all of us.

I am concerned, and I am sure you are, that the 2012 budget proposal does not request funding for the mathematics and science partnership program. In Alabama, my State, funds from this formula program have helped finance the highly successful Alabama math, science, and technology initiative, a leading model for math and science education reform nationwide.

In the place of the mathematics and science partnerships, the Department—your Department—proposes to create a new competitive grant program for science, technology, engineering, and math.

How does the Department intend to ensure that all States will be able to compete for math and science funding when it is no longer distributed by a formula, as my understanding? And how will this program close the growing achievement gap between the United States and our global competition?

WELL-ROUNDED EDUCATION

Secretary DUNCAN. We have talked about—a lot about STEM. Let me even broaden it a little bit further. One of my greatest concerns is that due to the current law and sometimes due to budget issues, we have seen a narrowing of the curriculum around the country. And that is probably the biggest complaint I hear as I travel, urban, rural, suburban, from students, from teachers, from parents across the board.

So, we are asking for significant investment, not just in STEM, but in literacy, in arts, in PE, in all those things to give children what we call a world-class, well-rounded education. So, we want to invest at a different level there, getting behind those States and districts, again, whatever they look like, those that are committed to giving their children a well-rounded, world-class education. And this is not just at the high school level; this has to be for first and second and third and fourth graders——

Senator SHELBY. Absolutely.

Secretary DUNCAN [continuing]. To give them a chance to build their skills. So, we are absolutely committed there, and want to put significant resources behind that effort.

Senator SHELBY. If we do not do this, where are the jobs going to come from in the future?

Secretary DUNCAN. Well, the jobs will continue to migrate.

Senator SHELBY. Thank you.

Thank you, Mr. Chairman.

Senator HARKIN. Senator Cochran. No other questions.

There are no other questions, Mr. Secretary. Thank you very much. You have been very generous with your time, and we appreciate your appearance here.

ADDITIONAL COMMITTEE QUESTIONS

And we will keep the record open for 10 days for any other questions that the Senators may have.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

PELL GRANTS

*Question.* Congress continues to make a significant investment in the Pell Grant program, in order to help make college more affordable for low-income students. The number of Pell Grant recipients has grown from 6.2 million in 2008 and is projected to reach 9.6 million in 2011. At the same time, 56 percent of all bachelor degree students graduated within 6 years and 28 percent of all associate degree students graduated within 3 years. For low-income students, these rates are even lower. Taking into account the difficult budget decisions Congress is facing in fiscal year 2012, what can be done to ensure that Congress' investment in Pell Grants is fully realized and low-income students complete their degrees at higher rates?

Answer. The Department agrees that certain cost-cutting measures are necessary, but does not believe sacrificing the Pell Grant maximum award—especially considering current financial conditions—should be one of them. As evidenced in its fiscal year 2012 budget request, the Department has made maintaining the Pell Grant at its current $5,550 maximum a priority. The Pell Grant will be an important piece of 9.6 million students' financial aid packages in the 2012–2013 academic year. Ensuring these students have sufficient financial aid to remain in school is an important first step in helping lead them to college completion.

Increasing college completion rates is another priority for the administration, and the fiscal year 2012 President's budget included a number of new programs—including College Completion Incentive Grants, First in the World, and College Access Challenge Grants—designed to help States and institutions focus on and adopt activities that are likely to contribute to higher completion rates. Some of the activities endorsed by these programs are: aligning high school graduation requirements with institutions' expectations for academic preparation; reducing a program's net price or time to degree; and providing low-income students assistance such as financial literacy training, need-based grant aid, or educational or career preparation.

WORKLOAD OF DIRECT LOAN PROGRAM

*Question.* Since Congress passed the Student Aid and Fiscal Responsibility Act (SAFRA) of 2010, new volume in the Direct Loan program has increased to an estimated $124 billion in 2012, up from $29 billion in 2009. What have been the implications of the increased workload on the Department's administration of the Direct Loan program and what has been the impact on customer service?

Answer.

*Impact of SAFRA on Direct Loans Administration*

The Department has undertaken a number of administrative initiatives to manage increased workload resulting from SAFRA:

—expansion of origination and disbursement capacity,

—expansion of servicing capacity, and

—addition of Government personnel to manage the increased workload. Each of these initiatives has driven increases in Department administrative costs. However, these initiatives have enabled over 2,500 domestic schools and 380 foreign institutions to smoothly transition to Direct Loans for the 2010–2011 award year, and millions of new Direct Loan borrowers to be successfully brought on by the Department's five private-sector loan servicers.

*Origination and Disbursement*

In anticipation of increased Direct Loan volume, in February 2010, the Department revised its Common Origination and Disbursement (COD) system contract to accommodate projected increases in Direct Loan originations. The Department further revised the COD contract in June 2011 based on updated projections of Direct Loan volume. A Final Management Information Report issued on September 16, 2010, by the Department's Office of Inspector General, "Federal Student Aid's Efforts to Ensure the Effective Processing of Student Loans Under the Direct Loan Program," notes that Federal Student Aid took all necessary actions to ensure processing of student loans as a result of SAFRA, and credits COD with successfully providing the capacity to transition to 100 percent Direct lending.

*Loan Servicing*

In order to accommodate expected increases in loan volume, foster improved performance through competition, and prepare for the eventual expiration of the existing loan servicing contract, the Department awarded four new servicing contracts in June 2009, known collectively as the Title IV Additional Servicers (TIVAS). The four vendors receiving awards were American Education Services/Pennsylvania Higher Education Assistance Agency (AES/PHEAA); Great Lakes Education Loan Services; Nelnet, Inc.; and Sallie Mae Corporation (SLM). These vendors began servicing FFEL loans purchased by the Department in September 2009 and new Direct Loans starting June 2010. Together, these vendors provided a broad base of servicing capacity well equipped to handle the dramatic increase in workload post-SAFRA. As of June 2011, these four vendors held 50.4 percent of the total loan volume managed by the Department. In accordance with SAFRA, the Department is currently working on awarding additional performance-based Not-For-Profit loan servicer contracts, which will further expand loan servicing capacity.

*Government Personnel*

In order to properly manage the increased loan portfolio, the Department increased its FTE from fiscal year 2010 through fiscal year 2011 after undergoing a 4 percent decrease in FTE from fiscal year 2008 to fiscal year 2009. In response to SAFRA, over 100 new Federal staff have been added to handle an increased level of contract oversight, school reconciliation support, school training, and call center management. The increase represents a 9 percent rise from fiscal year 2009 level; over the same period, the number of Direct Loan schools nearly doubled; the number of new Direct Loan originations grew by 158 percent, and the Government-held servicing portfolio grew by 132 percent.

Additional Federal staff are needed in fiscal year 2012 to effectively manage up to 30 or more new Not-For-Profit contracts during fiscal year 2012 through fiscal year 2013.

*Budget Impact*

In order to meet the demands of the increased portfolio, the Student Aid Administration Account has required a budgetary increase of 74 percent for COD and 198 percent in total servicing, including Not-For-Profit and For-Profit servicers, from 2009 to 2012. As the number of borrowers serviced continues to grow, servicing costs will continue to rise. These costs are not only necessary to manage effectively the student loan portfolio and provide quality customer service; they are essential for achieving approximately $67 billion in savings over the next 10 years, according to CBO estimates, for the transition of all Federal student loan originations to the Direct Loan program.

*Impact on Consumer Service*

There were no negative impacts to customer service during the transition. Schools have generally been highly satisfied with the Direct Loan process and the Department is aware of no students who have been unable to receive Federal Student Aid due to the transition. In fact, by uniting all Department-held loans for a single borrower with a single servicer, the Department has improved customer service for 1.6 million student loan borrowers.

In addition, increased workload stemming from SAFRA has not prevented the Department from continuing efforts to improve its service to students and borrowers who have been traditionally under-represented in postsecondary education. For example, the Free Application for Federal Student Aid (FAFSA) Completion program has allowed the Department to work with State and local education agencies and secondary schools to increase the number of completed FAFSA applications. Also, by reducing the number of questions an applicant must answer and streamlining financial information through the IRS Data Retrieval tool, FAFSA simplification efforts have made it much easier for applicants to apply successfully for Federal student aid.

TEACHER INCENTIVE FUND—VANDERBILT AND RAND STUDIES ON PERFORMANCE-BASED PAY

*Question.* Last year, the Center for Performance Incentives at Vanderbilt University found little evidence to support a primary goal of the Teacher Incentive Fund (TIF)—that rewarding teachers for improved student test scores would cause scores to rise. This rigorous evaluation funded by the Department raises serious questions about the idea behind this program. And, just last week a RAND evaluation of New York City's program came to similar conclusions about performance-based pay. New York permanently canceled its program after the study's release.

I understand that the Vanderbilt and RAND studies didn't examine all of the performance-based pay systems across the country. However, they raise the question whether we should continue to provide $400 million per year for TIF given the need to reduce deficits and the significant amount of funding for these grants already.

Mr. Secretary, what is your view of these evaluations of performance-based pay programs, and how will they shape your Department's thinking and priorities in fiscal year 2012?

Answer. These evaluations provide important information about some of the challenges schools, districts, and States face when reforming human capital systems to focus on improving student outcomes. But the Teacher Incentive Fund (TIF) differs in important ways from the performance-pay programs studied by Vanderbilt and RAND. In addition, the Department plans to significantly strengthen TIF as part of the 2012 new grant competition.

*Performance-based Compensation Systems*

While all of the 2010 TIF grant cohort projects include as one statutorily required element the development and implementation of performance-based compensation systems (PBCSs), these TIF projects support broader activities than just making performance-related payments to effective (as measured by student achievement gains and observations) teachers and principals. As you mentioned, the Vanderbilt study focused on awards to teachers based solely on increases in student achievement. Teachers received no additional support, such as mentoring or professional development, and the awards were not permanent or incorporated into district-wide human capital management systems. Finally, although about two-thirds of teachers participating in the study expressed support for the general notion that teachers should receive additional compensation if their students show outstanding achieve-

ment gains, a similar proportion felt that the program in which they participated did not do a good job of distinguishing effective and ineffective teachers. Likewise, large majorities agreed that the program ignored important aspects of performance not measured by test scores.

In the 2010 TIF competition, on the other hand, in order to be eligible for a grant, applicants had to provide evidence that the proposed PBCS is aligned with a coherent and integrated strategy for strengthening the educator workforce, including the use of data and evaluations for professional development and retention and tenure decisions in the LEA or LEAs participating in the project during and after the end of the TIF project period. In addition, applicants could receive a competitive priority by demonstrating that their proposed PBCS is designed to assist high-need schools in:

—serving high-need students,

—retaining effective teachers in teaching positions in hard-to-staff subjects and specialty areas, such as mathematics, science, special education, and English language acquisition, and

—filling vacancies with teachers of those subjects or specialty areas who are effective or likely to be effective.

Applicants also had to provide an explanation for how they would determine that a teacher filling a vacancy is effective or likely to be effective, and demonstrate the extent to which the subjects or specialty areas they propose to target are hard-to-staff. Lastly, applicants had to demonstrate that they would implement a process for effectively communicating to teachers which of the LEA's schools are high-need and which subjects and specialty areas are considered hard to staff.

*New York City's Schoolwide Performance Bonus Program*

The RAND study similarly found that New York City's Schoolwide Performance Bonus Program had limited impact. The New York City Department of Education set annual performance targets for each participating school's "Progress Reports," which are based in part on student growth. Schools meeting or exceeding those targets were eligible to receive a school-wide award of up to $3,000 per union-represented staff member. A committee at each school determined how to distribute the funds. However, the study noted that over one-third of teachers did not understand basic aspects of the program, "including the target their school needed to reach, the amount of money their school would receive if they met their target, the source of the funding, and how committees decide on distribution plans." In addition, teachers reported that the bonus was too small to provide any incentive for changing behavior. Also, most compensation committees chose to distribute bonuses equally across all school staff members, further limiting the potential for such a policy to reward and motivate improved performance. Research suggests that performance-based incentive plans work best when participating individuals have a strong understanding of the program, when participants expect that their own effort can control the outcome, and when rewards are sufficient enough to drive action. New York City's teacher bonus program was not strong in these areas. Even the RAND report's authors question whether the NYC system was sufficiently designed to motivate or effect change.

*Teacher Incentive Fund Performance-based Compensation Systems*

In contrast, under TIF, a grantee must show that it has a plan for effectively communicating to teachers, administrators, other school personnel, and the community at-large the components of its PBCS. Grantees must also provide evidence of the involvement and support of teachers and principals and the involvement and support of unions in participating school districts (where they are the designated exclusive representatives for the purpose of collective bargaining) that is needed to carry out the grant. Finally, TIF emphasizes performance-based compensation systems that include compensation that is differentiated and substantial. The RAND study authors noted that these characteristics were integral to successful implementation of performance-based compensation reforms.

*Creating Innovative Human Capital and Evaluation Systems*

In the 2012 TIF competition, the Department will provide support for State and school district efforts to develop and implement innovative approaches to creating human capital and evaluation systems that improve teacher and leader effectiveness and student outcomes. This new competition would emphasize supporting, retaining, and rewarding teachers and principals who raise student achievement. The Department would continue to require TIF grantees to develop and implement these human capital and evaluation systems with meaningful input and support of teachers and school leaders.

PROMISE NEIGHBORHOODS

*Question.* Promise Neighborhood grantees have been fully engaged and supported by State and city public officials, as well as private players. In fact, all 21 of the federally funded Promise Neighborhoods planning grantees have leveraged nearly $7 million in matching funds from public and private sources—including investment from foundations. Their planning efforts are progressing and generating a ground swell of local support.

How are the current grantees planning to leverage existing resources to achieve the goals of their local communities?

Answer. There are a number of examples where the 2010 Promise Neighborhoods grantees are leveraging existing resources to help meet the objectives of their planning grants. In Worcester, Massachusetts, the Main South Promise Neighborhood is partnering with Clark University in several ways. Clark is developing the longitudinal data system required by the program, and its students serve as formal and informal mentors to young residents in the neighborhood. Developed as a partnership between Clark and Worcester Public Schools, University Park School is an effective, comprehensive high school within the Main South neighborhood. Clark also waives tuition for any resident of Main South who has lived in the neighborhood for at least 5 years and who meets the university's entrance requirements.

In the rural Mississippi Delta, the Indianola Promise Community is partnering with Mississippi State's National Strategic Planning and Analysis Research Center, a grantee of the Department's State Longitudinal Data Systems program. Mississippi is one of the few States with a data system that links K–12 and postsecondary data through the use of a unique identifier. The partnership with the Data Center, specifically the opportunity to leverage the Department's investment in the State's longitudinal data system, creates an opportunity for the Indianola Promise Community to manage outcomes at the student level from preschool through college.

MAXIMIZING PUBLIC AND PRIVATE PARTNERSHIPS

*Question.* Additionally, how can we maximize this public/private partnership moving forward?

Answer. Peer reviewers of Promise Neighborhoods applications evaluate the extent to which applicants would leverage and integrate high-quality programs and related public and private investments into their work. We can maximize these types of partnerships by placing a similar priority in other Department grant programs. Moreover, guidance on productivity [1] released by the Department's Office of Innovation and Improvement early this year identified additional opportunities for supporting such partnerships. State and local health and human services agencies, departments of public safety and parks and recreation, community-based organizations, businesses, and other entities have a significant stake in the success of our children and youth. Many have long provided academic and enrichment opportunities in the form of before- and after-school programming, apprenticeships, nursing, or counseling support. Breaking down barriers and better aligning and using community resources may also help school systems identify and access low-cost services or facilities. Governors, working with policy-makers and educators, can put in place State-level policies addressing these issues or issue guidance to districts, schools, nonprofits, and institutions of higher education that encourages collaboration and leverages public-private investments as part of school reform strategies.

RECOVERY ACT OF 2009 AND THE EDUCATION JOBS FUND OF 2010

*Question.* Mr. Secretary, I know that you share my concern about the state of the economy and the continuing challenges that many families are facing, especially when it comes to finding jobs. In my opinion, the best way to solve our debt crisis is to get more people working, because when people are working they pay more taxes, buy more goods, and keep our economy growing.

Jobs are a particular concern in our Nation's schools, where we're hearing more reports every day of possible teacher layoffs. It's timely, therefore, to take a look back at the Recovery Act of 2009 and the Education Jobs Fund of 2010. Some have said that today's unemployment figures prove those investments were a waste of money. However, in my home State of Iowa, these bills have helped save or create almost 4,000 education-related jobs (960 Ed Jobs through March 2011 plus almost 2,800 education-related jobs through the Recovery Act).

That's the story in Iowa. What is your assessment of these bills from a national perspective?

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[1] http://www.ed.gov/oii-news/increasing-educational-productivity.

Answer. I share your concern about our economy and how it affects our Nation's families and children. To do our part to minimize the effects of these difficult times on students, we worked with you to provide States and school districts with unprecedented resources in the Recovery Act and through the Education Jobs Fund to save and create education jobs. Based on State-reported data, we estimate that the Recovery Act and the Education Jobs Fund have funded over 400,000 educator jobs since February 2009. We know that the strain of the economy continues to force States and school districts to make difficult choices, and we know that these two efforts helped to save our students from an even heavier burden that would have been felt in our Nation's schools.

COST SAVINGS AND EFFICIENCIES INITIATED BY THE DEPARTMENT OF EDUCATION IN FISCAL YEAR 2009 AND FISCAL YEAR 2010

*Question.* The fiscal year 2012 budget request identifies savings in program administration related to decreased travel costs generated by a greater use of teleconferencing. In fiscal years 2009 and 2010, what actions did the Department take to create efficiencies in its programs, eliminate lower-priority spending and realize other cost savings?

Answer. The Department took a variety of actions in 2009 and 2010 to create efficiencies in its programs, eliminate lower-priority spending, and realize other cost savings. These included the following items:

—In 2009, the Department closed its office at the U.S. Mission to the United Nations Educational, Scientific, and Cultural Organization in Paris, France and eliminated its attaché position.

—In 2009, the Department closed the National Institute for Literacy, which provided national leadership on issues related to literacy, and coordinated literacy services and policy. Funding for the Institute ended in fiscal year 2009. The Institute's broad mission and lack of clear management oversight led to a diffuse and incoherent system of delivery, as well as duplication of efforts with other Department of Education and Federal offices. The functions of the Institute are more efficiently being carried out by other Department offices, primarily the Office of Vocational and Adult Education.

—The Department eliminated the Secretary's Regional and Deputy Regional Representatives in the Department's 10 regional offices. These positions were primarily used for communication and outreach, which may be done as effectively by other personnel.

—The Department undertook two steps to reduce the cost of information technology equipment it leases. The number of computers used per person was reduced from 1.5 to 1.1, with a total reduction of 1,600 computers. In addition, the number of printers on employees' desktops was reduced from 5,700 to 1,400.

—Starting in fiscal year 2010, the Department required any conference or meeting occurring in Washington, DC with an attendance of 250 or less to take place in either of the Department's two large capacity auditorium facilities.

—In fiscal year 2010, the Department negotiated with one of its Direct Loan servicing vendors to eliminate transfer fees for migrating servicing accounts between this vendor and any other Direct Loan servicing vendor.

COST SAVINGS PLANNED FOR FISCAL YEAR 2011 AND FISCAL YEAR 2012

*Question.* What additional steps will be completed in fiscal year 2011, and what other steps are proposed in the fiscal year 2012 budget request?

Answer. The Department will complete additional cost savings actions in 2011 and is planning more in 2012, as follows:

—The Department plans to save 7 percent of contract spending by the end of 2011, using 2008 acquisition expenditures as a base. Some actions already taken have been described in the response for fiscal year 2009 and fiscal year 2010. The Department will continue to achieve contract savings by ending contracts that do not meet program needs or projects that are no longer needed, restructuring high-risk cost reimbursement contracts as fixed price contracts, improving contract terms and conditions, improving the procurement process, and investing in a highly skilled acquisition workforce.

—In 2011, the Department partially implemented an initiative to use double-sided printing as the default printing option. Currently, 25 percent of printing is two-sided. The Department is moving towards using double-sided printing 50 percent of the time.

—Due to the elimination of several programs administered by the Office of Safe and Drug-Free Schools (OSDFS), and to maximize limited resources, the Department is planning to move the remaining programs administered by OSDFS

programs into the Office of Elementary and Secondary Education (OESE). This change will provide new opportunities for staff from OESE and OSDFS to work together to improve school environments and support children's learning, health, and well-being.

—The Grant Award Notification (GAN) process provides the Department's grantees with official documentation of their Federal grant award and instructions for grants management. This process is currently paper-based, requiring a traditional signature from the Department's representative and mailing the 2 copies of the signed GAN to the grantee. In fiscal year 2012, the Department will provide mechanisms for:

—Electronically signing the GAN documentation sent from the Department to grantees;

—Electronically transmitting the GAN documentation from the Department to grantees; and

—Electronically filing and retrieving the GAN documentation.

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## QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

### ETHNIC AND IMMIGRANT STUDENT PERFORMANCE

*Question.* In Hawaii, Filipino Americans represent the second largest ethnic group in the public school systems but are consistently ranked second to last in the Hawaii State Assessments. These tests, in which Filipino students in 2010 scored only 69 percent in reading and 51 percent in math proficiencies, indicate that these students are in need of additional assistance throughout their primary, K–12, education. Furthermore, a study conducted by the John A. Burns School of Medicine, in Honolulu, indicated a significant connection between low Filipino cultural identification and low family support with delinquency. What new creative efforts are being considered by your administration to improve student performance within large ethnic and recently immigrated communities, such as the Filipinos, while maintaining the integrity of their cultural values?

Answer. The Department is focusing much of its current efforts on improving student performance, as detailed below. Most of these efforts are not focused on particular ethnic or recently immigrated communities, but are designed to improve performance in a wider range of student populations.

Many of the top priorities of the Department are found in A Blueprint for Reform, which proposes a reauthorized Elementary and Secondary Education Act intended to help give all children the world-class education that they deserve and that America needs to ensure future economic prosperity. The Blueprint focuses on key priorities aimed at improving educational outcomes for all students, including:

—recognizing and rewarding student academic growth and school progress;

—ensuring that students complete high school prepared for college and a career, based on rigorous, State-developed standards;

—putting a great teacher in every classroom and a great principal in every school; and

—focusing intensive support and interventions on our lowest-performing schools that serve our neediest students and communities, including the "dropout factories" that account for one-half of the estimated 1 million students who leave school each year without a high school diploma.

Together, these changes support the goal of ensuring that, by 2020, the United States will once again have the highest proportion of college graduates in the world—a key goal not only for restoring and increasing our economic prosperity, but also for securing the more equal, fair, and just society envisioned by our Nation's founders.

More specifically, the Department is emphasizing the following goals:

*Sustaining Reform Momentum*.—The Department will reform America's public schools to deliver a 21st century education that will prepare all children for success in the new global workplace, building on the achievements already gained by the Race to the Top and Investing in Innovation (i3) programs. Race to the Top will focus on supporting district-level reform plans while also emphasizing cost-effective strategies that improve student achievement in a time of tight budgets. The i3 program will prioritize science, technology, engineering, and mathematics (STEM) education and early learning, as well as focus overall on increasing productivity to achieve better student outcomes more cost-effectively. The Department also will place high priority on Promise Neighborhoods to support comprehensive, innovative and cost effective approaches to meeting the full range of student needs, drawing

on the contributions of schools, community-based organizations, local agencies, foundations, and private businesses.

*Great Teachers and Leaders*.—Nothing is more important, or more likely to improve student achievement and other key educational outcomes, than putting a great teacher in every classroom and a great principal in every school. To help achieve this goal, the Department will support ambitious reforms, including innovative teacher evaluation and compensation systems, to encourage effective teachers, principals, and school leadership teams to work in high-need schools. Emphasis will also be placed on expanding high-quality traditional and alternative pathways into teaching and preparing 10,000 new STEM teachers over the next 2 years, as part of the President's plan to prepare 100,000 new STEM teachers over the next decade.

*College Completion*.—The Department is committed to ensuring that America will once again lead the world in college completion by 2020. Regardless of their intended educational path after high school, all Americans should be prepared to enroll in at least 1 year of higher education or job training to ensure we have a better prepared workforce for a 21st century economy.

ACCESS TO 4-YEAR INSTITUTIONS

*Question.* Super rural and isolated communities, such as those existing on some of the neighboring islands of Hawaii, face many obstacles when it comes to accessing higher education. On the Hawaiian island of Kauai, for example, residents have access to a local 2-year community college but would have to relocate to another island to be able to attend a 4-year institution. How is the Department of Education improving access to 4-year higher education programs for potential university students residing in super rural and isolated areas, such as Kauai, without diverting funds from existing local community colleges?

Answer. The Department provides aid to students based on their estimated family contribution, not their location. If a student chooses to attend a more expensive school, attend a degree or certificate program that would keep him in school for a longer period of time, or attend a school in a different location, the total Federal and State financial aid he would be able to receive would be influenced by these circumstances.

Additionally, a student may find useful the net price calculator on his desired institution's website, to see the potential costs of attending that school. In accordance with the Higher Education Opportunity Act of 2008, all postsecondary institutions are required to have a version of this calculator on their websites by October 29, 2011. The net price number produced from the calculator will be able to help the student see the full cost of attending that school, and help him evaluate and make a more informed decision about whether it is financially possible for him to attend that institution.

STUDENT HEALTH INITIATIVES

*Question.* Nurses in schools provide a vital service to the educational system. As your Department has established, proper health and nutrition are key to students being considered "ready to learn" and maximizing their educational opportunities. How is your Department supporting and funding initiatives in States, such as Hawaii, that lack a robust school health nursing infrastructure and what other creative initiatives have been put forward to provide access to school-based nurse managed health centers in these targeted States?

Answer. The administration's Elementary and Secondary Education Act reauthorization proposal includes the Successful, Safe, and Healthy Students program. This new program would provide resources and increased flexibility for States and districts to design and implement strategies that best reflect the needs of their students and communities, which may include programs that support student physical health. Depending on the activity, projects that support the efforts of school-based nurses could be funded. Additionally, the administration is working to improve student health outside of the Department of Education. Under the Affordable Care Act, the Department of Health and Human Services awarded $95 million in July 2011 to school-based health center programs across the country. These grants will help improve the health and wellness of children through screenings, health promotion, and disease prevention activities.

CAROL M. WHITE PHYSICAL EDUCATON PROGRAM

*Question.* Your Department has found that students who come to school ready to learn perform better in their classes and on standardized tests. Good health is a vital component of being considered "Ready to Learn." In light of the increasing prevalence of chronic conditions, how is the Department of Education supporting

health screening, prevention and treatment of obesity, and support for students with diabetes, asthma, and other increasingly prevalent, chronic conditions so that they may be best prepared to get the most out of their education?

Answer. Currently, the Department's primary contribution to the physical wellness of students is the Carol M. White Physical Education program. Through rulemaking in fiscal year 2010, the Department established a competitive priority for the Physical Education program for projects that incorporate the collection of body mass index data as part of a comprehensive assessment of health and fitness for the purposes of monitoring the weight status of their student population across time. In addition, the administration's ESEA proposal for the Successful, Safe, and Health Students program would provide funding for States and districts to design and implement strategies that best reflect the needs of their students and communities, which may include programs that support student physical health.

21ST CENTURY COMMUNITY LEARNING CENTERS

*Question.* How would changing the 21st Century Community Learning Centers (CCLC) program to a competitive grant program affect Hawaii? If Hawaii can no longer rely on a consistent funding formula for the 21st CCLC program, program administration and planning for future years may become more difficult for the State.

Answer. We believe that transforming the 21st CCLC program from a formula to a competitive grant program will improve program quality. States developing high-quality plans to compete for the 21st CCLC funds would lead to more of a focus on improved outcomes for students. If we encourage all States to submit high-quality applications, we believe that would drive more improvements in the field in general. Additionally, we believe that numerous States would continue to receive funding under a competitive 21st CCLC program.

*Question.* How can States maintain consistent program administration without formula funds?

Answer. Those States that would not receive funding under a competitive 21st CCLC program would be in the best position to determine whether local programs that had received 21st CCLC formula funds are worth investing in if 21st CCLC funds are not available. States could, for example, choose to invest more State funds in programs currently funded by the 21st CCLC program. Another option could be that States could encourage school districts to dedicate more title I funds to lengthening the school day and providing services outside of regular school hours.

TEACH GRANTS AND PROPOSED PRESIDENTIAL TEACHING FELLOWS PROGRAM

*Question.* The Education Department's fiscal year 2012 budget proposal would replace the TEACH Grant program for institutions of higher education (IHEs) with a new Presidential Teaching Fellows grant program for States. Under the TEACH Grant program, many eligible students do not receive grants either because the schools they attend do not participate in the program or they anticipate being unable to fulfill the program's employment requirements. Did these shortcomings prompt the administration to propose replacing the program with its new proposal; are there other reasons why the administration wants to effectively end the TEACH Grant program?

Answer. Yes, based on preliminary data, it does not appear that the program is fulfilling its intended purpose of encouraging students to enter, and remain in, the teaching profession. As many as 75 percent of students receiving a TEACH Grant fail to fulfill its requirements. Additionally, many of the students receiving a TEACH Grant may be doing so in lieu of other institutional aid, which often does not need to be repaid.

The Presidential Teaching Fellows program is designed specifically to target students who demonstrate an interest in teaching later in their undergraduate career, as well as those individuals in programs that have a proven ability to produce quality teaching candidates.

INSTITUTIONAL PARTICIPATION IN THE TEACH PROGRAM

*Question.* According to the Education Department, five institutions for higher education (IHE) in Hawaii are TEACH Grant eligible. Can you explain why some IHEs did not participate?

Answer. There are many reasons why an institution may not participate in this program, but it would be reasonable to say their decision is likely based, at least in part, on the decision that nonparticipation is in the best interest of their students and institution. Many of the problems with the nature of the TEACH Grant pro-

gram, as described earlier, may be contributing factors into an institutions' reasoning when choosing whether or not to participate.

PRESIDENTIAL TEACHING FELLOWS

*Question.* How many of Hawaii's institutions will be considered eligible for the Presidential Teaching Fellows program?

Answer. Any Hawaiian institution's participation would be dependent upon if the State chose to participate in the program. In order for the institutions in a State to be eligible, the State must first agree to embrace certain reforms, including making licensure and certification systems more rigorous, measuring the effectiveness of teacher preparation programs based on multiple outcomes, including their graduates' success in improving student achievement, and to be willing to shut down persistently low-performing programs.

CAREER AND TECHNICAL EDUCATION

*Question.* The President has set a goal of having the United States improve college completion rates and become the Nation with the highest percentage of college graduates among its adults by 2020. The Carl D. Perkins Career and Technical Education Improvement Act of 2006 is the principal source of Federal funding to the States for the improvement of secondary and postsecondary career and technical education programs. The Department of Education's (ED's) fiscal year 2012 budget proposes reducing Federal funding to States under the act from $1.124 billion in fiscal year 2011 to $1 billion in fiscal year 2012, following a $140 million reduction from fiscal year 2010 to fiscal year 2011. Hawaii's $6.121 million allocation in fiscal year 2010 will be reduced an estimated $595,000 in fiscal year 2011 and an additional $608,000 in fiscal year 2012. How will this proposal support the administration's goal and the Nation's projected employment needs?

Answer. While career and technical education (CTE) is vitally important to America's future, the Perkins CTE program as it is currently structured is not operating in a way that produces optimal results for students. ED is currently engaged in developing our reauthorization proposal for the Carl D. Perkins Career and Technical Education Act. Our intent is to develop a proposal that will improve the statute by ensuring that all CTE programs become viable and rigorous pathways to postsecondary and career success, providing students with the career skills necessary to compete in a global marketplace, and collecting better program performance data.

CAREER AND TECHNICAL EDUCATION IN HAWAII

*Question.* What effect will this funding decrease have for Hawaii, in particular?

Answer. While the State of Hawaii would receive a reduced grant award under the administration's $1 billion request for the CTE State Grants program, the State would still continue to benefit from the .25 percent set aside under section 116(h) of the Perkins Act for programs that benefit Native Hawaiian individuals. The State could also supplement the funds distributed to local agencies and institutions of higher education by taking advantage of the authority in section 112(c) of the Act that allows it to reserve State funds for awards in rural areas or areas with high percentages or numbers of CTE students.

DISTANCE EDUCATION REGULATIONS

*Question.* Mr. Secretary, Hawaii has a large number of military members assigned to bases throughout our State. I am concerned that the new regulations on distance education may have potential negative impacts on the ability of our military members to access distance learning opportunities, particularly since they frequently change duty location. What effect will this regulation have on military members?

Answer. The Department's regulations governing State authorization of distance education programs simply required institutions to comply with State laws where they exist. It imposed no additional requirements beyond being able to demonstrate that they complied with State law where those State laws exist. A Federal court recently took action to strike the provision of the Department's regulation, but did not overturn State law.

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QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

EARLY CHILDHOOD EDUCATION

*Question.* I was pleased with the investment in early childhood education you decided to make with the fiscal year 2011 Continuing Resolution Race to the Top fund-

ing. However, I think we both know there is much more that should be done. Early childhood education is one of the most important investments we can make in a child's education. Can you tell me your thoughts and plans for continued funding and investments to improve the quality of early childhood education for children in Washington State and across the country?

Answer. The administration wants to ensure that there continues to be funding to support the important work of improving the quality of early learning programs and services. We are excited about the RTT–ELC competition, which is focused on improving the early learning and development of young children by supporting States' efforts to increase the number and percentage of low-income and disadvantaged children in each age group of infants, toddlers, and preschoolers enrolled in high-quality early learning and development programs, and on States' efforts to design and implement an integrated system of high-quality early learning and development programs and services. We expect that the States that win these grants will serve as models for others, leading to improved quality of early learning and development programs across the Nation.

LITERACY FUNDING

*Question.* I am very troubled by the elimination of almost all Federal aid for literacy programs and what it could mean for the future of the Federal commitment to literacy. Providing high-quality literacy programs for children across the country has always been a priority for me. How does the Department plan to support further investments in literacy, given its importance in the educational success of students?

Answer. The fiscal year 2011 compromise agreement included many painful cuts, and the reductions for literacy programs were particularly difficult. The administration requested increased funding for literacy in fiscal years 2011 and 2012, so we are very concerned about the cuts to literacy programs. We want to work with you to find a way to restore funding for literacy programs.

The President's fiscal year 2012 budget request included funding for the proposed Effective Teaching and Learning: Literacy program, which would replace the previously fragmented literacy programs to support States in carrying out a comprehensive, pre-kindergarten through grade 12 literacy strategy. States would target funds to high-need districts to implement high-quality evidence-based literacy instruction. States and districts would have the flexibility to target funds on the activities and grade spans where local need and the potential impact on student learning are greatest. In addition, the Department just made awards under the Striving Readers Comprehensive Literacy (SRCL) program using fiscal year 2010 funds. That competition is aligned in many ways with the proposed Effective Teaching and Learning: Literacy program. The President's budget request includes continuation funds for the SRCL grants in the request for the new literacy program.

21ST CENTURY COMMUNITY LEARNING CENTERS

*Question.* The budget proposal you submitted proposes adding new purposes and programs to the existing 21st Century Community Learning Centers initiative, including summer school and longer school days. In this budget environment, I am very concerned that diverting afterschool funds to schools to extend the regular school day will inevitably mean fewer afterschool programs and fewer communities being served. How can you guarantee that these proposed changes will not result in fewer children being served by afterschool programs that keep our students safe and give them enriching educational activities?

Answer. The fiscal year 2012 request for the 21st Century Community Learning Centers program, which is aligned with the administration's proposal to reauthorize the Elementary and Secondary Education Act (ESEA), would allow local recipients to use program funds to expand learning time by significantly increasing the number of hours in a regular school schedule and comprehensively redesigning the school schedule for all students in a school. The administration's ESEA reauthorization proposal would continue to allow funds to be used for before- and after-school programs, summer enrichment programs, and summer school programs, and, additionally, would permit States and eligible local entities to use funds to support expanded-learning-time programs and full-service community schools. This enhanced flexibility would allow communities to determine the best strategies for enabling their students and teachers to get the time and support they need.

EXTENDED-DAY AND AFTER-SCHOOL PROGRAMS

*Question.* Many extended-day programs only keep students in school until 4 PM, or earlier. And, since the majority of afterschool programs end between 5 pm and

7 pm and sometimes later, how is extending the school day going to fill that gap, ensuring students are off the streets, until their working parents get home?

Answer. I agree that it is critically important that children have a safe, enriching place to go between the time that they are dismissed from school and when they are supervised at home. The administration's reauthorization proposal assumes that local communities are best suited to determine how best to provide such support for children and their families, whether through afterschool programs, expanding the regular school day, week, or year, or a combination of these strategies. Under our reauthorization proposal, all of these options would be allowed, including afterschool programs.

INITIATIVES AND INVESTMENT IN EDUCATIONAL TECHNOLOGY

*Question.* As you know, the first round of Race to the Top Assessments are scheduled to be performed online in 2014. Many States and districts are unprepared technologically and in terms of training people to administer them and yet funding for classroom technology was cut from this and last year's budget proposals. Can you explain the Department's rationale for failing to invest in classroom technology, and, are there any plans to assist States and districts in ramping up to meet the technology challenges of implementing the Common Core assessments?

Answer. The administration believes that technology is integral in improving educational quality for students, and that technology can be a valuable tool for enhancing student learning and better supporting teachers. For that reason, instead of continuing to fund a separate, narrowly defined formula program for education technology, the administration is proposing, through the Elementary and Secondary Education Act (ESEA) reauthorization and fiscal year 2012 budget request, new ways of investing and integrating technology across ESEA programs. We believe that this new approach would offer more flexibility and provide greater support to States, districts, and schools in their efforts to integrate technology into curricula and instruction and also would encourage the replication of effective technology-based practices.

*Educational Technology in the Fiscal Year 2012 Budget Request*

As you are aware, the President's fiscal year 2012 budget request includes $835 million for the proposed Effective Teaching and Learning for a Complete Education initiative, which would address the need to strengthen instruction and increase student achievement, especially in high-need local educational agencies, through three programs focused on literacy; science, technology, engineering, and math; and ensuring a well-rounded education. Under this proposed initiative, the Department would support States and districts in developing strategies and practices to meet the needs of their students and teachers across subject areas, including through innovative uses of technology in classroom instruction and professional development. The initiative's national activities authority also would support States in strengthening their use of technology in the core academic subjects, including the development and implementation of technology-enabled curriculum, assessments, professional development, and tools and resources.

The fiscal year 2012 budget request also includes $300 million for a reauthorized Investing in Innovation Fund and $90 million for the new Advanced Research Projects Agency—Education (ARPA–ED). The Investing in Innovation Fund would support the use of technology to drive improvements in educational quality and productivity. The ARPA–ED initiative would pursue breakthrough developments in educational technology and learning systems, support systems for educators, and tools that result in improvements in student outcomes. Other programs that would encourage the integrated use of technology in classrooms include Expanding Educational Options, College Pathways and Accelerated Learning, Effective Teachers and Leaders State Grants, Teacher and Leader Pathways, Assessing Achievement, and English Learner Education. The administration is also proposing to allow States and districts to set aside a sizable percentage of the $14.8 billion request for Title I, Part A, College- and Career-Ready Students program to support capacity-building activities, including for technology.

*Computer-based Assessments*

In addition to these new ways of investing and emphasis on the integration of technology across programs, the administration is committed to supporting States and districts as they begin to make greater use of computer-based assessments. Under the Race to the Top Assessments competition, the Department awarded grants to consortia of States to develop reading-English language arts and mathematics assessments that are aligned with standards that are held in common by participating States. The administration's ESEA reauthorization proposal and fiscal

year 2012 budget request include support for the Assessing Achievement program (currently titled State Assessments), which would allow States to use program funds to administer assessments that are aligned with college- and career-ready standards, as well as for other activities relating to implementation of such assessments and reporting of assessment data. The administration believes that these resources would increase the number of States implementing assessment systems that measure whether students are on track to being college- and career-ready by the time they graduate from high school, and they also would help States align their standards and high school graduation requirements with college and career expectations.

CAREER AND TECHNICAL EDUCATION

*Question.* Across America, unemployment levels remain high, but we know there are jobs available for individuals who have the right skill sets. Career and Technical Education (CTE) programs work to ensure that students have the academic, technical and employability skills necessary for real career readiness. And at the Federal level, it is important that we support programs that help our workforce gain the skills necessary to be successful. Can you discuss how schools can offer CTE programs to help students attain these skills without Perkins funding?

Answer. The Perkins Act funding assists States in expanding and implementing CTE education in high schools, technical schools, and community colleges. While it constitutes a small percentage of the total funding used by States, districts, and institutions of higher education for CTE programs, targeted Federal funding can continue to spur reform and innovation.

The majority of the funding for CTE programs comes from State and local sources. Therefore, as long as students, school systems, and business leaders find that these programs are valuable and provide students with relevant and useful skills, these programs are likely to continue to exist.

REAUTHORIZATION OF PERKINS ACT—CAREER AND TECHNICAL EDUCATION

*Question.* The Department has mentioned that one reason for cutting Perkins funding is an inconsistency in the quality of programs across the country. However, I think that cutting funding for Perkins will likely exacerbate program quality inconsistencies. Furthermore, due to the nature of this formula grant, even high-quality programs will lose a significant amount of funding. Can you discuss how the Department expects CTE programs to succeed under this loss of funding?

Answer. The administration's intent is to work with Congress during the upcoming reauthorization of the Perkins Act to improve the program and ensure that it provides students with the career and technical skills necessary to compete in a global marketplace. The current accountability system under the act cannot effectively differentiate between low- and high-quality CTE programs, nor does it provide incentives to distribute funds to schools and postsecondary institutions based on performance. We need to ensure that we invest in high-quality CTE programs, those that provide multiple pathways to success in careers and postsecondary education or training and align academic and technical coursework with challenging postsecondary expectations, industry needs, and certifications, and respond to the changing needs of the global economy.

IMPACT AID FUNDING

*Question.* Impact Aid is an important education program for many schools around the country and, specifically, in my home State of Washington. Impact Aid remains a bipartisan priority of the United States Senate. Could you please explain for me your plan for continued investment in the Impact Aid program?

Answer. The Department is committed to maintaining funding for the Impact Aid program. Since 2001, funding for the Impact Aid program has increased by over 28 percent. The administration's budget request would maintain the current level of funding and provide over $1.2 billion in financial assistance to school districts affected by Federal activities. Our request would maintain the Department's commitment to over 937,000 federally connected students and ensure that sufficient funding remains available for Basic Support Payments, Payments for Children with Disabilities, Facilities Maintenance, Construction, and Payments for Federal Property.

IMPACT AID PAYMENT PROCESS

*Question.* Additionally, how does the Department plan to rectify ongoing, consistently late Impact Aid payments to districts?

Answer. With regard to late payments to districts, as you may know, the Impact Aid program is not fully funded and as a result we follow payment proration rules

that are set by statute. In order to make final payments for any fiscal year, all data for all applicants must be complete and approved. When we begin making payments for any fiscal year, this is not the case. There are a number of reasons why this happens, such as amendments submitted by some applicants in September, incomplete field reviews (the monitoring process), pending property or Indian policy and procedure reviews, eligibility determinations that are not final, data questions regarding total current expenditures, attendance or local contribution rate figures, and submissions for military base housing undergoing renovation that have not been approved. As a result of these pending questions, we have to set the payment level at a lower level for the first year to avoid making overpayments to a large number of districts. In addition, we must set an initial payment rate in our system in May or June in order to be prepared to begin making payments on October 1, when funds become available for the new fiscal year. As this is well before an appropriation is enacted, we must consider the possibility that the program will not receive an increase or even be level funded for the next fiscal year. When we operate under a continuing resolution for part of the fiscal year, as we have for many recent years, we have limited funds to distribute and try to provide funding to as many applicants as possible, which is another reason for setting the initial payments at a lower rate. Once we have an appropriation for the full fiscal year, we raise that rate and issue another set of payments.

Under the Impact Aid statute, we actually have 6 years to complete payments, the year of the appropriation and 5 more. However, our goal is to get this down to only 2 years so that we can get our funds out to the LEAs as soon as possible. What generally happens during a fiscal year is that we make initial and interim payments for the current year and the prior year, and final payments for the second prior year. Together these payments are usually equal to approximately the full amount of the payments for the current year. The LEAs with the highest percentages of federally connected students in their enrollments have received the highest proportions of their final payments in the first year, which we feel is an appropriate outcome. We continually strive to improve and expedite our payment processing while ensuring that our payments to all applicants are accurate.

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## QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

### TEACH FOR AMERICA

*Question.* Because of the zeroing out of several critical education programs, worthwhile organizations like Teach For America have been struggling to find alternative sources of Federal funding. To support this effort, this subcommittee recently approved a competitive funding stream to be set aside for national programs that recruit, train, and professionally develop teachers at an amount of 1 percent of title IIa funds. Meanwhile, the programs eligible to compete for these funds were awarded over $100 million last year, and they will be left to vie for a slice of merely $25 million if this set aside is left at 1 percent. Nearly 90 Members of Congress—from both parties and chambers—have written in support of increasing this competitive funding pot to 5 percent of title IIa.

Mr. Secretary, do you support this increase; if so, why, and if not, why not?

Answer. Under the President's fiscal year 2012 budget request, Teach For America, along with other nonprofit organizations, States, local educational organizations, and institutions of higher education, would be eligible to apply for $250 million in competitive grant awards under the Teacher and Leader Pathways program, for which the creation or expansion of high-quality alternative pathways into the teaching profession would be an authorized activity. In addition, Teach For America would also be eligible to compete for funding under the Investing in Innovation program, through which Teach For America received $50 million in 2010 and for which $300 million was requested for 2012. Finally, Teach For America could partner with States and districts to use funds awarded under the Effective Teachers and Leaders State grants program to support Teach For America projects. The Department believes that the funds requested for these programs would significantly expand the resources available for Teach For America and other States, local educational agencies, nonprofit organizations, and institutions of higher education to compete for funding to support their efforts to recruit, prepare, and develop, and retain effective and highly effective teachers.

### RACE TO THE TOP FUNDING COMPETITION

*Question.* Every State (except Georgia) that won Race to the Top in the first two rounds has now amended its State reform plan in some way—usually to push back

a timeline or scale back an initiative. According to the list of approved amendments listed on the U.S. Department of Education's Web site, 12 winners have changed their plans 25 times, overall.

Delaware, the District of Columbia, Florida, Georgia, Hawaii, Maryland, Massachusetts, New York, North Carolina, Ohio, Rhode Island, and Tennessee won Race to the Top funding based on their ambitious plans for reform. Now, nearly all of these States and the District of Columbia are making changes to their plans.

The administration has requested an additional $900 million for Race to the Top. Before appropriating additional funding to this competition, it's worth asking if the Department of Education is learning any lessons from the first two rounds.

Could you address any improvements the Department of Education intends to make to Race to the Top to ensure that only the States truly committed to their bold reform plans win the funds?

Answer. We are working closely with States to ensure that the only changes they make to the plans in their winning applications are those that preserve the ambitious work they set out to do. We are open to revisions so long as they preserve the long-term trajectory of the work while addressing short-term implementation challenges. If a State fails to follow through on the commitment in their application, we will freeze or take back its grant award.

*Question.* Additionally, can you please discuss the specifics of the administration's proposal to expand the Race to the Top competition to regions and cities, not just States?

Answer. We still have details to work out, but it is our intention that districts in States that received Race to the Top grants, as well as those in all the other States, would be eligible to compete in the district competition. In States that won Race to the Top grants last year, we do not want to get in the way of the great work these States are already doing. District plans should be aligned with the State's plans, and we would seek input from the field on how best to ensure that alignment. We also recognize the concern that districts in Race to the Top States may be further ahead in developing comprehensive reform plans. We would explore the best way to ensure a level playing field for all districts, whether they are in Race to the Top States or not.

RACE TO THE TOP PHASE 3

*Question.* Finally, could you also provide a status update on the $200 million fiscal year 2011 Race to the Top competition for the nine high-scoring finalists that did not receive funds in the first two rounds of the competition?

Answer. The Department will dedicate (for what we are calling "Race to the Top Phase 3") approximately $200 million for the nine highest-ranked but unfunded finalist States from the 2010 Race to the Top Phase 2 competition. The grant application for Race to the Top Phase 3 will be available in early fall for the nine eligible States: Arizona, California, Colorado, Illinois, Kentucky, Louisiana, Pennsylvania, New Jersey, and South Carolina. We are working on the final details of the grant opportunity, but the focus will be on supporting the States' 2010 Race to the Top applications in order to drive continued education reform in those States. The Department plans to make awards in December 2011.

EMERGENCY PREPAREDNESS IN SCHOOLS

*Question.* According to the National Commission on Children and Disasters, in its October 2010 Report to the President and Congress, a major concern is the lack of comprehensive disaster planning and preparedness for schools across the country. The Commission echoes a 2007 GAO Report that identified many gaps in aligning school emergency plans with federally-recommended practices.

The U.S. Department of Education manages the Readiness and Emergency Management for Schools (REMS) grant competition to improve emergency preparedness in schools. It is the only Federal grant program solely dedicated for this purpose. In fiscal year 2010, the Department received $30 million and awarded grants to about 120 school districts (local educational agencies). The fiscal year 2011 budget request was again $30 million.

The Commission noted that $30 million is insufficient to improve emergency preparedness for over 130,000 public and private schools in our country. For fiscal year 2011, the Department intends to spend just $4 million and provides only $6 million in its fiscal year 2012 budget request.

Given the concerns of the Commission and GAO, why isn't improving emergency preparedness for schools a higher priority to the Department, and worthy of greater investment?

Answer. The Department remains committed to emergency preparedness planning, and believes that a more cost-effective and efficient strategy is to build State-level capacity for emergency preparedness planning. Instead of funding grants for Readiness and Emergency Management for Schools (REMS) to school districts, the Department plans to award grants in 2012 to States to provide support to districts and schools, including those that face unique challenges in implementing emergency management activities, that will help them prepare to address a variety of potential hazards and crises.

REMS currently does not enable the Department to achieve meaningful progress towards sustainable, continuous improvement in K–12 emergency management. The REMS grants program has served a small fraction of all school districts and is too small to have a significant impact on emergency preparedness nationally. Since 2003, the Department has distributed 823 grants to districts, a small proportion of the 14,200 public school districts nationwide.

*State Grants for Emergency Management*

Supporting statewide efforts will ultimately allow the Department to reach more districts. Also, moving to this new approach will allow the Department to support State efforts to develop best practices and innovative models that can be shared with and adapted or adopted by other States.

Further, the National Commission on Children and Disasters 2010 Report to the President and Congress recommended the approach we have proposed, stating, "the Commission recommends that competitive disaster preparedness grants be awarded to States through the REMS program as an initial step toward developing innovative models designed to ensure a higher level of school preparedness statewide." This approach also would align our emergency preparedness efforts with the Department's overall priority to build the capacity of State educational agencies across the country.

We had hoped to initiate the State Grants for School Emergency Management in 2011 but, due to the $98 million cut in funding for Safe and Drug-Free Schools and Communities (SDFSC) National Activities under the fiscal year 2011 full-year continuing resolution, the Department did not have enough 2011 funds to make any new SDFSC grant awards.

Also, in 2012 under SDFSC National Activities the Department plans to award additional Safe and Supportive Schools grants to States to support statewide measurement of, and targeted programmatic interventions to improve, conditions for learning in order to help schools improve safety and reduce substance use. Promoting readiness and emergency management for schools would be among the programmatic interventions supported with those grants.

FEDERAL TRIO PROGRAMS

*Question.* Over the last 5 years, Federal TRIO programs have lost 37,000 participants as a result of stagnant funding. The $26.6 million cut in fiscal year 2011 may result in as many as 107,000 fewer participants. The administration has requested $920 million for TRIO in fiscal year 2012. This funding is critical to growing the capacity of TRIO and thereby increasing the rate of college completion for students from lower socioeconomic backgrounds. Could you discuss how the administration will support and defend its recommended funding level for TRIO in fiscal year 2012?

Answer. The administration believes that the Federal TRIO programs play an important role in assisting low-income students and students whose parents never completed college with support and preparation to enter and complete postsecondary education programs. In designing the TRIO competitions for 2012, particularly Upward Bound, the Department is focused on ensuring that grantees pursue strategies and activities that will maximize the number of students to which they can provide high-quality services. The Department also believes that the TRIO programs can play an important role in ensuring that our investment in Pell Grants results in more students persisting and completing because they enroll in postsecondary education better prepared to succeed.

The administration remains committed to increasing college enrollment and completion rates among traditionally underrepresented populations. In demonstration of this commitment, we have prioritized protecting the $5,550 maximum Pell Grant award in fiscal year 2012 and beyond, with the goal of ensuring that more than 9 million low-income students can continue to rely on Pell Grants to enter into, and complete, a postsecondary education. However, low-income students need more than just financial support to enter and complete college; they also need supportive services like those provided by our Federal TRIO programs.

EDUCATIONAL STABILITY FOR FOSTER YOUTH

*Question.* Children in the foster care system face unique challenges on their path to high school graduation and college success. On average, foster children move one to two times per year, and often change schools when they move. When students change schools, they lose 4 to 6 months of educational progress. Only about half of foster children graduate from high school, and a mere 3 percent earn bachelor's degrees. As the Co-Chair of the Senate Caucus on Foster Youth and an advocate for foster youth, I am concerned that children in the foster care system do not have the educational stability they need to graduate from high school—on time and with the strong educational foundation they need to access and complete college.

Mr. Secretary, do you believe the U.S. Department of Education should invest in promoting educational stability for the nearly 450,000 children in foster care, and, if so, what would that investment look like? Might this investment include school vouchers for youth in care over 18 months; stronger collaboration between State Educational Agencies and State child welfare agencies; Federal funding for the transportation needed to keep foster youth in their school of choice; or other solutions?

Answer. All students, especially those in foster care, need educational stability in order to succeed in school. We certainly need to do more for youth in foster care, who are more likely to repeat a grade, and score lower on standardized tests, than youth who are not in foster care. Between one-quarter and almost one-half of all children in foster care are also in special education, well above the average for the general population.

Collaboration among State educational agencies (SEAs), State child welfare agencies, local educational agencies (LEAs) and schools is key to tackling these challenges. In letters to Chief State School Officers and State Child Welfare Directors, we are planning to encourage States and LEAs to develop or review and, if appropriate, revise their policies and guidelines for serving children in foster care, in order to minimize the disruptions to education that can come from being placed in foster care. We have encouraged SEAs, LEAs, and child welfare agencies to collaborate during this process and to publicize these policies and guidelines so that school administrators, teachers, social workers, and parents understand and can replicate and reinforce their efforts to increase the educational success of foster children. ED has also urged child welfare agencies to collaborate with LEAs on policies and procedures to ensure that foster children remain in and receive transportation to their school of origin in cases where this is in the best interest of the foster child, using funding under title IV, part E of the Social Security Act and other available resources for such purposes. We have pushed for all States and LEAs to have any revised policies and guidelines in place prior to the start of the 2011–2012 school year.

ED is also collaborating with the Department of Health and Human Services (HHS) on this issue, by providing HHS with the information and technical assistance needed to successfully carry out that agency's work under the Fostering Connections to Success and Increasing Adoptions Act of 2008 (FCA). For example, we have worked closely with HHS in providing input and assistance as it develops guidance and other material on the FCA. ED has also shared with HHS resources developed by the National Center for Homeless Education (NCHE), our technical assistance contractor for the McKinney-Vento Education for Homeless Children and Youth program. NCHE provides technical assistance to ED on issues related to homeless students, but it has also put together information and recommendations on the education of students who are eligible for homeless services while they are awaiting foster care placement.

*Foster Care and Education National Meeting in 2011*

Finally, ED and HHS will co-host a Foster Care and Education National Meeting on November 3 and 4 of 2011 to bring together State teams, representing each State's educational, child welfare, and court systems, to discuss how to promote educational stability and improve educational outcomes for children in foster care. Our goals for this meeting are to expand participants' understanding of each system and of the individual and collective opportunities that can contribute to improving educational outcomes for children in foster care; gain insight into foster youths' perspectives on what supports have aided in their educational success; familiarize participants with the educational provisions of the FCA; and showcase meaningful collaborative initiatives that have demonstrated positive educational outcomes. During the meeting, each State team will also create an action plan for cross-system collaboration to be implemented following the conference. All conference attendees will have access to additional technical assistance, such as webinars, on topics related to the FCA leading up to this national meeting.

HIGH SCHOOL DROPOUT RECOVERY/PREVENTION PROGRAMS

*Question.* A June 2011 MDRC report, "Staying on Course: Three-Year Results of the National Guard Youth ChalleNGe Evaluation," shows that the National Guard Youth ChalleNGe program is effectively reducing our Nation's high school dropout rate. According to the report, 3 years after entering the program, Youth ChalleNGe graduates were more likely to earn their high school diploma or GED, obtain college credits, be employed, and have substantially higher earnings than high school dropouts who were eligible, but did not participate in the ChalleNGe Program.

Are you aware of any comparable high school dropout recovery/prevention programs, and if so, how is the U.S. Department of Education investing in these programs?

Answer.

*Dropout Prevention Guidance*

Reducing our Nation's high school dropout rates is a key Department goal, and we have been actively engaged in identifying and disseminating information on effective dropout prevention and recovery practices. In fall 2008, the Institute of Education Sciences (IES) released Dropout Prevention: A Practice Guide, which provides recommendations for dropout interventions using evidence from previously implemented programs that positively affected students' progress and persistence in school. Using material from this guide, the Department developed a Dropout Prevention section for the Doing What Works Web site, which provides practitioners with research-based information and tools for improving outcomes. The Office of Elementary and Secondary Education has also recently initiated an effort to identify a set of promising dropout prevention and recovery models. In addition, IES continues to fund research on dropout prevention programs, currently including a study of the Check & Connect dropout prevention model.

*Departmental Dropout Prevention and Reentry Programs*

The Department has invested in dropout prevention and reentry efforts through the High School Graduation Initiative (HSGI, formerly School Dropout Prevention) program, which received $48.9 million in fiscal year 2011 and provides competitive grants to States and local school districts to implement, at schools with below-average graduation rates, effective, sustainable dropout prevention and reentry activities, including activities similar to those of the National Guard Youth ChalleNGe program. In our proposal to reauthorize the Elementary and Secondary Education Act, we propose to consolidate this and two other programs that seek to improve outcomes for high school students or offer accelerated learning opportunities into a single authority, the College Pathways and Accelerated Learning program. This program would support comprehensive efforts to increase high school graduation rates and preparation for college matriculation and success by providing college-level and other accelerated courses and instruction in middle and high schools with concentrations of students from low-income families and in high schools with low graduation rates. It would also allow considerable local flexibility for activities including efforts to prevent students from dropping out and to reengage out-of-school youth, including early warning systems and comprehensive prevention and reentry plans. The President's fiscal year 2012 request includes $86 million for this program.

In addition, high schools with high dropout rates receive significant assistance through the Title I School Turnaround Grants (formerly School Improvement Grants) program. Under the administration's recent program regulations and ESEA reauthorization proposal, Title I secondary schools with a graduation rate below 60 percent may receive priority for School Turnaround funds. These school turnaround grants will provide hundreds of millions of dollars to help restructure significant numbers of the Nation's "dropout factories."

Also, the Department will continue to invest in efforts to keep students in school and on the path to college through programs authorized under the Higher Education Act, including the TRIO-Talent Search and GEAR UP programs.

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QUESTION SUBMITTED BY SENATOR RICHARD J. DURBIN

STUDY ABROAD AND FOREIGN LANGUAGE INSTRUCTION

*Question.* Currently, only about 1 percent of college students study abroad each year, few of whom are minority students, community college students, or students studying in the STEM fields or to be teachers. Less than 10 percent of students enrolled in higher education institutions in the U.S. are taking foreign languages. Given the increasingly global nature of our economy, what plans does the Depart-

ment have to help more students graduate college with the global mindset and foreign language skills necessary to be successful in today's global economy?

Answer. The Department agrees that a world-class education must integrate global competencies and is committed to increasing the global competency of all U.S. students, including those from traditionally disadvantaged groups. The Department expects these objectives to be reflected in a strategy it is currently developing that would govern all its international activities. The Department currently administers 18 discretionary grant programs authorized under the Higher Education Act and the Mutual Educational and Cultural Exchange Act of 1961 that are designed to strengthen the capability and performance of American education in foreign languages and in area and international studies, and to improve secondary and postsecondary teaching and research concerning other cultures and languages, as well as the training of specialists, and the American public's general understanding of the peoples of other countries. The Department intends to further align activities to be supported in fiscal year 2012 under these programs with the Department's goals to advance global educational competency for American citizens and to increase access and quality in postsecondary education.

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## QUESTIONS SUBMITTED BY SENATOR JACK REED

### SCHOOL LIBRARIES

*Question.* Given that more than 60 education and library studies have shown evidence that effective school libraries are linked to increased student achievement and knowing that digital literacy skills are essential to being college and career ready, what is the administration's plan to ensure that students in title I schools have access to effective school library programs?

Answer. The administration's proposed Effective Teaching and Learning: Literacy program would address the need to comprehensively strengthen instruction and increase student achievement in literacy in high-need districts and schools. The administration believes that this new program would help ensure that States and high-need districts have in place a solid infrastructure across the grade levels to support high-need schools in implementing high-quality, developmentally appropriate, and systematic literacy instruction (which may include programs that support school libraries).

*Question.* What changes does the administration plan to make to competitions such as Race to the Top to encourage States and school districts to provide effective school library programs?

Answer. Race to the Top provides significant flexibility to States and encourages them to pursue approaches that improve student outcomes and best meet State and local needs. Depending on the strategies adopted by individual States (and by local educational agencies, if we are able to hold a district-level RTT competition), the approaches may include activities to strengthen school libraries. In addition, the proposed Effective Teaching and Learning: Literacy program would encourage States and LEAs to implement high-quality literacy instruction, which could include support for school libraries.

### TEACHER QUALITY PARTNERSHIP GRANTS

*Question.* The President's fiscal year 2012 budget calls for the Teacher Quality Partnership program to be consolidated, along with four others, into a new authority called Teacher and Leader Pathways. Teacher Quality Partnership Grants are currently the Federal Government's only investment in reforming teacher preparation at institutions of higher education, which prepare nearly 90 percent of all teachers. Why is the administration planning to switch course before full implementation of the Teacher Quality Partnership Grants?

Answer. In its March 2011 report entitled "Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue," the Government Accountability Office (GAO) specifically identified the Teacher Quality Partnerships Grants program as a current teacher quality program that overlaps with another program in the Department based on its allowable activities or shared objectives and target groups. The GAO report noted that the administration had already proposed to reform the current fragmented approach to improving teacher quality through its Blueprint for the reauthorization of the Elementary and Secondary Education Act.

By consolidating several overlapping and sometimes narrowly targeted programs, the administration has proposed an integrated approach to recruiting, preparing, developing, rewarding, and retaining effective teachers and school leaders that builds

on the best elements of existing programs and approaches at the Federal, State, and local level. The President's fiscal year 2012 budget requests $250 million for the Teacher and Leader Pathways program to support the preparation of new teachers, with particular emphasis on the preparation of science, technology, engineering, and mathematics, or STEM, teachers. Institutions of higher education, along with States, local educational agencies, and nonprofit organizations, would be eligible for competitive grants to support the creation or expansion of high-quality traditional and alternative pathways into the teaching profession.

PROJECTS FUNDED UNDER TEACHER QUALITY PARTNERSHIP GRANTS

*Question.* What are the preliminary results from the current Teacher Quality Partnership Grants?

Answer. The Department is currently administering 40 grants under the Teacher Quality Partnership Grants program, including 19 teacher residency projects, 12 pre-baccalaureate teacher preparation projects, and 9 projects that support both a teacher residency project and pre-baccalaureate teacher preparation. Although it is too early to know if these teacher preparation programs are producing more effective teachers as a result of the reforms they are implementing through these grants, the annual performance reports for the second year of these grants indicate that most projects are implementing their projects as planned.

The grants supporting teacher residency projects prepared 620 teacher candidates last year. These projects focused on preparing candidates who will be certified to teach elementary education, mathematics, science, or special education. The graduates of these residency projects will be teaching in high-need schools in high-need districts in the 2011–2012 school year. Due to reductions in State and local funding, some of the partnering high-need districts for the residency projects have been unable to meet their original commitments to hire as many residents to teach in high-need schools. Since grantees are required to place successful graduates of residency projects in teaching positions in high-need schools, these grantees have had to reduce the number of candidates they admitted. The Department is hopeful that the partnering districts will be able to commit to hiring more teacher residents in the remaining years of these grants and will continue to work with grantees to ensure that these projects are as successful as possible despite the challenging economic conditions.

For the pre-baccalaureate teacher preparation grants, six institutions of higher education have incorporated information into their traditional course offerings to ensure that their teacher preparation candidates are prepared to teach students in urban, high-need schools more effectively. Four pre-baccalaureate projects are focused on preparing candidates to teach students in high-need rural schools and rural education is an area of emphasis for several other projects. Both pre-baccalaureate and residency projects reported that they are establishing or expanding clinical experience requirements for teacher candidates. In addition to preparing teachers to enter the classroom, six projects also have reported that they are offering professional development for teachers in partnering schools.

FEDERAL PARTNERSHIPS AND NEED-BASED STUDENT GRANT AID

*Question.* Does the administration see a need for a Federal-State partnership to support need-based grant aid for students? What are the administration's plans to rebuild such a partnership now that the Leveraging Educational Assistance Partnerships, or LEAP, program has been defunded?

Answer. Cooperation between the Department and States is vital to achieve good educational outcomes. This is why the 2012 President's budget included proposals for new Federal-State partnerships in the form of the College Completion Incentive Grant (CCIG) program, and the College Access Challenge Grant program. CCIG is designed for twofold activity: to encourage States to engage in reforms to increase college completion rates (and ensure these students are well-prepared), and to reward institutions that are successful at achieving these goals. States must apply to receive funding, and include with their application a plan of how they will make certain reforms.

The College Access Challenge Grant Program, as proposed, would provide formula aid to States to bolster access, persistence, and completion activities, specifically targeted toward low-income students. This program would fund activities to ensure low-income students are prepared to enter and succeed in postsecondary education, such as providing them need-based grant aid, promoting financial literacy and debt management, and providing postsecondary education and career preparation for students and their families.

*Question.* Does the administration see a need for a Federal-institutional partnership to provide need-based grant aid for students? How can we strengthen the current aid programs to improve these partnerships?

Answer. Besides the funding that is able to be granted to institutions from States via the College Completion Incentive Grants and College Access Challenge Grant programs, the First in the World program, included in the 2012 President's budget request, would go directly to programs that are evidence-based and willing to undergo rigorous evaluation. This would be a competitive grant program, and would place priority in the first year on projects that could reduce net price, improve outcomes, reduce time to degree or instructional costs; and/or improve access and completion rates.

RACE TO THE TOP FUNDING AND VENDORS

*Question.* With billions of dollars awarded, Race to the Top is the largest competitive grant program at the Department of Education. It is essential that the use of these funds is fully transparent. Please provide information on which vendors States are using to implement their grants and the amount of Race to the Top dollars that are being awarded to the top vendors across the States.

Answer. We have not aggregated the information about the vendors with whom the Race to the Top States are working to implement their plans. All of the States and school districts that received Race to the Top funds must meet the reporting requirements set forth in section 1512 of the Recovery Act. Those requirements include identifying any vendors that receive payment of $25,000 or more in a given quarter, and that information is publicly available on Recovery.gov. In addition, States must follow State procurement laws, which may require the public release of the names of entities that are awarded contracts and other awards under the program.

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## QUESTIONS SUBMITTED BY SENATOR MARK PRYOR

LEVEL PLAYING FIELD FOR RURAL AREAS IN GRANT COMPETITIONS

*Question.* You testified that over 80 percent of the Department of Education's funding allocations remain formula based. However, I have heard from many of my constituents that are concerned that they do not have the ability or the resources necessary to effectively compete for the remaining 20 percent of funding in competitive grants. What steps is the Department of Education taking to ensure that poor and rural school districts are able to apply for competitive grants and compete on a level playing field?

Answer. The Department recognizes that capacity constraints in remote and rural areas can make applying for competitive grants difficult. To help level the playing field for rural districts, the Department is using absolute and competitive priorities to award additional points to applications from these districts or other applicants serving rural areas. For example, the Department included a rural priority and a tribal priority in the Promise Neighborhoods grant competition. The Department also has proposed structuring new competitions for the Race to the Top and i3 programs to reflect the needs of rural districts. Our goal would be to ensure that rural districts are able to compete for Race to the Top funds in our proposed district-level competition, and that i3 recipients serve geographically diverse communities. Under i3, for example, we hope to fund providers proposing evidence-based approaches to addressing the unique needs of rural districts and schools. Also under i3, we plan to recruit peer reviewers experienced in working with rural students and schools, and to improve our training methods so that all peer reviewers are aware of the unique needs of students and schools in rural communities and our expectations for applications that respond effectively to the rural priority.

The Department also is using its Comprehensive Centers to provide technical assistance designed to increase the capacity of rural districts, working with Rural Education Achievement Program (REAP) State coordinators to increase awareness of competitive grant opportunities for rural areas, and encouraging the development and expansion of consortia and partnerships to help make rural districts more competitive. Finally, the Department's recent experience with the School Improvement Grants (SIG) program suggests that rural districts can hold their own in properly structured competitive grant competitions. Rural schools made up just under 20 percent of all schools eligible for SIG funds in the fiscal year 2009 State SIG competitions, but totaled 23 percent of grant recipients in that year.

RACE TO THE TOP APPLICATION PROCESS AND RURAL DISTRICT APPLICANTS

*Question.* The President has requested $900 million for fiscal year 2012 for Race to the Top. Can you take me through the process of selecting applications for award?

Answer. We have not yet developed the specific process for the district-level competition, but would do so with input from stakeholders in a diverse array of districts.

*Question.* Additionally, what metrics or criteria do you have in place to ensure that rural and underserved States and school districts will be evaluated on a level playing field with States and school districts that may have more resources?

Answer. While we do not have specific metrics or criteria in place, we would develop the competition with rural districts in mind. If a single set of criteria are not appropriate for both rural and non-rural districts, we may develop different criteria. We have not yet decided what approach we would use.

EDUCATION AND EMPLOYMENT

*Question.* I am increasingly concerned about the ability of students with a degree or certification from a high school, technical or vocational school, or community college to find gainful employment. How can we make sure these students graduate with the knowledge and skills that employers are looking for?

Answer.

*Ensuring All Students Graduate College- and Career-Ready*

President Obama and I share your commitment to ensuring that all students graduate college- and career-ready, both to expand individual opportunity for further education and success in the job market and to ensure our Nation's continued competitiveness in the global economy. We recognized early on that one of the unintended consequences of No Child Left Behind was that it encouraged States to lower the quality of their K–12 academic standards, primarily to avoid the law's overly prescriptive school improvement requirements. This is why all of our key initiatives in elementary and secondary education have emphasized the development and adoption of more rigorous college- and career-ready academic standards and aligned assessments. In particular, the Race to the Top program has had a tremendous impact in this area, encouraging the vast majority of States to adopt a common set of State-developed college- and career-ready standards and supporting State consortia as they develop the next generation of high-quality assessments aligned with these standards.

The development and implementation of college- and career-ready standards is also at the core of our proposal to reauthorize title I of the Elementary and Secondary Education Act (ESEA), which would provide resources to States and school districts for this purpose. It is important to recognize, however, that the Department cannot prescribe or impose particular standards or curricula on America's schools, and that the States bear the primary responsibility for developing, adopting, and successfully implementing high-quality academic standards linked to success in college and careers. Our role is to highlight the need for such standards and, wherever possible, create the incentives for States to do the right thing for their students and for our Nation.

*College Pathways and Accelerated Learning Program*

Our ESEA reauthorization proposal would create other new programs that aim to improve student college and career readiness including the College Pathways and Accelerated Learning program, which would consolidate several current ESEA programs into a single, more comprehensive and flexible authority that supports State and local efforts to better prepare students for college and the workforce by providing college-level and other accelerated courses and instruction, including dual enrollment and early college high school programs, in secondary schools with concentrations of students from low-income families and with low graduation rates. The President's fiscal year 2012 request includes $86 million for this program.

*Carl D. Perkins Career and Technical Education Act*

The Department is also in the process of developing a reauthorization proposal for programs under the under the Carl D. Perkins Career and Technical Education Act (Perkins Act). We are looking at options for making the Perkins Act a better vehicle for ensuring that all career and technical education programs are viable and rigorous pathways to postsecondary and career success. College and career pathways provide multiple pathways to the same destination: achievement of both success in college and an upwardly mobile career. These pathways must align academic and technical coursework with challenging postsecondary expectations, as well as industry needs and certifications, and be designed and implemented in close collabo-

ration with employers in order to respond to the changing needs of the global economy. The President's fiscal year 2012 request includes $1 billion for this program.

PUBLIC-PRIVATE PARTNERSHIPS AS TOOL IN ENSURING COLLEGE- AND CAREER-READINESS

*Question.* In your opinion, would public-private partnerships be an effective tool? If so, how can we incentivize educational institutions to create partnerships with businesses to develop effective programs?

Answer. Public-private partnerships can definitely be a valuable tool for helping young people acquire the knowledge and skills that employers are looking for. Surveys of business leaders show that, despite the high unemployment rate, they are having difficulty finding sufficiently skilled workers to fill many job openings. However, few business leaders report that they are working with postsecondary institutions to help them improve programs that prepare individuals for careers.

The Department is currently developing its reauthorization proposal for the Carl D. Perkins Career and Technical Education Act. One of the issues we are considering is how to create incentives for educational institutions and businesses to work together to ensure that students acquire the knowledge and skills they need to get good jobs and succeed in high-wage, high-skill careers.

SUPPLEMENTAL EDUCATIONAL SERVICES OVERSIGHT

*Question.* Many educators in my State have voiced concern about the lack of proper oversight of title I funds for supplemental educational services (SES). How can we ensure that these valuable funds are being used effectively and in the best interest of students?

Answer. Under the ESEA, States are responsible for approving SES providers and monitoring provider performance in providing tutoring and other academic enrichment services to eligible students. To help States carry out these responsibilities, the Department in recent years has provided extensive technical assistance to States on questions and issues related to the provision of SES, including questions regarding the allowable use of title I funds by providers for specific activities and incentives. The Department also monitors the implementation of SES, sometimes including the delivery of services by particular providers, as part of the title I monitoring process.

SUPPLEMENTAL EDUCATIONAL SERVICES EVALUATION

*Question.* What level of evaluation of the impact of SES on student achievement is currently underway?

Answer. The Department is currently completing a rigorous evaluation of the impact of supplemental educational services on individual student achievement in six school districts with approximately 24,000 students eligible for SES. The study also will examine whether the impact of SES on student achievement is associated with particular characteristics of services, providers, students, or practices in the school district. This study currently is undergoing peer review and is expected to be released by the end of 2011.

COMMON CORE STATE STANDARDS

*Question.* What do you think about the new Common Core State Standards and the corresponding Partnership for Assessment of Readiness for College and Careers assessment system?

Answer. The administration believes the adoption of State-developed, college- and career-ready academic standards is an essential first step toward developing next generation accountability systems that will help students prepare more effectively for college and careers and ensure that our Nation is able to compete successfully in the global economy of the 21st century. As a result of the leadership of our Governors and Chief State School Officers, the vast majority of States have now voluntarily adopted common, college- and career-ready standards. The administration also believes that the development and implementation of new State assessments linked to these standards, including the work currently under way by the Partnership for Assessment of Readiness for College and Careers, will be a game-changer in public education. These new assessments will, for the first time, effectively measure whether America's students are on track for college and careers while providing teachers with timely, high-quality formative assessments that measure student academic growth and help to improve teaching and learning.

FUNDS FOR IMPLEMENTING ACADEMIC STANDARDS AND ASSESSMENTS

*Question.* Are you concerned about resources for teachers and schools to implement these Common Core State standards?

Answer. The Department, as enunciated in both its budget requests and in our proposal for reauthorizing the ESEA, intends to continue providing State formula grant funding to help States implement high-quality standards and assessments, as well as competitive grants for States and LEAs to support instruction aligned with college- and career-ready standards. For fiscal year 2012, the President's request includes $420 million under a reauthorized Assessing Achievement program, as well as $835 million under a reauthorized Effective Teaching and Learning for a Complete Education program. In addition, the Department believes that the near-universal voluntary adoption of common academic standards by the States is evidence of a commitment to make available the State and local resources required to implement these standards as well as aligned assessments.

AYP WAIVER REQUEST

*Question.* In March 2011, Arkansas requested that you waive a requirement of NCLB to allow its AYP targets to be held at the 2011–2012 levels until it fully implements the Common Core State Standards (2014–2015 school year). I understand that their request was denied. Did you grant any AYP waivers?

Answer. No, we have not granted any waivers of adequate yearly progress (AYP) targets. Several States have submitted amendments to their Accountability Workbooks that are consistent with the ESEA statute and regulations, but these are not waivers.

NO CHILD LEFT BEHIND REQUIREMENTS FLEXIBILITY PLAN

*Question.* The reason given for the waiver denial was that these issues should be addressed in an Elementary and Secondary Education Authorization bill. As we all know, it is highly unlikely that we will see such a bill this year. Based on that information, will you take a second look at Arkansas's request for a waiver?

Answer. The Department is developing a plan to provide flexibility regarding NCLB requirements for those States that are moving forward with reforms that will increase the quality of instruction and improve student achievement. Final details on the flexibility package will be available in mid-September, and we encourage all interested States, including Arkansas, to request it.

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## QUESTIONS SUBMITTED BY SENATOR SHERROD BROWN

ELIMINATION OF IN-SCHOOL SUBSIDY FOR UNDERGRADUATE STUDENTS

*Question.* Last year, the Deficit Reduction panel proposed the elimination of the in-school subsidy for undergraduates as a way to find savings. It is my understanding that this was on the table during debt ceiling recent negotiations. Eliminating the in-school subsidy for undergraduates would have an extremely negative impact on students. How does the administration plan to balance the needs of middle class students who may qualify for the in-school subsidy, but not the Pell Grant?

Answer. While the Budget Control Act of 2011 eliminated subsidized loans for graduate and professional students—which the administration endorsed as part of its 2012 budget proposal—undergraduate students still retain the ability to take out subsidized loans. Students who are not interested in a Stafford loan, and are not otherwise Pell-eligible, should consider the campus-based aid programs—Supplemental Educational Opportunity Grants (SEOG), Work-Study grants, and Perkins loans—as a good source of aid. Part of the 2012 budget request was to maintain the current level of funding for SEOG and Work-Study, and to reform the Perkins program with $8.5 billion in volume—eight and one-half times the current volume—which could enable it to reach over 3 million students at over 2,700 institutions.

STUDENT LOAN CONVERSION

*Question.* In May, I introduced the Student Loan Simplification and Opportunity Act which was a part of the Presidents' Pell Grant Protection Act. This legislation would allow students with both Federal Family Education Loan Program (FFELP) loans and Direct Loans to simplify their loan repayment process and provide borrowers with 2 percent off of their FFELP principal for converting their loans, while saving the Government $1.8 billion. Does the administration support this policy included in the bill?

Answer. The administration supports the policy as presented in its fiscal year 2012 budget proposal to Congress. The administration believes this policy will make loan repayment simpler for the estimated 6 million split borrowers—those with loans both in the Direct Loan and FFEL programs—and make it less likely they will default as a result.

RACE TO THE TOP—EARLY LEARNING CHALLENGE PROGRAM

*Question.* In July, Senator Hagan and I introduced the Ready Schools Act of 2011. This legislation is based off of the great work of the Spark Partnership in Ohio and the North Carolina Ready Schools Initiative. This legislation focuses on the importance of school readiness in addition to the student readiness. Early childhood education plays an important role in the short- and long-term success of students. I appreciate your efforts in establishing the Early Learning Challenge Grant Program but am concerned that this funding will only benefit a limited number of children. As childhood poverty rates continue to grow, it is important that we invest in all young children. Why did the Department decide to spend $500 million for this program when the success of the Race to the Top model is still unknown? What is included in the budget to improve the systematic alignment and delivery of early childhood education?

Answer. The Race to the Top—Early Learning Challenge program will support States that demonstrate their commitment to integrating and aligning resources and policies across all of the State agencies that administer public funds related to early learning and development. Winning States will serve as models of how to build a more unified approach to supporting young children and their families—an approach that increases access to high-quality early learning and development programs and services, and helps ensure that children enter kindergarten with the skills, knowledge, and dispositions toward learning they need to be successful.

All States can undertake this work by using existing funds that support early learning and development from Federal, State, private, and local sources, such as the Child Care and Development Fund, title I and II of the ESEA, the Individuals with Disabilities Act, State-funded preschool programs, and Head Start.

FEDERAL TRIO PROGRAMS

*Question.* In your fiscal year 2012 budget request, you recommend a $67 million increase to the TRIO programs. As you know, this is not really an "increase" but rather it provides funding to ensure that the 180 Upward Bound programs funded by the College Cost Reduction and Access Act—including three programs in Ohio—would not have to close their doors in December 2011. In light of recent funding cuts to TRIO in fiscal year 2011, could you reaffirm your commitment to TRIO, particularly the administration's fiscal year 2012 funding request for the program?

Answer. The administration believes that the Federal TRIO programs play an important role in assisting low-income students and students whose parents never completed college with support and preparation to enter and complete postsecondary education programs. In designing the TRIO competitions for 2012, particularly Upward Bound, the Department is focused on ensuring that grantees pursue strategies and activities that will maximize the number of students to which they can provide high-quality services. The Department also believes that the TRIO programs can play an important role in ensuring that our investment in Pell Grants results in more students persisting and completing because they enroll in postsecondary education better prepared to succeed.

The administration remains committed to increasing college enrollment and completion rates among traditionally underrepresented populations. In demonstration of this commitment, we have prioritized protecting the $5,550 maximum Pell Grant award in fiscal year 2012 and beyond, with the goal of ensuring that more than 9 million low-income students can continue to rely on Pell Grants to enter into, and complete, a postsecondary education. However, low-income students need more than just financial support to enter and complete college; they also need supportive services like those provided by our Federal TRIO programs.

TECH PREP PROGRAM

*Question.* The Tech Prep program provides college and career training for students beginning in high school so that they are prepared for success in business and industry. This program also helps to ensure more students are on the path to complete higher education and thus the United States is on the path to compete in a global economy. Why did the administration choose to merge the Tech Prep State Grant with the title I basic State grant and then reduce the overall appropriation?

Answer. The Tech Prep program duplicates activities authorized under the Career and Technical Education (CTE) State Grants program. The purpose of the Tech Prep program is to support development and implementation of programs of non-duplicative, sequential courses of study that incorporate secondary education and postsecondary education with work-based learning experiences. However, the CTE State Grants program also requires States to develop these types of programs, and to do so within the larger context of CTE programs within the State. In addition, 28 States consolidated at least a portion, and generally all, of their Tech Prep funds into State Grants during school year 2010–2011.

In order to maintain fiscal discipline by placing a priority on programs that are most aligned with the President's reform agenda and most likely to demonstrate results, the Department did request a reduction in funding for CTE for fiscal year 2012. While CTE is vitally important to America's future, the Perkins CTE program as it is currently structured is not operating in a way that produces optimal results for students. The Department is currently engaged in developing our reauthorization proposal for the Carl D. Perkins Career and Technical Education Act. Our intent is to develop a proposal that will improve the statute by ensuring that all CTE programs become viable and rigorous pathways to postsecondary and career success, providing students with the career skills necessary to compete in a global marketplace, and collecting better program performance data.

FAMILY ENGAGEMENT IN EDUCATIONAL OUTCOMES FOR CHILDREN

*Question.* I have heard a lot of discussion about family engagement in education from the administration, which is a step in the right direction. In your blueprint for ESEA reauthorization, you propose the establishment of a Family Engagement and Responsibility Fund, along with an increase in the title I set-aside for family engagement initiatives. However, the Parent Information Resource Center (PIRC) funds are consolidated in the Department 2012 budget. Parental Information and Resource Centers exist to work in partnership with, and build the capacity of, State and local educational agencies and provide technical assistance on implementing research-based and effective family engagement strategies.

How does the administration plan to ensure that districts and States build their capacity to carry out this work without the PIRC program?

Answer. Enhancing family engagement is crucial to improving educational outcomes for children, and the administration's budget and Elementary and Secondary Education Act (ESEA) reauthorization proposals reflect our commitment to making sure that families are informed of and better involved in the educational opportunities available in their community. The Department is also committed to pursuing actions that will help build the capacity of States, school districts, and schools to effectively leverage resources for strengthening family engagement in education. As you mentioned, the administration's ESEA reauthorization proposal for the renamed College- and Career-Ready Students (CCRS) program (currently title I grants to local educational agencies) would significantly increase State and local spending on parent and family engagement activities, ensuring that every district receiving title I funds is developing and implementing a family engagement plan focused on raising student achievement and developing promising new strategies to engage parents and families. States would be permitted to reserve up to 5 percent of their title I, part A allocations to carry out activities to build State and local capacity to improve student achievement, including by improving capacity to carry out effective family engagement strategies.

*Family Engagement and Responsibility Fund*

States also would be permitted to set aside up to 1 percent of their title I, part A allocations to fund programs that support family engagement and to identify and disseminate best practices in this area. This Family Engagement and Responsibility Fund would support and expand district-level best practices, with a priority for evidence-based parental involvement activities. PIRCs, along with districts, community-based organizations, and other nonprofit organizations, would be eligible to compete for these funds.

*Title I Set-aside and Family Engagement*

Our reauthorization proposal would also double the local title I set-aside for parent and family engagement, from 1 to 2 percent, increasing the total from about $145 million to approximately $270 million. PIRCs would be eligible to partner with school districts or consortia of school districts in implementing activities funded under this set-aside. Additional elements of the administration reauthorization proposal (including our proposals for Safe and Healthy Students, Promise Neighbor-

hoods, and Expanding Educational Options) would also focus specifically on issues related to family engagement.

*Capacity Building and Technical Assistance for Family Engagement Activities*

Finally, you asked about the Department's plan to provide capacity-building and technical assistance to States and districts on family engagement in education. We will continue to support these goals through our new Implementation and Support Unit (ISU), in the Office of the Deputy Secretary, and through programs like the Comprehensive Centers. The ISU provides technical assistance directly to States implementing comprehensive reforms under the Education Jobs Fund, Race to the Top, Race to the Top Assessment, and State Fiscal Stabilization Fund programs. The Comprehensive Centers also help increase State capacity to assist districts and schools in meeting their student achievement goals. In fiscal year 2012, the Department will make approximately 21 new competitive grant awards to support the first year of a second cohort of Comprehensive Centers. Because family engagement is a priority for the administration and for the Secretary, it will be one of the key issues addressed through these efforts.

SCHOOL-BASED COUNSELING PROGRAMS

*Question.* School counselors, school psychologists, and school social workers provide counseling and other learning support services to students who are struggling with issues that create barriers to learning. The Elementary and Secondary School Counseling Program is the only Federal grant specifically targeted to providing assistance to school districts to establish and enhance school counseling programs, including ensuring access to these highly trained professionals to address students' social and emotional needs. Given the serious impact on students' academic success that children can face because of anxiety related to a parent's military deployment, issues related to homelessness, or other types of mental illness, as well as the need for prevention and early intervention to avoid more serious problems, how will the priorities of the Elementary and Secondary School Counseling Program be preserved under the proposed consolidation program?

Answer. The administration is committed to addressing student mental health issues and believes that school-based counseling programs offer great promise for improving prevention, diagnosis, and access to treatment for children and adolescents.

*Successful, Safe, and Healthy Students Program*

Under the proposed Successful, Safe, and Healthy Students program, State educational agencies (SEAs), high-need local educational agencies (LEAs), and their partners, that are interested in establishing or expanding elementary and secondary school counseling programs would be eligible to apply for competitive grant funding to develop and implement programs that measure and improve conditions for learning based on local needs. The administration believes that this broader, more flexible approach, through which grantees could address students' mental health and related social needs comprehensively, rather than a narrowly focused program, would be more successful in building State, district, and school capacity and in providing the resources necessary to design and implement strategies for promoting healthy development and successful students.

PROMISE NEIGHBORHOODS APPLICATIONS

*Question.* There were 339 communities who applied for $10 million in Promise Neighborhoods funding in fiscal year 2010. More than 80 of these communities scored 80 or higher on the application process. Nine of these communities were in Ohio. Many of these communities would have been awarded planning grants if additional funding were available. I am pleased that for fiscal year 2011, there is $30 million available for Promise Neighborhoods, and that ED is offering implementation grants, in addition to a second round of planning grants. I understand that the notice of intent for this second round was due last week; do you have a sense of how many communities applied for the new implementation? Specifically, do you know how many communities are seeking implementation verse planning grants?

Answer. As of the July 22 deadline for Intents to Apply in the fiscal year 2011 competition, 501 entities had submitted their intent for the planning grant competition and 161 entities had submitted their intent for the implementation grant competition. The deadline to submit a full application for both the planning and implementation grant competitions is September 6, 2011.

PROMISE NEIGHBORHOODS FUNDING

*Question.* What is the Department of Education doing to meet the national need and demand for Promise Neighborhoods?

Answer. The President's fiscal year 2012 budget request includes $150 million to provide continued funding to fiscal year 2011 implementation grantees in addition to funding a new round of planning and implementation grants. We consider this a priority within our 2012 budget request. In addition, as part of the White House Neighborhood Revitalization Initiative (NRI), the Department is partnering with other Federal agencies to provide comprehensive technical assistance to additional communities, many of which have expressed interest in the Promise Neighborhoods program, as part of the NRI's Building Neighborhood Capacity program. This program will support organizations with limited capacity, but serving high-poverty neighborhoods, through hands-on technical assistance. Designed to serve an initial cohort of five neighborhoods, the program will provide an online resource center and leverage assistance from multiple Federal agencies and other sources in support of local neighborhood revitalization initiatives.

TECHNICAL ASSISTANCE TO PROMISE NEIGHBORHOODS GRANTEES

*Question.* For those communities who did receive planning grants, how is the Department providing the necessary coaching and technical assistance needed to ensure success?

Answer. The fiscal year 2010 appropriation did not provide Federal resources to support coaching or technical assistance for the planning grantees. Nevertheless, the Promise Neighborhoods Institute (PNI), an independent, foundation-supported nonprofit resource, is meeting many of the needs of the communities. PNI offers tools, information, and strategies to assist any community interested in participating in the Promise Neighborhoods program. In addition, PNI provides technical support directly to the program's grantees for planning, identifying quality approaches, building partnerships, assessing needs, and many more essentials for successfully building a Promise Neighborhood. The $30 million fiscal year 2011 appropriation will support national activities, including technical assistance for the first cohort of Promise Neighborhood implementation grantees.

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## QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

PELL GRANTS FUNDING

*Question.* The unsustainable growth in the costs of the Pell Grant program continues to be an anchor dragging down the entire budget for the Department of Education. While the fiscal year 2012 budget request does propose some policy changes to address the growth in Pell Grant costs, the administration also proposes a $5.6 billion increase in discretionary funding. How will the fiscal year 2012 budget request address the fiscally unsustainable path of the Pell Grant program?

Answer. The President's budget for fiscal year 2012 seeks to protect the $5,550 maximum award for those students with the greatest need, while also finding ways to reduce the overall cost impact of the Pell Grant program. One way the request does this is by not seeking to raise the maximum award, instead keeping it level with the prior 2 years. Additionally, in the President's budget, the administration outlined a comprehensive plan to cover rising Pell Grant costs and help close the program's shortfall through changes to other student aid programs, and changes to the administration of Pell itself. In total, these changes are estimated to save $100 billion over 10 years.

REDUCING PELL GRANTS COSTS

*Question.* Specifically, how is the administration proposing to reduce the overall rapid cost growth in the Pell Grant program?

Answer. The Department's plan for reducing Pell Grant costs specifically includes eliminating the availability of a second Pell Grant in an award year, FAFSA simplification, creating easier student repayment through a debt conversion plan, expanding and modernizing the Perkins Loan program so it can assist more students, replacing the TEACH Grants program with Presidential Teaching Fellows, creating the College Completion Incentive Grants program to achieve better outcomes for students, and eliminating subsidized loans for graduate and professional students. Two of these policy proposals—the elimination of the second Pell Grant in an award year, and the elimination of subsidized loans to graduate and professional students—have already been adopted by Congress. In total, the Department estimates

these changes will reduce Pell's discretionary appropriations need by $13.2 billion in 2012 alone.

STATE AUTHORIZATION OF DISTANCE EDUCATION PROGRAMS

*Question.* There continues to be concerns raised by colleges and universities regarding State authorization provisions under the proposed Program Integrity regulations and the potential impact on access to distance education at higher education institutions. At the risk of losing Federal financial aid, colleges and universities will be required to request permission to offer their distance education programs in every State in which a student is located while receiving instruction. Many States already have legislation that requires registration. Why is the Department of Education moving forward with regulations where States already have efficient and equitable policies in place regarding distance learning?

Answer. The Department's regulations governing State authorization of distance education programs simply required institutions to comply with State laws where they exist; it imposed no additional requirements beyond being able to demonstrate that they complied with State law where those laws exist. A Federal court recently took action to strike the provision of the Department's regulation but did not overturn State law. The United States is still evaluating whether to appeal.

With that said, Alabama has set high standards and imposed significant charges on institutions that offer distance learning in the State. While we do not endorse these requirements, we do acknowledge that each State has the ability to regulate higher education institutions operating in the State.

*Question.* How will the Department ensure universities that have already been approved by their home State's Higher Education Commission and accredited by the relevant regional accrediting authority that they will not be unduly burdened by duplicative, costly, time consuming, and academically unnecessary regulations?

Answer. The Department's regulations governing State authorization of distance education programs simply required institutions to comply with State laws where they exist; it imposed no additional requirements beyond being able to demonstrate that they complied with State law where those laws exist. A Federal court recently took action to strike the provision of the Department's regulation but did not overturn State law. The United States is still evaluating whether to appeal.

With that said, Alabama has set high standards and imposed significant charges on institutions that offer distance learning in the State. While we do not endorse these requirements, we do acknowledge that each State has the ability to regulate higher education institutions operating in the State. So, States, including Alabama, can take steps to reduce the burden imposed on institutions of higher education if they believe those burdens are duplicative, costly, time consuming, and academically unnecessary. The Federal Government ought not to limit the authority of States but if that were to be done it would involve preempting State laws. Such preemption would require either congressional action or a regulatory action. Such regulations would need to be developed consistent with the Executive Order of Federalism signed by President Reagan.

HIGH SCHOOL GRADUATION INITIATIVE AND THE COLLEGE PATHWAYS AND ACCELERATED LEARNING PROGRAM

*Question.* The fiscal year 2012 Department of Education budget request proposes to consolidate 38 programs into 11 new authorities in line with the administration's Elementary and Secondary Education Act reauthorization proposal. Beginning in 2010, the Mobile County School System will receive nearly $9 million over 5 years under the High School Graduation Initiative to support the implementation of effective, sustainable, and coordinated dropout prevention and reentry efforts in high schools. However, the fiscal year 2012 budget request would eliminate the High School Graduation Initiative and replace the program with a new College Pathways and Accelerated Learning program. How will the Department of Education ensure that schools who have been awarded funding under the High School Graduation Initiative continue to receive their promised funding under the budget request?

Answer. The administration's proposal for the College Pathways and Accelerated Learning program would require the Secretary to reserve funds to pay for grants made under the High School Graduation Initiative and Advanced Placement programs through the grants' completion.

## QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

### TARGETING OF TITLE I FUNDS TO LOCAL EDUCATIONAL AGENCIES

*Question.* It is clear that the funds appropriated for title I could be distributed in a more equitable manner that targets those for whom the program is intended: children in concentrated poverty. Is the Department of Education actively pursuing potential changes to title I distribution formulas to ensure Federal education funding better reaches disadvantaged children?

Answer. The administration is strongly committed to ensuring that title I funds are targeted to high-poverty schools, regardless of geographic location, and stands ready to work with the Congress, through the reauthorization process, on ways to improve the targeting of title I funds.

### NATIONAL NOT-FOR-PROFIT ORGANIZATIONS AND THE IMPROVING TEACHER QUALITY STATE GRANTS PROGRAM

*Question.* There continues to be concern with the consolidation of existing programs into 11 new authorities in the administration's reauthorization proposal for the Elementary and Secondary Education Act. Specifically, the Department of Education budget appears to direct funding to programs for States and localities without a path for national not-for-profit organizations with a proven track record to compete. In fiscal year 2011 Congress addressed this concern by including a 1 percent set aside under the Improving Teacher Quality State Grants program for a competition for national not-for-profit organizations that provide teacher training or professional development activities. When does the Department of Education intend to have a competition for national not-for-profit (NFP) organizations under the Improving Teacher Quality State Grants program?

Answer. A notice inviting applications for new awards under this set-aside was published in the Federal Register on September 8, 2011. Our goal is to make awards in early 2012, well before the period of availability ends on September 30, 2012.

### NATIONAL NFP ORGANIZATIONS SET-ASIDE COMPETITION

*Question.* Can you please provide details to this subcommittee on how the Department intends to conduct a competition for these funds, including any expected priorities for the competition?

Answer. Through the new Supporting Effective Educator Development competition, the Department will make grants to national non-profit organizations to support projects that are supported by at least moderate evidence, as defined in the notice inviting applications. Grantees will use the funds to recruit, select, and prepare or provide professional enhancement activities for teachers or for teachers and principals.

*Supporting Effective Educator Development Competition Absolute Priorities*

An applicant may apply under any of three absolute priorities:

—Under Absolute Priority 1, the Department will support the creation or reform of practices, strategies, or programs that are designed to increase the number or percentage of teachers (or teachers and principals) who are highly effective, especially teachers (or teachers and principals) who serve concentrations of high-need students, by identifying, recruiting, and preparing highly effective teachers or teachers and principals. To meet this priority, an applicant must propose a plan demonstrating that teacher or principal participation in the applicant's proposed activities will be determined through a rigorous, competitive selection process.

—Under Absolute Priority 2, we will support projects that will increase the quality of student literacy and writing by creating or reforming practices, strategies, or programs that improve teachers' knowledge, understanding, and teaching of English language arts with a specific focus on writing through high-quality professional development or professional enhancement programs.

—Under Absolute Priority 3, the Department will fund projects that encourage and support teachers or teachers and principals seeking advanced certification or advanced credentialing through high-quality professional enhancement programs designed to improve teaching and learning for teachers or for teachers and principals. To meet this priority, an applicant must demonstrate or propose a plan to demonstrate that the award of the advanced certification or advanced credential will be determined on the basis of a rigorous evaluation with multiple measures that include measures of student academic growth.

The Department will also award points in this competition based on two competitive preference priorities. An applicant may receive additional points by proposing:

—a project that is supported by strong evidence of effectiveness (as defined in the notice inviting applications), or
—a project that is designed to significantly increase efficiency in the use of time, staff, money, or other resources while improving student learning or other educational outcomes. Projects that receive points under the second competitive preference priority may include innovative and sustainable uses of technology, modification of school schedules and teacher compensation systems, use of open educational resources, or other strategies.

NATIONAL NONPROFIT COMPETITIONS AND ESEA REAUTHORIZATION

*Question.* Will the Department of Education commit to supporting a dedicated funding stream for the same purpose in fiscal year 2012?

Answer. Our proposal for ESEA reauthorization includes several competitions in which many national nonprofit organizations would be eligible to participate. For example, organizations such as Teach for America, the National Writing Project, and the National Board for Professional Teaching Standards, the organizations no longer receiving earmarked assistance, could partner with schools to apply for an Investing in Innovation grant. In addition, Teach for America could compete for funds under the proposed new Teacher and Leader Pathways program. The National Board for Professional Teaching Standards could partner with States in the Teacher and Leader Innovation Fund to strengthen State standards for certification and licensure. The National Writing Project could receive funding under the national activities set-aside in the new Effective Teaching and Learning initiative and could also partner with States on comprehensive literacy strategies.

PROMISE NEIGHBORHOODS COMPETITION—ABSOLUTE PRIORITY FOR RURAL COMMUNITIES

*Question.* The fiscal year 2012 budget request includes $150 million for the Promise Neighborhoods program, which supports projects designed to improve education and life outcomes for children and youth within a distressed geographic area. The Indianola Promise Community in Mississippi was awarded one of the first Promise Neighborhood grants in fiscal year 2010. However, there are concerns that as the process moves forward the Indianola Promise Community will have to compete on a national scale with large, urban school districts for implementation grant funding. Please provide details on the steps that the Department has taken under the Promise Neighborhoods program to ensure rural communities can compete for grant funding to implement reform efforts.

Answer. In fiscal year 2010, the Department included an absolute priority for rural communities applying for Promise Neighborhood grants. The Delta Health Alliance in Indianola applied for and received a planning grant under this rural community priority. The fiscal year 2011 competition again includes an absolute priority for rural communities as well as tribal communities, for both planning and implementation grants, in order to ensure that communities such as Indianola are able to compete on a national scale for Promise Neighborhood funding.

IMPROVING COMPETITIVE STANCE OF RURAL COMMUNITIES FOR EDUCATION FUNDING

*Question.* Does the Department plan to take similar steps in the future to ensure that rural communities are less disadvantaged under competitive grant opportunities, as it has with the Promise Neighborhoods and Investing in Innovation programs?

Answer. Through the rulemaking process, the Secretary has created supplemental priorities to target funds to high-priority areas. These priorities include a priority for improving the achievement and high school graduation rates of students in rural school districts. The Department is considering applying this priority in competitions for absolute or competitive preference in a number of programs for fiscal year 2012.

INNOVATIVE STRATEGIES IN EARLY LEARNING

*Question.* The Department recently announced that $500 million of the fiscal year 2011 funding for the Race to the Top program will be awarded to States to help build comprehensive early learning systems. For fiscal year 2012, the administration requested an additional $900 million for the Race to the Top program and $350 million for a new Early Learning Challenge Fund. What plan does the Department have in place to ensure that funding awarded through Race to the Top or the Early Learning Challenge Fund prioritizes innovative strategies for early learning, including the implementation and expansion of full-day kindergarten?

Answer. We want to provide funding to support the important work of transforming early learning programs and services from a patchwork of disconnected programs with uneven quality into a coordinated system that prepares children for success in school and in life. The purpose of the Race to the Top-Early Learning Challenge (RTT–ELC) program, which we are implementing with about $500 million of the fiscal year 2011 appropriation for Race to the Top, is to improve the quality of early learning and development and close the achievement gap for children with high needs. The overarching goal is to make sure that many more children, especially children with high-needs, enter kindergarten ready to succeed. The competition for RTT–ELC grants also includes an invitational priority to encourage States to sustain positive early learning program effects in the early elementary grades.

GEOGRAPHY EDUCATION

*Question.* According to results from the National Assessment of Educational Progress that were released on July 19, 2011, fewer than one-third of the Nation's students achieve at or above the proficient level in geography. As the sponsor of S. 434, the "Teaching Geography Is Fundamental Act," which would create a dedicated program to improve geographic literacy, these recent results are gravely concerning. Will the Department of Education commit to do more to ensure that funding is directed to geographic education activities?

Answer. The Department is committed to ensuring that our Nation's students have access to high-quality instruction across academic content areas. Our proposal to reauthorize the Elementary and Secondary Education Act (ESEA) includes the Effective Teaching and Learning for a Well-Rounded Education program, which would support efforts to improve instruction in a wide range of subjects, including geography, while providing States and local school districts with greater flexibility to meet the needs of their students and teachers. The President's fiscal year 2012 request includes $246 million for this new program.

Although geography is included among the subjects in the current ESEA definition of "core academic subjects," geography education is not the focus of any current ESEA program and, thus, most likely does not receive significant Federal support under current law. Enactment of the Effective Teaching and Learning for a Well-Rounded Education program would give the Department and grantees a better vehicle for supporting the evaluation and expansion of geography education programs as well as efforts to integrate geography more prominently in instruction in other subject areas.

CAREER AND TECHNICAL EDUCATION

*Question.* Across the country, unemployment levels are still high, but there are jobs available for individuals with the right skill sets. The Career and Technical Education program works to ensure that students have the academic, technical and employability skills necessary for career readiness in the current workforce. In fiscal year 2012, the Department of Education budget request proposes an almost $125 million reduction to the Career and Technical Education State Grants. How will the Department of Education ensure that schools can continue to offer Career and Technical Education programs to help students attain these skills with a decrease in funding?

Answer. While CTE is vitally important to America's future, the Perkins CTE program as it is currently structured is not operating in a way that produces optimal results for students. The Department is currently engaged in developing our reauthorization proposal for the Carl D. Perkins Career and Technical Education Act. Our intent is to develop a proposal that will improve the statute by ensuring that all CTE programs become viable and rigorous pathways to postsecondary and career success, providing students with the career skills necessary to compete in a global marketplace, and collecting better program performance data.

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## QUESTIONS SUBMITTED BY SENATOR LINDSEY GRAHAM

INCENTIVE COMPENSATION REGULATIONS

*Question.* It is my understanding that recent sub-regulatory language related to incentive compensation rules issued by your Department would prohibit one or two entities from providing support services to other colleges and universities, services that other companies can provide without reservation. If this is accurate, this regulation would be arbitrarily picking winners and losers. It is difficult to comprehend either the statutory grounds or rationale for interfering with the provision of services to educational institutions.

In order to better understand the intent of the regulation, I respectfully request clarity on the statutory grounds and why the Department would choose to include some institutions under the regulation while leaving others out.

Answer. On March 17, 2011, the Department issued guidance related to several areas of program integrity, including the issue of incentive compensation. This guidance was designed to assist institutions in understanding the regulations and provide examples of permissible activities. The guidance provided in this letter, and the regulations in general, seek to ensure title IV aid at all institutions is used to successfully train students.

Please be aware that there is no prohibition upon any entity providing support services to another entity. The only prohibition is upon the manner in which compensation may be provided should one of those services involve student recruitment. Pursuant to section 487(a)(20) of the HEA an "institution will not provide any commission, bonus, or other incentive payment based directly or indirectly on success in securing enrollments or financial aid to any persons or entities engaged in any student recruiting or admission activities or in making decisions regarding the award of student financial assistance." It is that statutory provision which the Department is enforcing when it monitors the manner in which student recruitment activities are compensated.

TITLE VI CENTERS FOR INTERNATIONAL BUSINESS EDUCATION (CIBER) PROGRAM

*Question.* For fiscal year 2011, your Department cut the title VI Centers for International Business Education and Research (CIBER) program by 55 percent. Over two decades, CIBERs have been engaged in cutting-edge activities to strengthen the Nation's global economic competitiveness on many levels.

I respectfully request detailed information on CIBERs' recent role in supporting an increase in our country's exports, including collaboration with business and government on the President's National Export Initiative. I also request information on how CIBERs have enhanced institutes of higher education, including underrepresented institutions such as HBCUs, MSIs, and community colleges, in meeting global demand for a competitive workforce.

Answer. In response to President Obama's recent announcement of the National Export Initiative, which calls for increased resources to expand international trade, the U.S. Commercial Service—the trade promotion arm of the U.S. Department of Commerce's International Trade Administration—plans to increase its efforts to move U.S. companies into new and emerging markets. The CIBERs have a good track record with the U.S. Department of Commerce and will work with President Obama's National Export Initiative, either directly or indirectly, by holding conferences and assisting businesses to improve their export strategies.

In the 2010 CIBER competition, the Department encouraged the applicants to help improve internationalization at minority-serving institutions (MSIs). Many applicants responded to the priority by incorporating activities into their 2010–2013 CIBER projects. For example, Michigan State University hosts a bi-annual training program for community colleges where the Commerce Department's teaching materials are featured.

As outreach to other constituencies, a number of CIBERs have developed 4-year training programs for faculty from HBCUs. The program includes mentoring institutions as well as individual faculty and providing for faculty study abroad. The program will be extended to Hispanic-Serving Institutions, and three CIBERS—Colorado, Hawaii, and Washington—will work with Alaska Native, Native Hawaiian, and Native American students and faculty during the 2010–2014 cycle.

In partnership with the University of Memphis, CIBERs and the Institute of International Public Policy, which is operated by the United Negro College Fund Special Programs Corporation, have been working with 46 Historically Black Colleges and Universities (HBCUs) to enhance understanding of interdisciplinary international business education. The consortium has been engaged in equipping HBCU faculty with discipline specific international knowledge, pedagogical tools, research methodologies, and study abroad experiences to incorporate international content into existing business courses and/or develop new courses, and to increase international business research. An integral component of the program is one-on-one assistance provided by the sponsoring CIBERs to their respective HBCUs in the implementation of international business education programs on HBCU campuses and in acquiring Federal grants to support these efforts.

CIBERs at Brigham Young University and the University of Colorado at Denver support a consortium of 36 community colleges and universities across 10 western States to provide CIBER programs to the region's small and medium-sized rural institutions and to facilitate the sharing of resources among regional schools with de-

veloping international business expertise. The consortium is now reaching out to Tribal Colleges and Universities (TCUs) recognized by the American Indian Higher Education Consortium, as 23 TCUs are located in 10 States with a significant number of Native American students.

NATIONAL IMPACT OF FISCAL YEAR 2011 BUDGET CUTS ON CIBERS

*Question.* Lastly, what has been the impact of the cuts on CIBERs nationally and their ability to continue their legislative mandates?

Answer. Besides producing the majority of internationally prepared business students and entrepreneurs, CIBERs are designed to serve as regional and national resources to businesses, students, and academics. The CIBERs are the equivalent of the National Resource Centers (NRCs) in Schools of Business. Most are located at major U.S. universities.

The most recent competition for new awards was held in fiscal year 2010 and 33 grants averaging $386,576 were awarded. The CIBER allocation in 2011 is $5.7 million, a reduction of $7 million or 55 percent, below the 2010 funding. The reduced funding in 2011 will likely hamper activities supported by the CIBER program. Outreach to business, including export development; business language training and other interdisciplinary programs; outreach and faculty development to minority-serving institutions, community colleges, other colleges and universities, and K–12 schools in the 50 States; practical, policy-oriented international business research; and study abroad and international internships could be eliminated or reduced.

PLAN FOR CIBER PROGRAM FUNDING IN FISCAL YEAR 2012

*Question.* What is your plan for CIBER program funding in fiscal year 2012?

Answer. The Department is currently supporting 33 universities, designated as CIBERS, who were awarded multi-year grants in fiscal year 2010. Fiscal year 2012 funds would be used to cover, to the extent possible, funding for the third year of the 4-year grants.

Currently funded CIBERS institutions are: Brigham Young University, Columbia University, Duke University, Florida International University, George Washington University, Georgia Institute of Technology, Georgia State University, Indiana University, Michigan State University, Ohio State University, Purdue University, San Diego State University, Temple University, Texas A&M University, University of California, LA, University of Colorado at Denver, University of Connecticut, University of Florida, University of Hawaii at Manoa, University of Illinois at Urbana-Champaign, University of Maryland, University of Memphis, University of Miami, University of Michigan, University of Minnesota, University of North Carolina—Chapel Hill, University of Pennsylvania, University of Pittsburgh, University of South Carolina, University of Southern California, University of Texas—Austin, University of Washington, and University of Wisconsin—Madison.

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## QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

POSSIBLE WAIVERS OF ESEA REQUIREMENTS

*Question.* Secretary Duncan, you have stated recently that if reauthorization of the Elementary and Secondary Education Act (ESEA) is not completed by this September, you will look to issue States conditional waivers from No Child Left Behind's most troublesome requirements provided that States agree to make certain changes to their education systems. Specifically, what No Child Left Behind requirements would you waive for States and what changes would you require of States to receive such waivers?

Answer. The Department is still working out the details of possible flexibility from ESEA requirements pending the completion of reauthorization, and expects to announce the specifics in mid-September.

MEASURING STUDENT ACADEMIC GROWTH

*Question.* Mr. Secretary, last March, your Department released its Blueprint for the Reauthorization of ESEA, which outlined in broad terms proposed changes to the current law, including the development of new assessments of student growth. What do you see as the ideal "growth models" for States to measure individual student performance and how will these models be different from current "adequate yearly progress" (AYP) standards?

Answer. The Department believes that there are a number of valid and reliable methods for measuring student academic growth that States would be able to choose

from to meet the requirements of our reauthorization proposal. The key benefit of growth models is that they will track the academic progress of individual students over time, as opposed to simply measuring the percentage of students who have reached grade-level proficiency in a particular subject at a particular point in time, as under most assessment and accountability systems used by States under current law. The Department's reauthorization proposal would continue to require States to set performance targets for schools, similar to current AYP requirements, but schools would be able to meet such targets either by demonstrating that students are "on track" to college- and career-readiness or making adequate progress toward being on track to college- and career-readiness.

IMPACT OF THE ESEA ON STUDENT ACHIEVEMENT

*Question.* We all know that education is a primary key to increasing our country's global competitiveness. Knowledge and human capital are what drive innovation, entrepreneurship, and growth. We talk a lot about holding our schools and teachers accountable for creating our leaders of tomorrow, but we also need to hold ourselves accountable. Since the ESEA was enacted more than 45 years ago, Federal per-pupil spending has nearly tripled. However, our national graduation rates and other academic achievement measures have remained relatively flat and we have fallen in international education ranking. Considering these measures, why have we failed to improve and what are some examples you have seen in your travels across the country that represent a fresh approach where schools are raising the bar for student achievement?

Answer. I believe a number of factors have been holding us back educationally despite decades of effort to improve academic and other outcomes at the Federal, State, and local levels. First, I believe we have set the bar too low. We all know that young people tend to perform up to expectations, and our expectations for academic achievement in core subjects, as reflected in State standards and assessments, have simply been lower than many of our strongest economic competitors have for their students. In part this "dumbing down" of standards and assessments has been due to flawed and overly prescriptive accountability requirements, such as those we have experienced over the past decade under No Child Left Behind. The administration's response to these problems has been to encourage and create incentives for States to raise their standards, and thanks to the leadership of our Nation's Governors and Chief State School Officers, we have seen great success in this area with the voluntary adoption of common, State-developed, college- and career-ready standards by the vast majority of States over the past 2 years. And we are proposing to create, through the reauthorization of the ESEA, more nuanced accountability systems that ask States and school districts to focus their attention and support on the lowest-performing schools and schools with the largest achievement gaps, while also giving them considerable flexibility to develop and implement their own improvement strategies for most schools.

*Teacher Recognition and Academic Achievement*

Another issue is that we have not treated our teachers like the professionals that they are: we must provide needed support, reward excellence, and create incentives for our best teachers to work in our toughest schools. A key first step toward elevating the teaching profession is the development and implementation of rigorous and fair teacher evaluation systems that will help us identify, support, learn from, and reward effective teachers. We have been promoting the creation of those systems in several of our key initiatives, including Race to the Top, the Teacher Incentive Fund, School Improvement Grants, and our ESEA reauthorization proposal.

*Examples of Innovative Approaches to Ensuring Academic Success*

Despite these challenges to excellence in our education system, many districts and schools are finding innovative ways to make extraordinary progress in preparing their students for success in college and careers as well as for lifelong and active participation in our democracy. For example, Mooresville Graded School District in North Carolina has launched a Digital Conversion Initiative to promote the use of technology to improve teaching and learning. The district has provided laptops to every 4th to 12th grade student and interactive SMART Boards and Slates and Response Devices have been employed in every K–3 classroom. In addition to the use of computers as instructional tools, the Digital Conversion Initiative has resulted in a shift to digital textbooks with content that is aligned with State standards. Traditional textbooks may still be used, but generally as supplemental materials. The use of digital textbooks and other technology can increase student achievement and enhance the learning of 21st century skills.

In Florida, the Florida Virtual School also taps into technology to provide online learning options for students in grades K–12. The school has modified the way most traditional public school systems work by moving to a completely results-based funding model in which a school receives funding only for students who successfully complete courses. It allows students to progress at their own pace—usually faster than normal seat-time classes would allow—and provides many traditional schools economical options for providing courses they would have difficulty staffing locally.

And in Mobile, Alabama, George Hall Elementary School underwent a restructuring plan that involved hiring a new principal and replacing a majority of school staff. The new staff signed contracts to stay at the school for at least 5 years. The principal focused on developing staff cohesion, a positive culture, and a curriculum that was aligned with State standards and connected from one grade level to the next. Since then student achievement has risen sharply. In reading, the percentage of students scoring at or above the proficient level almost doubled from 24 percent in 2003–2004 to 43 percent in 2004–2005; math gains were even larger, rising from 34 percent to 69 percent. By 2008–2009, the percentage of students who scored proficient or above reached 90 percent in reading and 94 percent in math.

CAREER AND TECHNICAL EDUCATION

*Question.* In Kansas and many other States, career and technical education is critical to economic growth and expansion of a competitive workforce. Your Department's Blueprint for the Reauthorization of ESEA references developing and implementing new statewide assessments for career and technical subjects. Specifically, what role do you see career and technical education playing in a reauthorized ESEA?

Answer. For too long, career and technical education (CTE) has been a neglected part of the education reform movement. That neglect must end, and CTE must change its mission to play a key role in the goal of ensuring that all students graduate high school ready for college and careers. President Obama has suggested that every American earn both a high school diploma and a degree or an industry-recognized certification. CTE can and must help ensure that young adults receive those two credentials, both of which are essential to securing a good job.

ESEA TITLE I ACCOUNTABILITY STRUCTURE

*Question.* Also, how do we successfully incorporate career and technical education and other learning that may take place outside the traditional classroom into ESEA's accountability structure?

Answer. The ESEA title I accountability structure is based on student performance on assessments in reading/language arts and mathematics, as well as additional academic indicators such as high school graduation rates. Students who participate in career and technical education are included in those assessments, but they typically are assessed in the 10th grade, before they begin taking CTE coursework, and the assessments do not measure their progress in CTE.

Many observers of the current title I accountability structure have criticized it as being too focused on reading/language arts and mathematics, which may have resulted in a narrowing of the curriculum. The administration's ESEA reauthorization blueprint includes a number of proposals that would seek to ensure that students have access to a broad, well-rounded curriculum that is not dominated by the tested subjects.

*Accountability in Career and Technical Education Programs*

In addition, in the context of the upcoming reauthorization of the Carl D. Perkins Career and Technical Education Act, we are seeking to develop mechanisms for holding career and technical education programs appropriately accountable for results— mechanisms that would track student programs in CTE as well as in the academic subjects. We believe that this type of strategy is likely to be more successful than trying to incorporate CTE skill and knowledge acquisition within the title I framework.

CONCLUSON OF HEARINGS

Senator HARKIN. And with that, the—we are done. The subcommittee will stand in recess.

[Whereupon, at 11:40 a.m., Wednesday, July 27, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2012

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

[CLERK'S NOTE.—The subcommittee was unable to hold hearings on departmental and nondepartmental witnesses. The statements and letters of those submitting written testimony are as follows:]

## DEPARTMENTAL WITNESSES

### PREPARED STATEMENT OF THE CORPORATION FOR PUBLIC BROADCASTING

Chairman Harkin, Ranking Member Shelby, and members of the subcommittee, thank you for allowing me to submit testimony on behalf of our Nation's public media system.

Every day across the country, people turn to public radio and television for programs that inform and inspire; for lifelong education; for local news and information; for arts and cultural content, and for a variety of other services. Public broadcasting, or what should more accurately be called "public media," has many faces, and employs around 24,000 people, but is best-known by the 1,300 local public radio and television stations across the country that provide unique local service to their communities. These stations collectively reach more than 98 percent of the U.S. population with free, over-the-air television and radio programming and other services. When Congress appropriates money to the Corporation for Public Broadcasting (CPB), it is benefitting the 170 million Americans who use public broadcasting each month by supporting the stations that serve them.

CPB distributes Federal funds in accordance with a statutory formula contained in the Public Broadcasting Act of 1967, under which more than 70 percent of our funds go directly to local public television and radio stations. CPB also supports the creation of programming for radio, television, and digital media. The statute ensures diversity in this programming by requiring CPB to fund independent and minority producers. CPB fulfills these obligations by funding the Independent Television Service and the five Minority Consortia in television (which represent African American, Latino, Asian American, Native American, and Pacific Islander producers) and similar organizations in radio. CPB funds the National Program Service at PBS, which supports signature programs like "PBS NewsHour", "NOVA" and "American Experience"; as well as educational, scientifically researched, impactful and trusted children's programming like "Sesame Street", "Curious George", and "Word Girl".

In addition, CPB spends 6 percent of its funds on projects that benefit the entire public broadcasting community, befitting its role as the only entity responsible for and answerable to the entirety of the public media system. CPB negotiates and pays music royalties for all of public broadcasting, for example, and funds research to explore audience needs and technological opportunities. Added together, these efforts account for 95 percent of the funds appropriated to CPB (which is limited by law to an administrative budget of no more than 5 percent).

Some have suggested that public broadcasting can easily do without Federal funding. Let me briefly explain the critical importance of Federal funding to public media as it exists today, and what the impact would be if it were to go away. Congress designed the public media system in this country as a public-private partner-

ship, where minimal Federal dollars are leveraged to the maximum extent to ensure universal service to every American and every community. While CPB's appropriation accounts for around 15 percent of the entire cost of public broadcasting, this "lifeblood" funding leverages critical investments from State and local governments, universities, businesses, foundations and from viewers and listeners of local stations. Put simply, CPB funding is the foundation on which the entire system is built. Undermining the foundation puts the entire structure in jeopardy.

CPB funding is particularly important to minority-owned public stations and stations in rural areas, which are more challenging to operate due to low population density of viewers and listeners; the need to operate multiple transmitters to reach far-flung populations; and the limited disposable incomes and potential for private support often found in rural America. In fiscal year 2009, individual donations represented 17 percent of an average rural station's total revenue, versus almost 28 percent for the industry as a whole. The disproportional importance of Federal funding to stations in rural areas is clear—in fiscal year 2009, 108 rural stations relied on CPB for at least 25 percent of their revenue; while 22 rural stations, many on Native American reservations, relied on CPB funding for at least 50 percent of their revenue.

Finally, CPB funding is also the only funding source without a station cost associated with it—all other fundraising costs money (for stations and for any nonprofit). For example, in fiscal year 2008 it costs the average station 40 cents on the dollar to raise funds from individuals and local businesses.

Numerous studies, including one conducted by the Government Accountability Office (GAO), have shown that the loss of Federal funding would create a void not easily filled by other sources of funding. For the vast majority of stations, this would mean a drastic and immediate cutback in service, local programming and personnel, and in many cases stations would "go dark." Further, the loss of Federal funding would have a severe impact on a station's ability to acquire national programming, such as "The Electric Company", "Super Why!", "NOVA", "American Experience", "Frontline", "PBS NewsHour", Marketplace and many others, from PBS, NPR, American Public Media and other sources. Federal funding has been the basis for this highly successful public media model since CPB was created nearly 45 years ago. Without it, public media ceases to exist as its creators intended.

*Core System Support*

One of CPB's core responsibilities is to preserve, protect, and advance public media. Public television and radio stations are facing an unprecedented array of challenges. These include the challenging economy, reductions in Federal and State support, shifting community demographics, fracturing audiences and emerging patterns in the way content is delivered and consumed. Public television has been hit especially hard. Over the past two years, the public television economy has declined by $250 million, and CPB projects a further $250 million decline over the next two years. In addition, while the digital conversion in public television has provided exciting new opportunities for service, digital equipment becomes obsolete much more quickly than the analog equipment it replaced. The more or less constant cost of equipment replacement is further affecting public television. To cope with declining revenue and increasing equipment expenses, many stations have been forced to cut local service. As a result, the need to maintain infrastructure is draining resources from content and local service at stations.

CPB is working in two areas to help the system begin to facilitate collaboration and operational efficiencies: mergers and consolidations, and joint master control operations.

*Mergers and Consolidation*.—Most communities are served by one or more stand-alone public broadcasting stations. While independent local stations theoretically have a great deal of flexibility in choosing how to serve their community, the limited scale of many stand-alone operations drives up operating costs and constrains stations' ability to offer local service.

State networks like Iowa Public Television and Alabama Public Television have demonstrated the advantage of taking an alternative approach. Combining management and back office operations to serve multiple communities can increase efficiency and free resources for additional local service. CPB plans to continue to work with stations to explore operating models that bring multiple stations together as an important focus of our work. Our efforts include offering informal advice to stations considering mergers and, once stations issue a formal intent to merge, providing some financial assistance with merger-related costs.

*Central Master Control*.—A master control room is the central hub of a television station's technical operation, the point where content sources come together to be routed to the station transmitter. In the past, each television station has needed a

master control room. Digital technology now allows the master control function to be provided from a remote location. A single master control facility can now serve multiple stations. This is important because master controls are expensive; they are both capital- and people-intensive. Combining master control operations can yield significant cost savings, increase productivity, and encourage station collaboration in other back-office areas.

CPB is supporting the design and construction of multi-station master control facilities. We are also exploring the practicality of creating a nationwide "master plan" for master control facilities. As the specifics of a new consolidated master control function evolve, there is an opportunity to realize cost savings, reduce the capital burden on stations, and improve efficiency for public television.

*American Graduate*

In the words of our statute, "[I]t is in the public interest to encourage . . . the use of [public] media for instructional, educational, and cultural purposes." Education continues to be a core value of the public broadcasting community, as it has been since its inception. For over 40 years, public broadcasting stations have made a robust and vital contribution to education and an informed and strengthened civil society, and these contributions are reflected in CPB's recently-launched American Graduate initiative.

American Graduate is a significant new public media initiative to help improve our Nation's high school graduation rates. Every year, more than 1 million students drop out of high school. If that trend continues, over the next 10 years, it will cost the Nation more than $3 trillion in lost wages, productivity and taxes. American Graduate expands on public media's record of success in early childhood education to reach students in middle school—a critical point when the disengagement that leads to dropping out in high school often begins. Local public radio and television stations are at the core of this initiative and are uniquely positioned to educate and engage various stakeholders on the dropout problem, rally support and help coordinate efforts in communities, something experts say is crucial to a solution.

*CPB's Requests for Appropriations*

Public media stations continue to evolve, both operationally and more importantly in the myriad ways they serve their communities. Stations are committed to reaching viewers and listeners on whatever platform they use—from smart phones to iPads to radios to television sets. While stations can and will continue to adapt and thrive in the digital age, without sufficient support they cannot provide service on evolving platforms. As the Federal Communications Commission's National Broadband Plan noted, "Today, public media is at a crossroads . . . [it] must continue expanding beyond its original broadcast-based mission to form the core of a broader new public media network that better serves the new multi-platform information needs of America. To achieve these important expansions, public media will require additional funding."

*CPB Base Appropriation (Fiscal Year 2014).*—CPB has requested a $495 million advance appropriation for fiscal year 2014, to be spent in accordance with the Public Broadcasting Act's funding formula. The two-year advance appropriation for public broadcasting, in place since 1976, is the most important part of the "firewall" that Congress constructed between Federal funding and the programs that appear on public television and radio. President Gerald Ford, who initially proposed a 5-year advance appropriation for CPB, said it best when he said that advance funding "is a constructive approach to the sensitive relationship between Federal funding and freedom of expression. It would eliminate the scrutiny of programming that could be associated with the normal budgetary and appropriations processes of the government."

Our fiscal year 2014 request balances the fiscal reality facing our Nation with the stark fact that stations are struggling to maintain service to their communities in the face of shrinking non-Federal revenues—a $218 million, or 9.2 percent, drop between fiscal year 2008 and 2009 alone. Even with these challenges, public broadcasting contributes to American society in many ways that are worthy of greater Federal investment. In fiscal year 2014, CPB will continue to support a range of programming and initiatives through which stations provide a valuable and trusted service to millions of Americans.

*CPB Digital Funding (Fiscal Year 2012).*—CPB requests $48 million for CPB Digital for fiscal year 2012, $11.5 million less than requested in fiscal year 2011. The digital conversion of public media is a much more extensive process than simply replacing analog with digital equipment. Digital conversion requires the development of new organizational models optimized for the digital environment, with new workflows, multi-channel services, and multi-platform distribution. CPB Digital

funding, which can fund a wider range of projects than our formula-governed main account, has led to some of the most important innovation in public broadcasting's history. The continuing availability of this funding is critical to public broadcasting's progress toward a true, digital public service media.

*Ready To Learn (Fiscal Year 2012).*—CPB requests that the U.S. Department of Education's Ready To Learn (RTL) program be funded at $27.3 million, the same level as fiscal year 2011. A partnership between the Department, CPB, PBS and local public television stations, RTL leverages the power of digital television technology, the Internet, gaming platforms and other media to help millions of young children learn the reading and math skills they need to succeed in school. The partnership's work over the past few years has demonstrably increased reading scores particularly among low-income children and has erased the performance gap between children from low-income households and their more affluent peers. An appropriation of $27.3 million in fiscal year 2012 will enable RTL to develop tools to improve children's performance in math as well as reading and bring on-the-ground, station-convened early learning activities to more communities.

All told, the Federal contribution to public media through CPB amounts to $1.39 per American per year and, in a model private-public partnership, the public media system takes each of these dollars and raises six dollars more. The returns for taxpayers are exponential. They include in-depth news and public affairs programming on the local, State, national and international level; unmatched, commercial-free children's programming; formal and informal educational instruction for all ages; and inspiring arts and cultural content.

Mr. Chairman and Ranking Member, thank you again for allowing CPB to submit this testimony. We are under no illusions about the pressures you face on a daily basis as Congress works to address our country's perilous fiscal situation. As such, on behalf of the public broadcasting community, including the stations in your states and those they serve, we sincerely appreciate your support.

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## PREPARED STATEMENT OF THE RAILROAD RETIREMENT BOARD

We are pleased to present the following information to support the Railroad Retirement Board's (RRB) fiscal year 2012 budget request.

The RRB administers comprehensive retirement/survivor and unemployment/sickness insurance benefit programs for railroad workers and their families under the Railroad Retirement and Railroad Unemployment Insurance Acts. The RRB also has administrative responsibilities under the Social Security Act for certain benefit payments and Medicare coverage for railroad workers. During the past 2 years, the RRB has also administered special economic recovery payments and extended unemployment benefits under the American Recovery and Reinvestment Act of 2009 (Public Law 111–5). More recently, we have administered extended unemployment benefits under the Worker, Homeownership, and Business Assistance Act of 2009 (Public Law 111–92), and the Tax Relief, Unemployment Insurance Reauthorization, and Job Creation Act of 2010 (Public Law 111–312).

During fiscal year 2010, the RRB paid $10.8 billion, net of recoveries, in retirement/survivor benefits to about 582,000 beneficiaries. We also paid $156.3 million in net unemployment/sickness insurance benefits to some 38,000 claimants. Unemployment benefits included $19.4 million under Public Law 111–92, and about $0.8 million under Public Law 111–5. In addition, the RRB paid benefits on behalf of the Social Security Administration amounting to $1.3 billion to about 116,000 beneficiaries.

### PROPOSED FUNDING FOR AGENCY ADMINISTRATION

The President's proposed budget would provide $112,239,000 for agency operations, which would enable us to maintain a staffing level of 902 full-time equivalent staff years (FTEs) in 2012. The proposed budget would also provide $1,810,000 for information technology (IT) investments. This includes $700,000 for costs related to systems modernization and e-Government, and $654,000 for improvements related to cyber security and continuity of operations. The remaining $456,000 would be used for network operations, infrastructure replacement and emergency restoration services.

### AGENCY STAFFING

The RRB's dedicated and experienced workforce is the foundation for our tradition of excellence in customer service and satisfaction. Like many Federal agencies, however, the RRB has a number of employees at or near retirement age. Nearly 70 per-

cent of our employees have 20 or more years of service at the agency, and about 40 percent of our current workforce will be eligible for retirement by January 1, 2013. To help prepare for the expected staff turnover in the near future, we are placing increased emphasis on strategic management of human capital. Our human capital plans provide for employee support and knowledge transfer, which will enable the RRB to continue achieving its mission. In addition, with the agency's formal human capital plan, succession plan and various action plans in place, we are ensuring that succession management supports a systematic approach to ensuring a continuous supply of the best talent through helping individuals develop to their full potential.

In connection with these workforce planning efforts, our budget request includes a legislative proposal to enable the RRB to utilize various hiring authorities available to other Federal agencies. Section 7(b)(9) of the Railroad Retirement Act contains language requiring that all employees of the RRB, except for one assistant for each Board Member, must be hired under the competitive civil service. We propose to eliminate this requirement, thereby enabling the RRB to use various hiring authorities offered by the Office of Personnel Management.

## INFORMATION TECHNOLOGY IMPROVEMENTS

We are actively pursuing further automation and modernization of the RRB's various processing systems to support the agency's mission to administer benefit programs for railroad workers and their families. Key capital initiatives for fiscal year 2012 include projects to add new reporting services to our Employer Reporting System, and to continue with long-term system modernization efforts. In recent years, the agency has moved to a relational database environment and optimized the data that reside in the legacy databases. In fiscal year 2012, our staff will work with an experienced DB2 Database Administrator to ensure that the master database remains platform independent and to develop stored procedures that will be used by reengineered mainframe programs that access the master database. We also plan to move forward with reengineering the applications to the agency's LAN enterprise program platform, several of which are programmed in outdated, commercially unsupported technologies.

Our budget request also provides for cyber security improvements to ensure that the RRB continues to control the risks that threaten the agency's critical assets and to meet the security requirements set forth in the Federal Information Security Management Act (FISMA) of 2002, and infrastructure investments to maintain our operational readiness and provide a firm foundation for our target enterprise architecture.

## OTHER REQUESTED FUNDING

The President's proposed budget includes $51 million to fund the continuing phase-out of vested dual benefits, plus a 2 percent contingency reserve, $1,020,000, which "shall be available proportional to the amount by which the product of recipients and the average benefit received exceeds the amount available for payment of vested dual benefits." In addition, the President's proposed budget includes $150,000 for interest related to uncashed railroad retirement checks.

## FINANCIAL STATUS OF THE TRUST FUNDS

*Railroad Retirement Accounts*.—The RRB continues to coordinate its activities with the National Railroad Retirement Investment Trust (Trust), which was established by the Railroad Retirement and Survivors' Improvement Act of 2001 (RRSIA) to manage and invest railroad retirement assets. Pursuant to the RRSIA, the RRB has transferred a total of $21.276 billion to the Trust. All of these transfers were made in fiscal years 2002 through 2004. The Trust has invested the transferred funds, and the results of these investments are reported to the RRB and posted periodically on the RRB's website. The net asset value of Trust-managed assets on September 30, 2010, was approximately $23.8 billion, an increase of $0.5 billion from the previous year. As of April 2011, the Trust had transferred approximately $11 billion to the Railroad Retirement Board for payment of railroad retirement benefits.

In June 2010, we released the annual report on the railroad retirement system required by Section 22 of the Railroad Retirement Act of 1974, and Section 502 of the Railroad Retirement Solvency Act of 1983. The report addressed the 25-year period 2010–2034, and included projections of the status of the retirement trust funds under three employment assumptions. These indicated that barring a sudden, unanticipated, large decrease in railroad employment or substantial investment losses, the railroad retirement system would experience no cash flow problems for the next

23 years. Even under the most pessimistic assumption, the cash flow problems would not occur until the year 2033. The report did not recommend any change in the rate of tax imposed by current law on employers and employees.

*Railroad Unemployment Insurance Account*.—The RRB's latest annual report on the financial status of the railroad unemployment insurance system was issued in June 2010. The report indicated that even as maximum daily benefit rates rise 39 percent (from $64 to $89) from 2009 to 2020, experience-based contribution rates are expected to keep the unemployment insurance system solvent, except for small, short-term cash-flow problems in 2010 and 2011. Projections show a quick repayment of loans even under the most pessimistic assumption.

Unemployment levels are the single most significant factor affecting the financial status of the railroad unemployment insurance system. However, the system's experience-rating provisions, which adjust contribution rates for changing benefit levels, and its surcharge trigger for maintaining a minimum balance, help to ensure financial stability in the event of adverse economic conditions. No financing changes were recommended at this time by the report.

Due to the increased level of unemployment insurance payments during fiscal years 2009 and 2010, loans from the Railroad Retirement (RR) Account to the RUI Account became necessary beginning in December 2009. The balance of loans from the RR Account was $47.4 million at the end of fiscal year 2010, including $0.9 million in accrued interest. The estimated loan balance at the end of fiscal year 2011, is $3.0 million, and full repayment of the loans is expected during fiscal year 2012.

Thank you for your consideration of our budget request. We will be happy to provide further information in response to any questions you may have.

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## PREPARED STATEMENT OF THE INSPECTOR GENERAL, RAILROAD RETIREMENT BOARD

My name is Martin J. Dickman and I am the Inspector General for the Railroad Retirement Board. I would like to thank you, Mr. Chairman, and the members of the Subcommittee for your continued support of the Office of Inspector General.

### BUDGET REQUEST

I wish to inform you of our fiscal year 2012 appropriations request and describe our planned activities. The Office of Inspector General (OIG) respectfully requests funding in the amount of $9,259,000 to ensure the continuation of its independent oversight of the Railroad Retirement Board (RRB). During fiscal year 2012, the OIG will focus on areas affecting program performance; the efficiency and effectiveness of agency operations; and areas of potential fraud, waste and abuse.

### OPERATIONAL COMPONENTS

The OIG has three operational components: the immediate Office of the Inspector General, the Office of Audit (OA), and the Office of Investigations (OI). The OIG conducts operations from several locations: the RRB's headquarters in Chicago, Illinois; an investigative field office in Philadelphia, Pennsylvania; and five domicile investigative offices located in Arlington, Virginia; Houston, Texas; San Diego, California; Miami, Florida; and New York, New York. These domicile offices provide more effective and efficient coordination with other Inspector General offices and traditional law enforcement agencies with which the OIG works joint investigations.

### OFFICE OF AUDIT

The mission of the Office of Audit is to promote economy, efficiency, and effectiveness in the administration of RRB programs and detect and prevent fraud and abuse in such programs. To accomplish its mission, OA conducts financial, performance, and compliance audits and evaluations of RRB programs. In addition, OA develops the OIG's response to audit-related requirements and requests for information.

During fiscal year 2012, OA will focus on areas affecting program performance; the efficiency and effectiveness of agency operations; and areas of potential fraud, waste, and abuse. OA will continue its emphasis on long-term systemic problems and solutions, and will address major issues that affect the RRB's service to rail beneficiaries and their families. OA has identified four broad areas of potential audit coverage: Financial Accountability; Railroad Retirement Act & Railroad Unemployment Insurance Act Benefit Program Operations; Railroad Medicare Program Operations; and Security, Privacy, and Information Management.

During fiscal year 2012, OA must accomplish the following mandated activities with its own staff: Audit of the RRB's financial statements pursuant to the require-

ments of the Accountability of Tax Dollars Act of 2002 and evaluation of information security pursuant to the Federal Information Security Management Act (FISMA).

During fiscal year 2012, OA will complete the audit of the RRB's fiscal year 2011 financial statements and begin its audit of the agency's fiscal year 2012 financial statements. OA contracts with a consulting actuary for technical assistance in auditing the RRB's "Statement of Social Insurance", which became basic financial information effective in fiscal year 2006. In addition to performing the annual evaluation of information security, OA also conducts audits of individual computer application systems which are required to support the annual FISMA evaluation. Our work in this area is targeted toward the identification and elimination of security deficiencies and system vulnerabilities, including controls over sensitive personally identifiable information. OA will also conduct an audit of employer compliance with the provisions of the Railroad Retirement and Railroad Unemployment Insurance Acts. Our work in this area is designed to verify the completeness and accuracy of the external reviews performed by the RRB's compliance group.

OA undertakes additional projects with the objective of allocating available audit resources to areas in which they will have the greatest value. In making that determination, OA considers staff availability, current trends in management, Congressional and Presidential concerns.

### OFFICE OF INVESTIGATIONS

The Office of Investigations (OI) focuses its efforts on identifying, investigating, and presenting cases for prosecution, throughout the United States, concerning fraud in RRB benefit programs. OI conducts investigations relating to the fraudulent receipt of RRB disability, unemployment, sickness, and retirement/survivor benefits. OI investigates railroad employers and unions when there is an indication that they have submitted false reports to the RRB. OI also conducts investigations involving fraudulent claims submitted to the Railroad Medicare Program. These investigative efforts can result in criminal convictions, administrative sanctions, civil penalties, and the recovery of program benefit funds.

### OI INVESTIGATIVE RESULTS FOR FISCAL YEAR 2010

| | |
|---|---|
| Civil Judgments | 19 |
| Indictments/Informations | 47 |
| Convictions | 50 |
| Recoveries/Receivables | $29,296,188 |

OI anticipates an ongoing caseload of about 450 investigations in fiscal year 2012. During fiscal year 2010, OI opened 244 new cases and closed 210. To date in fiscal year 2011, OI has opened 188 new cases and closed 135. At present, OI has cases open in 47 States, the District of Columbia, and Canada with estimated fraud losses of over $37 million. Disability fraud cases represent the largest portion of Ol's total caseload. These cases involve more complicated schemes and often result in the recovery of substantial amounts for the RRB's trust funds. They also require considerable resources such as travel by special agents to conduct surveillance, numerous witness interviews, and more sophisticated investigative techniques. Additionally, these fraud investigations are extremely document-intensive and require forensic financial analysis.

During fiscal year 2012, OI will continue to coordinate its efforts with agency program managers to address vulnerabilities in benefit programs that allow fraudulent activity to occur and will recommend changes to ensure program integrity. OI plans to continue proactive projects to identify fraud matters that are not detected through the agency's program policing mechanisms.

### CONCLUSION

In fiscal year 2012, the OIG will continue to focus its resources on the review and improvement of RRB operations and will conduct activities to ensure the integrity of the agency's trust funds. This office will continue to work with agency officials to ensure the agency is providing quality service to railroad workers and their families. The OIG will also aggressively pursue all individuals who engage in activities to fraudulently receive RRB funds. The OIG will continue to keep the Subcommittee and other members of Congress informed of any agency operational problems or deficiencies.

The OIG sincerely appreciates its cooperative relationship with the agency and the ongoing assistance extended to its staff during the performance of their audits and investigations. Thank you for your consideration.

## NONDEPARTMENTAL WITNESSES

### PREPARED STATEMENT OF THE ADAP ADVOCACY ASSOCIATION

Thank you on behalf of the ADAP Advocacy Association (aaa+) and its board of directors for the opportunity to submit our written testimony to the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services and Education (LHHSE) about the AIDS Drug Assistance Programs (ADAPs). aaa+ is a national 501(c)(3) nonprofit organization incorporated in the District of Columbia to promote and enhance the AIDS Drug Assistance Programs and improve access to care for persons living with HIV/AIDS. We appreciate the opportunity to share our testimony on fiscal year 2010 appropriations.

State ADAPs are primarily federally funded under Part B of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. ADAPs provide medications to treat HIV disease and prevent and treat AIDS-related opportunistic infections to low income, uninsured and underinsured individuals living with HIV/AIDS in the 50 States, District of Columbia, Puerto Rico, Guam, U.S. Virgin Islands, American Samoa, Marshall, and Northern Marianas Islands. Additional funding is directed toward State ADAPs from other Ryan White CARE Act funds, including Part A Eligible Metropolitan Area (EMA) funds. Many States also directly contribute funding. ADAPs represent the "access to treatment" window for the community-based continuum of HIV/AIDS healthcare so carefully built and supported by all the parts of the Ryan White CARE Act, which was reauthorized for 4 years by both Houses of Congress and signed into law by President Barack Obama on October 30, 2009. The law in general has enjoyed strong bipartisan support since it was first passed in the 1990s, and ADAPs specifically have been a Return on Investment (ROI) model since the Federal Government began pumping money into them when President Bill Clinton and Speaker Newt Gingrich were in office.

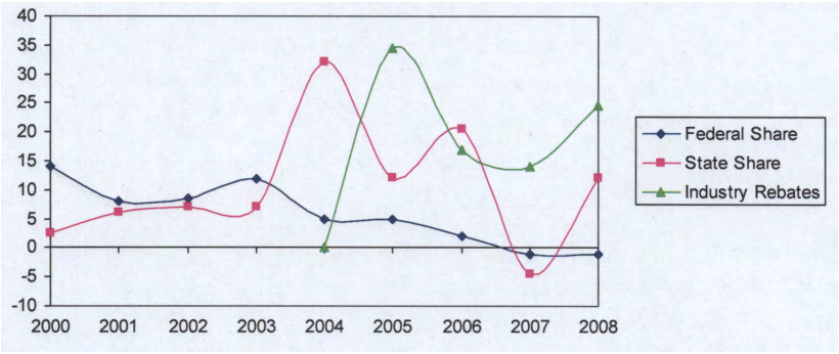
At the time when our testimony is being submitted to the subcommittee for its consideration, there are 7,553 people living with HIV/AIDS in 11 States on ADAP waiting lists—including 31 people in Arkansas, 3,848 people in Florida, 1,221 people in Georgia, 11 people in Idaho, 816 people in Louisiana, 21 people in Montana, 177 people in North Carolina, 303 people in Ohio, 560 people in South Carolina, 563 people in Virginia and 2 people in Wyoming. Overall, 95.54 percent of these people reside in the South. Additionally, it is being submitted for the people living with HIV/AIDS who are the "invisible" waiting lists because they have been kicked-off the program due to changes in eligibility requirements—including 99 people in Arkansas, 257 people in Ohio, and 89 people in Utah, as well as the 6,500+ people in Florida who have been transitioned off the program.

Faced with the "Perfect Storm" that is being fueled by high unemployment, record number of uninsured, State budgetary cutbacks, high cost of medications and inadequate Federal funding, there are a historic number of people being denied access to treatment. Without the subcommittee's leadership and fortitude to recognize the ROI from ADAPs, several thousand people living with HIV/AIDS will be at risk of developing Opportunistic Infections (OIs), and thousands of others who are HIV-negative will be at greater risk of contracting the virus because their HIV-positive counterparts are more infectious when not taking Highly Active Anti-Retroviral Therapy (HAART).

Each year a sophisticated pharmacoeconomic model is employed by the ADAP Coalition—a unique coalition of AIDS advocates, community-based organizations and representatives of research-based pharmaceutical and biotechnology companies—referencing the data collected from ADAPs from the previous 2 years to forecast the dollar resources that will be needed for the coming 2 years to enable ADAPs to provide HAART (combination antiretroviral therapy) to Americans living with HIV disease.

Many are familiar with this process and its remarkable accuracy over the past 12 years. The Congress and White House have provided us with support very close to the amounts we projected in fiscal year 1996, 1997, 1998, 1999, 2000, always in amounts above the original Administration budget requests; funding in subsequent fiscal year 2001–05 was sustainable, but often short of the necessary amounts needed to avert waiting lists. Between 2000 and 2008, States increased their share of the ADAP budget by 155 percent while the Federal Government increased its share by only 46 percent overall. The chart shows the increase by each party each year

over the previous fiscal year in percentage points. States have basically increased—as well as pharmaceutical rebates—while the Federal commitment has gone down!




The ongoing ADAP crisis is being fueled, by in large, because Federal spending has been inadequate—despite small budget increases under both President George W. Bush and President Obama since 2005. The Federal share of ADAP funding has fallen steadily over the last several years. In fiscal year 2003 the Federal earmark was 72 percent of the overall ADAP budget. In fiscal year 2009, the Federal share had fallen to 49 percent of the ADAP budget. ADAPs have long had a strong State-Federal partnership; however despite the economic downturn many States have increased funding in fiscal year 2010 by an additional $121 million for a total of $346.2 million. Pharmaceutical manufacturers have also helped to alleviate fiscal challenges for ADAP by agreeing to lower drug prices and enhance rebates, which amounted to $259 million in saving for fiscal year 2009. Supplemental agreements will save an additional $160 million per year starting in July 2010.[1]

ADAPs truly need an increase of $410 million in fiscal year 2012 to maintain their programs and fill the structural deficits that have built up over the last several years. In fiscal year 2012, the HIV/AIDS community is asking for an increase of $131 million to continue to serve an average of 1,312 new clients per month. The funding level of $991 million is the authorized level in the Ryan White reauthorization of 2009.[2]

A large gap remains for ADAPs in fiscal year 2010. Included in the fiscal year 2011 need number was a revised estimate for the ADAP Federal need number for fiscal year 2010 of $961 million, an increase of $126 million over the current funding level. The fiscal year 2010 need number was revised based upon new survey data. Coupled with estimated State funding, this funding will provide continued services to a total of 153,875 clients in fiscal year 2010, including the ability to enroll 15,760 new clients and eliminate waiting lists. This includes individuals who are fully covered by ADAP and those who receive assistance with Medicare Part D cost sharing requirements or private insurance continuation. The fiscal year 2010 need number has been adjusted from the previous level to account for the $20 million already received through the fiscal year 2010 Congressional appropriations process.[3] This problem is only worsens moving into fiscal year 2012.

The problem of growing ADAP waiting lists is exacerbated because we are facing an American HIV/AIDS epidemic of devastating proportion. According to some estimates, the number of people living with HIV/AIDS in the United States was approximately 2 million by the end of 2010. These numbers are not due to decrease in the near future. In 2006 alone, the Centers for Disease Control and Prevention (CDC) estimated that there have been more than 56,000 new HIV infections per year for the last decade. If this was not severe enough, the disease is far from color blind. Currently, the incidence rate of new HIV infection among African American men and women is seven times that of the Caucasian population. Furthermore, racial disparities are echoed regionally as the epidemic has seen its most recent unfettered growth in southern States, which often times have smaller State budgets and fewer access points to comprehensive care.

The ADAP need is being driven by simple factors. As we all know HAART AIDS treatments has dropped U.S. death rates from AIDS by about 75 percent starting

[1] The ADAP Coalition, ADAP Need Fiscal Year 2012, January 2011.
[2] The ADAP Coalition, ADAP Need Fiscal Year 2012, January 2011.
[3] The ADAP Coalition, ADAP Need Fiscal Year 2010 & Fiscal Year 2011, January 2010.

in 1996. Whereas annual AIDS deaths use to run about 40,000 a year, now 15,000 to 17,000, even less in areas of very good medical care.

While dramatic improvements in lifespan and quality of life are almost miraculous, HAART treatments must continue for ADAP patients. Therefore patients living longer will likely require ADAP services for medications longer. There are 200,000 to 300,000 Americans who are unaware that they are HIV+. Extensive multi-million dollar efforts for outreach and HIV testing are going on all over the country, and the CDC now urges routine testing for those at risk for HIV. Funded by churches, foundations, Minority Health Initiatives, pharmaceutical companies and AIDS service groups, these efforts are identifying "hard to reach" populations many of whom lack adequate health insurance. These individuals, when identified, must look to ADAP to cover the costs of their drugs. For most, access to Medicaid is limited. State Medicaid programs typically require disease progression to full-blown AIDS to meet the Social Security definition of disabled. U.S. Government treatment guidelines consider progression to full-blown AIDS to be months and years too late for optimum treatments. As we decided in Congress to allow timely early treatment of breast and cervical cancers in women, so too should we allow States the option to provide early treatments for HIV through Medicaid to both men and women.

While we hope that Congress will pass the Early Treatment for HIV Act (ETHA) to allow States the option to provide HIV care and treatments through Medicaid early in the disease process when health benefits are greater and costs are less, for now we are stuck with folks who can't qualify for Medicaid looking to ADAP for basic coverage. Increases in private sector health insurance costs forces steady streams of HIV+ patients from private health insurance programs to State ADAPs. This is a result of rising costs in premiums and co-payments that become unaffordable, and in some instances by HMO-type providers with drug benefits leaving the market for more profitable locations. These factors together, ensure need for State ADAPs for the coming years. The increasing rate of need will be substantial until key provisions of the Patient Protection and Affordable Care Act (PPACA) can provide adequate benefits to our entire senior, elderly and disabled populations. As the profile of the American AIDS epidemic has expanded further into communities of color, marginalized populations, rural areas, and particularly to women of color in their child bearing years, ADAPs feel these additional strains from groups which traditionally may work low-paying jobs with inadequate health insurance or no healthcare benefits.

In the past 12 months, 20 State ADAPs have instituted other cost-containment strategies. ADAPs with other cost-containment strategies instituted since April 1, 2009, as of February 2, 2011) include: Arizona: Reduced formulary, Arkansas: Reduced formulary, lowered financial eligibility to 200 percent of FPL, (disenrolled 99 clients in September 2009), Colorado: Reduced formulary, Florida: Reduced formulary, lower financial eligibility to 300 percent FPL, transition clients to Welvista from 2/14–3/31/11, Georgia: Reduced formulary, implemented medical criteria, continued participation in the Alternative Method Demonstration Project (AMDP), Idaho: Capped enrollment, Illinois: Reduced formulary, instituted monthly expenditure cap, Kentucky: Reduced formulary, Louisiana: Discontinued reimbursement of laboratory assays, North Carolina: Reduced formulary, North Dakota: Capped enrollment, instituted annual expenditure cap, lowered financial eligibility to 300 percent FPL, Ohio: Reduced formulary, lowered financial eligibility to 300 percent of FPL (disenrolled 257 clients), Puerto Rico: reduced formulary, South Carolina: Lowered financial eligibility to 300 percent FPL, Utah: Reduced formulary, lowered financial eligibility to 250 percent of FPL (disenrolled 89 clients), Virginia: Reduced formulary, only distribute 30-day prescription refills, Washington: Instituted client cost sharing, reduced formulary (for uninsured clients only), only pay insurance premium for clients currently on antiretrovirals, and Wyoming: Reduced formulary, instituted client cost sharing.

As previously stated, ADAP waiting lists—as well as the aforementioned cost-containment strategies put the lives of people living with HIV/AIDS at risk (e.g., developing OIs), as well as put HIV-negative people at higher risk of becoming infected (e.g., HIV-positive people are more infectious when not properly treated with HAART). Without congressional leadership and adequate Federal funding, current circumstances could easily lead to a public health emergency that will only cost the taxpayers much more.

In hindsight, it becomes easy to argue that ADAPs have historically been underfunded. In reality however, it is the emergence of highly active anti-retroviral therapy over the past 7 years and the successes of these treatment options that have made dramatic changes in people's lives; that have made access to HIV treatment and care such a dramatic national policy concern. We now understand how HIV replicates in the body, beginning its destructive impact on the immune system from the

moment of infection. Where in the recent past we divided people into categories such as asymptomatic and symptomatic in order to make treatment decisions, current treatments dictates that we no longer make these distinctions in our approach to therapy. The latter simply reflects a more advanced state of immune damage.

The standard of care today recommends that patients start on antiretroviral therapy with a combination of drugs earlier in the disease in order to preserve immune function. It also presumes the earliest possible knowledge of HIV status and informed medical care to decide the exact timing of treatment commencement and treatment type selection. Improved immune function has a direct impact on those topics you are most likely interested in today, saving and improving the quality of lives and cost savings to the healthcare system.

By now it is really not necessary to explain the benefits of antiretroviral treatments or even its cost effectiveness. Everyone knows these things. In fact thousands of people are dedicated to seeing that the "AIDS miracles" of the last few years available in the United States are delivered to the rest of the world before societal damage in excess of the plagues of the Middle Ages is inflicted upon whole countries in the Caribbean, Africa, Asia and parts of the former Soviet Union. In sharing the wealth of the medical knowledge and expertise, which the United States have lead in developing we must not, and should not forget the homeland. We must make sure that no American with HIV is forgotten and allowed to fall through the cracks. The time has come to end the wait for people living with HIV/AIDS.

In closing the following two hypothetical examples demonstrate the ROI of the AIDS Drug Assistance Program:

—Charlie is a 29-year old black single father living in Gadsden County Florida. He and his wife found out they were infected with HIV when she died from complications of AIDS related pneumonia the previous year. Charlie is on a waiting list to receive AIDS drugs but between his depression and efforts to care for his children he is unable to access the help he needs to navigate the Patient Assistance Programs. He himself gets sick. He enters an emergency room in Tallahassee, Florida and is subsequently admitted for a 5-day stay. His emergency room visit is near the average for this hospital at $2,783 (source Florida Heath Finder.org.) The hospital stay is near the national average of $24,000. He receives additional bills from doctors, radiologists and therapists for $750. You can compare this total to the cost of the AIDS drug he would need for an entire year. Charlie is what is known as therapy naive so the most inexpensive combination therapy drugs would be effective in reducing the virus to undetectable levels. The annual drug cost would be around $15,000 per year. Compare that to $33,830 in 6 days for hospitalization.

—Now consider Patricia. She has had AIDS for 20 years and the AIDS virus she carries is resistant to all but the most expensive AIDS drugs. She has fallen out of care and is now getting progressively sicker. She goes to ADAP at the nearest county health department which is 20 miles away only to be told that she has been wait listed due to budget shortfalls. Patricia falls ill while trying to navigate assistance programs and is hospitalized. Her ER costs are similar to that of Charlie's but she stays in the hospital for 20 days and then dies. Her costs are well over $100,000 not including funeral and burial costs. Her drugs would have cost $30,000 per year.

We urge to you fully fund the ADAP program in fiscal year 2012 with an increase of $131 million. No one need be denied the new standard of care for HIV disease. We have come too far as a Nation to turn our backs on HIV/AIDS now. Please make sure that the resources are there for every HIV-positive American to be treated regardless of their financial resources or ability to access adequate health insurance coverage.

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## PREPARED STATEMENT OF THE AD HOC GROUP FOR MEDICAL RESEARCH

The Ad Hoc Group for Medical Research is a coalition of more than 300 patient and voluntary health groups, medical and scientific societies, academic and research organizations, and industry. The Ad Hoc Group appreciates the opportunity to submit this statement in support of enhancing the Federal investment in biomedical, behavioral, and population-based research supported by the National Institutes of Health (NIH).

We are deeply grateful to the Subcommittee for its long-standing, bipartisan leadership in support of NIH. These are difficult times for our Nation and for people all around the globe, but the affirmation of science is the key to a better future. To improve Americans' health and strengthen America's innovation economy, the Ad

Hoc Group for Medical Research recommends $35 billion for NIH in fiscal year 2012.

The partnership between NIH and America's scientists, medical schools, teaching hospitals, universities, and research institutions continues to serve as the driving force in this Nation's search for ever-greater understanding of the mechanisms of human health and disease. More than 83 percent of NIH research funding is awarded to more than 3,000 research institutions located in every State. These are funded through almost 50,000 competitive, peer-reviewed grants and contracts to more than 350,000 researchers.

The foundation of scientific knowledge built through NIH-funded research drives medical innovation that improves health and quality of life through new and better diagnostics, improved prevention strategies, and more effective treatments. NIH research has contributed to dramatically increased and improved life expectancy over the past century. A baby born today can look forward to an average life span of nearly 78 years—almost three decades longer than a baby born in 1900, and life expectancy continues to increase. People are staying active longer, too: the proportion of older people with chronic disabilities dropped by nearly a third between 1982 and 2005. Thanks to insights from NIH-funded studies, the death rate for coronary heart disease is more than 60 percent lower—and the death rate for stroke, 70 percent lower—than in the World War II era.

NIH research continues to create dramatic new research opportunities, offering hope to the millions of patients awaiting the possibility of a healthier tomorrow. For example, a new ability to comprehend the genetic mechanisms responsible for disease already is providing insights into diagnostics and identifying a new array of drug targets. We are entering an era of personalized medicine, where prevention, diagnosis, and treatment of disease can be individualized, instead of using the standardized approach that all too often wastes healthcare resources and potentially subjects patients to unnecessary and ineffective medical treatments and diagnostic procedures.

Peer-reviewed, investigator-initiated basic research is the heart of NIH research. These inquiries into the fundamental cellular, molecular, and genetic events of life are essential if we are to make real progress toward understanding and conquering disease. The application of the results of basic research to the detection, diagnosis, treatment, and prevention of disease is the ultimate goal of medical research. Clinical research not only is the pathway for applying basic research findings, but it also often provides important insights and leads to further basic research opportunities. Additional funding is needed to sustain and enhance basic and clinical research activities, including increasing support for current researchers and promoting opportunities for new investigators and in those areas of science that historically have been underfunded.

Ongoing efforts to reinvigorate research training, including developing expanded medical research opportunities for minority and disadvantaged students, continue to gain importance. For example, the volume of data being generated by genomics research, as well as the increasing power and sophistication of computing assets on the researcher's lab bench, have created an urgent need, both in academic and industrial settings, for talented individuals well-trained in biology, computational technologies, bioinformatics, and mathematics to realize the promise offered by modern interdisciplinary research.

To move forward, it will be essential to maintain the talent base and infrastructure that has been created to date. Large fluctuations in funding will be disruptive to training, to careers, long range projects and ultimately to progress. The research engine needs a predictable, sustained investment in science to maximize our return.

Further, NIH-supported research contributes to the Nation's economic strength by catalyzing private sector growth and creating skilled, high-paying jobs; new products and industries; and improved technologies. Industries and sectors that benefit include the high-technology and high value-added pharmaceutical and biotechnology industries, among others. In particular, the NIH funds "enabling science" that explores and identifies discoveries at a point earlier than businesses often invest, stoking and sustaining the discovery pipeline.

The investment in NIH not only is an essential element in restoring and sustaining both national and local economic growth and vitality, but also is essential to maintaining this Nation's prominence as the world leader in medical research. As Raymond Orbach, former Under Secretary for Science at the Department of Energy for President George W. Bush, noted in a recent editorial in Science, "Other countries, such as China and India, are increasing their funding of scientific research because they understand its critical role in spurring technological advances and other innovations. If the United States is to compete in the global economy, it too must continue to invest in research programs." To succeed in the information-

based, innovation driven world-wide economy of the 21st century, we must recommit to long-term sustained growth in medical research funding.

The ravages of disease are many, and the opportunities for progress across all fields of medical science to address these needs are profound. In this challenging budget environment, we recognize the painful decisions Congress must make. The community appreciates that this subcommittee always has recognized that discoveries gained through basic research yield the medical advances that improve the fiscal and physical health of the country. Strengthening the Nation's commitment to medical research is the key to ensuring the future of America's medical research enterprise and the health of her citizens.

The Ad Hoc Group for Medical Research respectfully requests that NIH be recognized as an urgent national priority as the subcommittee prepares the fiscal year 2012 appropriations bills.

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## PREPARED STATEMENT OF THE AIDS HEALTHCARE FOUNDATION

On behalf of the over 1 million Americans with HIV/AIDS, and the over 56,000 Americans who will become infected with HIV this year, AIDS Healthcare Foundation (AHF) submits the following recommendations and proposals for funding domestic HIV/AIDS programs for fiscal year 2012.

AHF is the largest HIV/AIDS nonprofit in the United States. For over 20 years, it has delivered high quality medical care, pharmacy services, research, and HIV prevention and testing services throughout the country. It currently provides medical care to over 150,000 people with HIV/AIDS in 22 countries around the world.

Based on this experience, it is clear to AHF that the battle against HIV/AIDS is winnable, and that the keys to winning this fight are:

Find those Americans who have HIV, but don't know it.

It is estimated that approximately 20 percent of all Americans who have HIV do not know they are infected. It is not surprising that this group unwittingly is the source of up to 70 percent of all HIV infections in the United States—if you don't know you have HIV, you don't take steps to protect others, and you don't get treatment.

Provide AIDS drug treatment to all Americans with HIV/AIDS who need it.

It cannot be stressed enough—treatment is prevention. AIDS treatment is one of the most effective tools we have to prevent new infections. The point of treatment is to reduce the amount of the HIV virus in a person. People with HIV/AIDS who are on treatment are less infectious, and simply are far less able to transmit the virus. AIDS treatment is 92 percent effective in preventing new infections.

If we could find those who don't know they have HIV, and get them treatment, new HIV infections would plummet. Not only would these people be healthier and able to work and care for their families, but we would save tens of billions per year in future medical costs.

Currently, there are approximately 56,000 new HIV infections in the United States every year. As the lifetime medical cost (the majority of which will be borne by the Federal Government via Medicare, Medicaid, or the Ryan White CARE Act) for each HIV infection is over $600,000, the United States accrues over $36 billion in future medical costs every year due to new HIV infections.

Therefore, effectively battling the AIDS epidemic requires prioritizing scarce funds into two main areas: Testing (to find those who are unaware they have HIV) and treating (providing AIDS drugs and medical care to the newly diagnosed, to prevent new infections).

AHF recognizes the prevailing economic and budget climate, and understands that finding new money to pay for these necessary programs is extremely challenging. AHF therefore makes the following recommendations that would free up existing funding to focus more on testing and treatment:

Re-prioritize AIDS prevention funding within the Centers for Disease Control toward HIV testing.

Yearly new HIV infections have not declined for well over a decade. As a result, it is time to re-think the CDC's approach to HIV prevention. In recent times CDC has spent approximately 30 percent of its HIV prevention budget on HIV testing. AHF recommends that, for fiscal year 2012 and beyond, the CDC be required to spend at least 50 percent of its prevention budget on testing. The more tests the CDC performs, the more people who are unaware of their HIV status will be found, which is the first step in preventing new infections.

Increase funding for the AIDS Drug Assistance Program (ADAP) by $108 million.

ADAP is a lifeline for thousands of Americans who cannot afford AIDS treatment, which can cost well in excess of $12,000 per year. Nationwide, ADAP serves over

165,000 people, approximately one-third of all people on AIDS treatment in the United States.

Ensuring access to treatment is the backbone in our fight against HIV/AIDS. Without treatment, people with AIDS become sicker. Without treatment, new infections will increase, and every new infection carries with over $600,000 in lifetime medical costs. For these reasons, it is of grave concern that access to care for thousands of Americans is now at risk.

Currently, there are over 7,800 Americans on ADAP waiting lists across the country—7,800 people who cannot get access to these drugs due to budgetary constraints. This list continues to grow as infections continue, State financial support is reduced, and drug prices increase.

To reverse this trend, AHF supports the consensus of the AIDS community that ADAP funding should be increased by $108 million for a total of $991 million. In the absence of new money, AHF proposes funding this increase via the following means:

Implement administrative and overhead caps within CDC, HRSA, and NIH AIDS programs, and redirect the savings to ADAP.

In tight budgetary times, Government must become more cost effective. Currently, Government agencies like HRSA require that contractors spend no more than 10 percent of grants on administrative overhead. These agencies, which are tasked with implementing ADAP and other AIDS programs, spend a combined $2.3 billion on administration and overhead. As a recipient of Government funds that has operated under these requirements, AHF submits that these caps should be applied to these agencies as well. Controlling administrative costs will free up money that can be spent on services, not bureaucracy.

Secure additional drug price discounts/rebates from AIDS drug manufacturers.

Drug price increases are one of the main causes of the current ADAP crisis. Additional discounts would mean ADAPs could serve everyone who needs it without new funding. Moreover, given the unique nature of ADAP, these discounts would not have any significant impact on drug company profitability, as they would not impact price calculations for other drug programs or reduce drug company revenues.

AIDS Healthcare Foundation (AHF) supports increasing Federal funding for ADAP. However, additional funding must go hand in hand with changes to ADAP that protect the program from high drug prices. To achieve this, AHF proposes that for every dollar of additional Federal funding drug companies contribute $2 in additional rebates or price cuts. This would effectively triple the purchasing power of each additional ADAP dollar, and ensure the sustainability of this vital program. Congress can implement this solution by directing the Secretary of Health and Human Services to negotiate the drug company contribution as a condition of receiving new money for ADAP.

Call for the National Institutes of Health to make an independent review of prevention interventions being supported by CDC to determine their effectiveness.

Even though the AIDS epidemic is over 25 years old, there is still very little evidence concerning what prevention programs work, and are cost effective. In order to better target scarce resources to the most effective interventions, AHF recommends that $1 million of NIH's fiscal year 2012 AIDS research budget be spent on determining which HIV prevention methods are in fact cost-effective ways of reducing HIV infections.

The implementation of the recommendations would forcefully re-orient America's AIDS response in a way that would significantly reduce new infections, save billions of dollars, and improve the health of hundreds of thousands of Americans.

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## PREPARED STATEMENT OF AIDS UNITED

On behalf of AIDS United and our diverse partner organizations I am pleased to submit this testimony to the Members of this Subcommittee on the urgency of needed funding for the fiscal year 2012 domestic HIV/AIDS portfolio. AIDS United is a national organization that seeks to end the AIDS epidemic in the United States by combining private-sector fundraising, philanthropy, coalition building, public policy expertise, and advocacy—as well as a network of passionate local and State partners—to effectively and efficiently respond to the HIV/AIDS epidemic in the communities most impacted by it. Through its unique Community Partnerships program, Public Policy Committee and targeted special grant-making initiatives, AIDS United represents over 400 grassroots organizations. These organizations provide HIV prevention, care, treatment, and support services to underserved individuals and populations most impacted by the HIV/AIDS epidemic including communities of color,

women and people living with HIV/AIDS in the United States as well as education and training to providers of treatment services.

June 5, 2011 marks the 30th year since the Centers for Disease Control and Prevention (CDC) reported the first cases of what later became identified as HIV disease. Sadly, the HIV/AIDS epidemic in the United States is characterized by needless mortality, inadequate access to care, persistent levels of new infection, and stark population and regional disparities. Although improved treatment has made it possible for people with HIV disease to lead longer and healthier lives, these stark realities remain.

*HIV Remains a Major Public Health Danger*

More than 1.2 people are living with HIV or AIDS; nearly one-half living with HIV/AIDS are not in care.

56,300 people are estimated to have been newly infected with HIV in the United States in 2006, the year for which the most recent data is available—one new infection every 9½ minutes. According to the Centers for Disease Control and Prevention (CDC) the HIV infection rate has not fallen in 16 years.

There is neither a cure nor a vaccine for HIV and current treatments do not work for everyone.

*HIV Severely Affects African Americans, Latinos, Women and Gay Men*

African Americans represent 13 percent of the United States population but nearly 50 percent of all newly reported HIV infections.

Hispanics/Latinos represent 13 percent of the United States population but account for 18 percent of newly reported cases of HIV.

The percentage of newly reported HIV/AIDS cases in the United States among women tripled from 8 percent to 27 percent between 1985 and 2007. AIDS is a leading cause of death among black women aged 15–54.

Gay, bisexual, and other men who have sex with men, especially in communities of color, are the population most severely affected by HIV.

*AIDS United Supports the Goals of the National HIV/AIDS Strategy*

The Federal Government has created a first ever National HIV/AIDS Strategy that commits to four basic goals: reducing the number of people who become infected with HIV; increasing access to care and optimizing health outcomes for people living with HIV; reducing HIV-related health disparities; and achieving a more coordinated national response to the HIV Epidemic.

AIDS United strongly supports achievement of these goals and strongly urges the Labor, Health and Human Services, and Education Subcommittee of the Senate Appropriations Committee to ensure that meeting these goals is a top priority. Unfortunately given the growth in the epidemic, meeting these goals, particularly lowering the new HIV infection rate, will require greater funding than has been made available. The Federal Government's commitment to HIV domestic funding is even more important this year as we see many States lowering their State funding contributions due to the economic realities States are facing. AIDS United strongly urges Congress to meet this challenge through the good work of this subcommittee and to recognize and address the true funding needs of the programs in the HIV/AIDS portfolio.

*AIDS Budget and Appropriations Coalition HIV Community Fiscal Year 2012 Request (Increases Over Fiscal Year 2010)*

The HIV community has come together under the umbrella of the AIDS Budget and Appropriations Coalition with the community funding request for the HIV/AIDS domestic portfolio for fiscal year 2012, the comparisons are based on fiscal year 2010 finals. We fully understand the budgetary constraints that are impacting this time, but we feel it is imperative to let this subcommittee know of the true needs in the HIV community.

*HIV Prevention*.—According to CDC estimates contained in the agency's 2009 HIV/AIDS Surveillance Report, since the beginning of the epidemic there have been 1,142,714 AIDS cases reported with a total of 617,025 deaths in the United States. Based on previous CDC estimates more than 1.2 million people are living with HIV/AIDS and that an estimated 21 percent of people living with HIV are unaware of their HIV status and could unknowingly transmit the virus to another person. Prior to fiscal year 2010 funding had remained flat for more than 8 years. As a result, grants to States and local communities have decreased significantly even as the United States seeks to increase prevention and testing services. To begin to reach the goals of the National HIV/AIDS Strategy the Congress must give the CDC the necessary funding to invest in meaningful prevention. AIDS United requests an in-

crease of at least $57.2 million to $857.6 million in fiscal year 2012 to address the true need of $1,324.6 billion.

*Education*.—The National HIV/AIDS Strategy acknowledges the need to educate all Americans about the threat of HIV and how to prevent it. The United States must invest in programs that provide our young people with complete, accurate, and age-appropriate sex education that helps them reduce their risk of HIV, other STDs, and unintended pregnancy. AIDS United supports the Administration's teen pregnancy prevention initiative but urges Congress to find opportunities to fund true, comprehensive sex education that promotes healthy behaviors and relationships for all young people, including LGBT youth. Negative health outcomes are related to lack of knowledge and we must provide youth with the information and services they need to make responsible decisions about their sexual health. AIDS United requests that the teen pregnancy prevention initiative funding increase by $6.7 million to a level of $161.4 million. AIDS United also requests an increase of $10 million, for a total of $50 million, for the Division of Adolescent and School Health's HIV Prevention Education at the CDC. AIDS United is pleased that the President's budget includes zero funding for failed abstinence-only-until-marriage programs and urges the subcommittee also to ensure that funding is not included for these ineffective programs.

*Policy Rider, Syringe Exchange*.—CDC estimates that approximately 13 percent of all HIV cases and 60 percent of all hepatitis C cases in the United States are related to intravenous drug use. Eight Federal studies and numerous scientific peer reviewed papers have conclusively established that syringe exchange programs reduce the incidence of HIV among people who inject drugs and their sexual partners and that syringe exchange reduces drug abuse. Syringe exchange programs connect people who use drugs to healthcare services including substance abuse treatment, HIV and viral hepatitis prevention services and testing, counseling, education, and support. AIDS United recommends that the Subcommittee maintain the current compromise language letting local jurisdictions make their own decision about using Federal funds to prevent HIV and viral hepatitis through the use of proven syringe exchange programs.

*HIV/AIDS Treatment*.—The Ryan White HIV/AIDS Treatment Extension Act, administered by the Health Resources and Services Administration (HRSA) provides services to more than 529,000 people living with and affected by HIV throughout the United States and its territories. It is the largest source of Federal funding solely focused on the delivery of HIV services and has provided the framework for our national response to the HIV epidemic. In recent years, funding for the Ryan White Program has not kept pace with the growing epidemic leading to waiting lists and other cost containment measures for the AIDS Drug Assistance Program (ADAP), increasing wait times to receive medical appointments and loss of some support services. Ryan White Programs are designed to compliment each other. As such, all parts of the Ryan White Program require substantial increased funding to address the true needs of the hundreds of thousands of people living with HIV who are uninsured, underinsured, or who lack financial resources for healthcare and require Ryan White Program services. AIDS United recommends that the Ryan White Program funding level be increased by $369.7 million to a total of $2.686 billion in fiscal year 2012.

*Ryan White Programs, Part A*.—This Part of the Ryan White Programs provides physician visits, laboratory services, case management, home-based and hospice care, and substance abuse and mental health services in the jurisdictions most affected by HIV/AIDS. These core medical and supportive services are critical to ensuring patients have access to and can effectively utilize life-saving therapies. AIDS United recommends funding for Part A at $751.9 million, an increase of $73.8 million in fiscal year 2012.

*Ryan White Programs, Part B (base)*.—This program ensures a foundation for HIV related healthcare services in each State and territory, including the critically important ADAP. Part B base grants (excluding ADAP). AIDS United recommends funding for Part B base grants at $495.0 million, an increase of $76.2 million in fiscal year 2012.

*Ryan White Programs, Part B (ADAP)*.—The AIDS Drug Assistance Program provides medications for treating people with HIV who cannot access Medicaid or private health insurance. According to the 2011 National ADAP Monitoring Project, ADAP provided drugs to about 190,936 clients in fiscal year 2009, including 33,672 new clients. As of April 15, 2011, 11 State ADAPs had waiting lists of 7,885 individuals and an additional 8 States had taken or were considering taking cost-containment measures. According to a respected pharmacoeconomic study that measures the funds needed to let State ADAPs provide a minimum clinical standard formulary the actual need for increases last year was more than $370.1 million. The

community recognizes the difficult budget environment and asks for a much lower amount. AIDS United recommends $991 million, the authorized amount for ADAP, an increase of $131 million, in fiscal year 2012.

*Ryan White Programs, Part C*.—This Part awards grants to community-based clinics and medical centers, hospitals, public health departments, and universities in 22 States and the District of Columbia under the Early Intervention Services program. These grants are targeted toward new and emerging sub-populations impacted by the HIV epidemic. Part C funds are particularly needed in rural areas where the availability of HIV care and treatment is still relatively new. AIDS United requests $272.2 million, the authorized amount for Part C an increase of $65.8 million, in fiscal year 2012.

*Ryan White Programs, Part D*.—Part D awards grants under the Comprehensive Family Services Program to provide comprehensive care for HIV positive women, infants, children, and youth and their affected families. These grants fund the planning of services that provide comprehensive HIV care and treatment and the strengthening of the safety net for HIV positive individuals and their families. AIDS United requests $83.1 million, an increase of $5.5 million, for Part D.

*Ryan White Programs, Part F, the AIDS Education and Training Centers (AETCs)*.—The AETCs train Ryan White program doctors, advanced practice nurses, physicians' assistants, nurses, oral health professionals, and pharmacists about HIV treatment, testing, viral hepatitis and more. The AETCs also ensure that education is available to primary healthcare providers who do not specialize in HIV but are asked to treat the increasing numbers of HIV positive patients who depend on them for care. AIDS United requests a total of $50 million, a $15.2 million increase in fiscal year 2012.

*Ryan White Programs, Part F, Dental Care*.—Dental care is a crucial service needed by people living with HIV disease. Oral health problems are often an early manifestation of HIV disease. Unfortunately oral health is often neglected by those who cannot afford, or do not have access to, proper medical care creating missed opportunities to find early HIV infections. AIDS United request $19 million, a $5.4 million increase, for this program in fiscal year 2012.

*Department of Health and Human Services, Minority AIDS Initiative*.—The Minority AIDS Initiative directly benefits racial and ethnic minority communities that are the most deeply affected by HIV/AIDS infection rates with grants to provide technical assistance, infrastructure support and strengthen the capacity of minority community based organizations to deliver high-quality HIV healthcare and supportive services. Communities of color are deeply affected by the HIV epidemic. The Minority AIDS Initiative funds needed programs throughout HHS agencies and is included in every Part of the CARE Act. It was authorized within the Ryan White Program for the first time in 2006. AIDS United requests a total of $610 million for the Minority AIDS Initiative.

*HIV/AIDS Research*.—Research to prevent, treat and ultimately cure HIV is vital to the domestic and global control of the disease. The United States through the National Institute of Health (NIH) must continue to take the lead in the research and development of new medicines to treat current and future strains of HIV. The NIH's Office of AIDS Research must continue its groundbreaking research in both basic and clinical science to develop a preventative vaccine, microbicides, and other scientific, behavioral, and structural HIV prevention interventions. Commitment to research will ultimately help to bring the epidemic under control decreasing the funds that must be spent on care and treatment of HIV. AIDS United requests that the NIH be funded at $35 billion in fiscal year 2012 and the AIDS portfolio be funded at $3.5 billion, a $410 million increase.

The HIV epidemic is a continuing health crisis in the United States. We must expand resources for our domestic HIV prevention, treatment and care, and research efforts to meet the goals of the National HIV/AIDS Strategy. On behalf of our more than 400 participating organizations, HIV positive Americans and those affected by this disease, AIDS United urges the subcommittee help us save lives by to fully funding the domestic response to the ongoing, tragic, HIV epidemic in the United States.

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## PREPARED STATEMENT OF THE ADULT CONGENITAL HEART ASSOCIATION

*Introduction*

The Adult Congenital Heart Association (ACHA)—a national non-for-profit organization dedicated to improving the quality of life and extending the lives of adults with congenital heart disease (CHD)—is grateful for the opportunity to submit written testimony regarding fiscal year 2012 funding for congenital heart research and

surveillance. We respectfully request $3 million for CHD surveillance at the Centers for Disease Control and Prevention (CDC) as well as additional CHD research at the National Heart, Lung and Blood Institute (NHLBI).

*Adult Congenital Heart Disease*

Congenital heart defects are the most common group of birth defects occurring in approximately 1 percent of all live births, or 40,000 babies a year. These malformations of the heart and structures connected to the heart either obstruct blood flow or cause it to flow in an abnormal pattern. This abnormal heart function can be fatal if left untreated. In fact, congenital heart defects remain the leading cause of birth defect related infant deaths.

Many infants born with congenital heart problems require intervention in order to survive. Intervention often includes one or multiple open-heart surgeries; however, surgery is rarely a long-term cure. The success of childhood cardiac intervention has created a new chronic disease—CHD. Thanks to the increase in survival, of the nearly 2 million people alive today with CHD, more than half are adults, increasing at an estimated rate of 5 percent each year. Few congenital heart survivors are aware of their high risk of additional problems as they age, facing high rates of neuro-cognitive deficits, heart failure, rhythm disorders, stroke, and sudden cardiac death, and many survivors require multiple operations throughout their lifetime. 50 percent of all congenital heart survivors have complex problems for which life-long care from congenital heart specialists is recommended, yet less than 10 percent of adult congenital heart patients receive recommended cardiac care. Delays in care can result in premature death and disability. In adults, this often occurs during prime wage-earning years.

*ACHA*

ACHA serves and supports the more than 1 million adults with CHD, their families and the medical community—working with them to address the unmet needs of the long-term survivors of congenital heart defects through education, outreach, advocacy, and promotion of ACHD research.

In order to promote life-saving research and accessible, appropriate and quality interventions which, in turn, will reduce the public health burden of this chronic disease, ACHA advocates for adequate funding of CDC initiatives relating to CHD, and encourages funding within the National Institutes of Health (NIH) for CHD research. ACHA continues to work with Federal and State policy makers to advance policies that will improve and prolong the lives of those living with CHD.

ACHA is also a founding member of the Congenital Heart Public Health Consortium (CHPHC). The CHPHC is a group of organizations uniting resources and efforts to prevent the occurrence of CHD and enhance and prolong the lives of those with CHD through targeted public health interventions by enhancing and supporting the work of the member organizations. Representatives of Federal agencies serve in an advisory capacity. In addition to ACHA, the Alliance for Adult Research in Congenital Cardiology, American Academy of Pediatrics, American College of Cardiology, American Heart Association, March of Dimes Foundation, National Birth Defects Prevention Network, and the National Congenital Heart Coalition are all members of the CHPHC.

*Federal Support for Congenital Heart Disease Research and Surveillance*

Despite the prevalence and seriousness of the disease, CHD data collection and research are limited and almost non-existent for the adult CHD population. In 2004, the NHLBI convened a working group on CHD, which recommended developing a research network to conduct clinical research and establishing a national database of patients.

In March 2010, the first CHD legislation passed as part of Patient Protection and Affordable Care Act (ACA).[1] The ACA calls for the creation of The National Congenital Heart Disease Surveillance System, which will collect and analyze nationally representative, population-based epidemiological and longitudinal data on infants, children, and adults with CHD to improve understanding of CHD incidence, prevalence, and disease burden and assess the public health impact of CHD. It also authorized the NHLBI to conduct or support research on CHD diagnosis, treatment, prevention and long-term outcomes to address the needs of affected infants, children, teens, adults, and elderly individuals. These provisions included in the ACA were originally in the Congenital Heart Futures Act (H.R. 1570/S.621, 111th Congress), which garnered bi-partisan support in both the House and Senate and was

[1] Patient Protection and Affordable Care Act, § 10411(b).

championed by Senators Richard Durbin (D-IL) and Thad Cochran (R-MS), Representative Gus Bilirakis (R-FL) and former Representative Zack Space (D-OH).

Recently, the National Center on Birth Defects and Developmental Disabilities included preventing congenital heart defects and other major birth defects, in its recently published 2011–2015 Strategic Plan, specifically recognizing the need for understanding the contribution of birth defects to longer term outcomes (i.e., beyond infancy) and the economic impact of specific birth defects.

*The National Congenital Heart Disease Surveillance System at CDC*

As survival improves, so does the need for population-based surveillance across the lifespan. Funding to support the development of the National Congenital Heart Disease Surveillance System through both a pilot adult surveillance program, and the enhancement of the existing birth defects surveillance system will be instrumental in driving research, improving interventional outcomes, improving loss to care, and assessing healthcare burden. In turn, the National Congenital Heart Disease Surveillance System can serve as a model for all chronic disease states.

The current surveillance system is grossly inadequate. There are only 14 States currently funded by the CDC to gather data on birth defects, presenting limitations in generalizing the information across the entire population. Thus, there are significant inconsistencies in the methods of collection and reporting across the various State systems which limits the value of the data. Given the absence of population-based data across the lifespan, the data we do have excludes anyone diagnosed after the age of one, as well as those who are lost to care. It is this population, those lost to care, that is of greatest concern, and most difficult to identify. Evidence indicates that those with CHD are at significant risk for heart failure, rhythm disorders, stroke, and sudden cardiac death as they age, requiring ongoing specialized medical care. For those who are lost to care, for reasons such as limited access to affordable or appropriate care or poor education about the need for ongoing care, they often return to the system with preventable advanced illness and/or disability. Population based surveillance across the life span is the only method by which these patients can be identified, and, as a result, appropriate intervention can be planned. ACHA is currently working with the CDC to address these concerns through the National Congenital Heart Disease Surveillance System.

ACHA requests that Congress provide the CDC $3 million in fiscal year 2012 to support data collection to better understand CHD prevalence and assess the public health impact of CHD. This level of funding will support a pilot adult surveillance system and allow for the enhancement of the existing birth defects surveillance system.

*Funding of Research Related to Congenital Heart Disease at NIH*

Our Nation continues to benefit from the single largest funding source for CHD research, the NIH. Yet, as a leading chronic disease, congenital heart research is significantly underfunded.

The NHLBI supports basic and clinical research to establish a scientific basis for the prevention, detection, and treatment of congenital heart disease. The Bench to Bassinet Program is a major effort launched by the NHLBI to hasten the pace at which heart research on genetics and basic science can be developed into new treatments across the life span for people with congenital heart disease. The overall goal is to provide the structure to turn knowledge into clinical practice, and use clinical practice to inform basic research.

ACHA urges Congress to support the NHLBI in efforts to continue its work with patient advocacy organizations, other NIH Institutes, and the CDC to expand collaborative research initiatives and other related activities targeted to the diverse life-long needs of individuals living with congenital heart disease.

*Summary*

Thank you for the opportunity to highlight this important disease. We know that you face many difficult funding decisions for fiscal year 2012 and hope that you consider addressing the life-long needs of those with CHD. By making an investment in the research and surveillance of CHD, the return will be seen through reduced healthcare costs, decreased disability and improved productivity in a population quickly approaching 2 million.

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## PREPARED STATEMENT OF THE ALLIANCE FOR AGING RESEARCH

Chairman Harkin and members of the Subcommittee, for 25 years the not-for-profit Alliance for Aging Research has advocated for medical research to improve the quality of life and health for all Americans as we grow older. Our efforts have

included supporting Federal funding of aging research by the National Institutes of Health (NIH), through the National Institute on Aging (NIA) and other NIH institutes and centers. The Alliance appreciates the opportunity to submit testimony highlighting the important role that the NIH plays in facilitating aging-related medical research activities and the ever more urgent need for increased Federal investment and focus to advance scientific discoveries to keep individuals healthier longer.

Research toward healthier aging has never been more critical for so many Americans. In January 2011, the first of the baby boomers began turning age 65. Older Americans now make up the fastest growing segment of the population. According to the U.S. Census Bureau, the number of people age 65 and older will more than double between 2010 and 2050 to 88.5 million or 20 percent of the population; and those 85 and older will increase three-fold, to 19 million, according to the U.S. Census Bureau. Late-in-life diseases such as type 2 diabetes, cancer, neurological diseases, heart disease, and osteoporosis are increasingly driving the need for healthcare services in this country. Many diseases of these aging are expected to become more prevalent as the number of older Americans increases. Preventing, treating or curing chronic diseases of the aging, is perhaps the single most effective strategy in reducing national spending on healthcare.

Consider that the number of Americans age 65 and older with Alzheimer's disease is projected to more than double by 2030. A report in the Journal of Clinical Oncology projected cancer incidence will increase by about 45 percent from 2010–2030, accounted for largely by cancer diagnoses in older Americans and minorities, and by 2030, people aged 65 and older will represent 70 percent of all cancer diagnoses in the United States. Currently, the average 75-year old has three chronic health conditions and takes five prescription medications. Six diseases—heart disease, stroke, cancer, diabetes, Alzheimer's and Parkinson's diseases—cost the United States over $1 trillion each year. In the absence of new discoveries to better treat and prevent osteoporosis, it is estimated to cost the United States $25.3 billion per year by 2025. According to an Alzheimer's Association report from 2010, research breakthroughs that slow the onset and progression of Alzheimer's disease could yield annual Medicare savings of $33 billion in 2020 and as much as $283 billion by 2050.

The rising tide of chronic diseases of aging threatens to overwhelm the U.S. healthcare system in the coming years. Research which leads to a better understanding of the aging process and human vulnerability to age-related diseases could be the key to helping Americans live longer, more productive lives, and simultaneously reduce the need for care to manage costly chronic diseases. Scientists who study aging now generally agree that aging is malleable and capable of being slowed. Rapid progress in recent years toward understanding and making use of this malleability has paved the way for breakthroughs that could increase human health in later life by opposing the primary risk factor for virtually every disease we face as we grow older—aging itself. Better understating of this "common denominator" of disease could usher in a new era of preventive medicine, enabling interventions that stave off everything from dementia to cancer to osteoporosis. As we now confront unprecedented aging of our population and staggering increases in chronic age-related diseases and disabilities, a modest extensions of healthy lifespan could produce outsized returns of extended productivity, reduced caregiver burdens, lessened Medicare spending, and more effective healthcare in future years.

The NIA leads national research efforts within the NIH to better understand the aging process and ways to better maintain the health and independence of Americans as they age. NIA is poised to accelerate the scientific discoveries. The science of aging is showing increasing power to address the leading public health challenges of our time. Leaders in the biology of aging believe it is now realistically possible to develop interventions that slow the aging process and greatly reduce the risk of many diseases and disabilities, including cancer, diabetes, Alzheimer's disease, vision loss and bone and joint disorders. While there has been great progress in aging research, a large gap remains between promising basic research and healthcare applications. Closing that gap will require considerable focus and investment. Key aging processes have been identified by leading scientists as potentially yielding crucial answers in the next 3–10 years. These include stress response at the cellular level, cell turnover and repair mechanisms, and inflammation.

A central theme in modern aging research—perhaps its key insight—is that the mutations, diets, and drugs that extend lifespan in laboratory animals by slowing aging often increase the resistance of cells, and animals, to toxic agents and other forms of stress. These discoveries have two main implications, each of which is likely to lead to major advances in anti-aging science in the near future.

First is the suggestion that stress resistance may itself be the facilitator (rather than merely the companion) of the exceptional lifespan in these animal models,

hinting that studies of agents that modulate resistance to stress could be a potent source of valuable clinical leverage and preventive medicines. Second is the observation that the mutations that slow aging augment resistance to multiple varieties of stress—not just oxidation, or radiation damage, or heavy metal toxins, but rather resistance to all of these at the same time.

The implication is that cells have "master switches," which, like rheostats that can brighten or dim all lights in a room, can tweak a wide range of protective intracellular circuits to tune the rate of aging differently in long-lived versus short-lived individuals and species. If this is correct, research aimed at identifying these master switches, and fine-tuning them in ways that slow aging without unwanted side-effects, could be the most effective way to postpone all of the physiological disorders of aging through manipulation of the aging rate itself. Researchers have formulated, and are beginning to pursue, new strategies to test these concepts by analysis of invertebrates, cells lines, laboratory animals and humans, and by comparing animals of species that age more quickly or slowly.

One hallmark of aging tissues is their reduced ability to regenerate and repair. Many tissues are replenished by stem cells. In some aged tissues, stem cell numbers drop. In others, the number of stem cells changes very little—but they malfunction. Little is currently known about these stem cell declines, but one suspected cause is the accumulation of "senescent" cells. Cellular senescence stops damaged or distressed cells from dividing, which protects against cancer. At advanced ages, however, the accumulation of senescent cells may limit regeneration and repair, a phenomenon that has raised many questions. Do senescent cells, for instance, alter tissue "microenvironments," such that the tissue loses its regenerative powers or paradoxically fuel the lethal proliferation of cancer cells?

A robust research initiative on these issues promises to illuminate the roots of a broad range of diseases and disabling conditions, such as osteoporosis, the loss of lean muscle mass with age, and the age-related degeneration of joints and spinal discs. The research is also essential for the development of stem cell therapies, the promise of which has generated much public excitement in recent years. This is because implanting stem cells to renew damaged tissues in older patients may not succeed without a better understanding of why such cells lose vitality with age. Importantly, research in this area would also help determine whether interventions that enhance cellular proliferative powers would pose an unacceptable cancer risk.

Acute inflammation is necessary for protection from invading pathogens or foreign bodies and the healing of wounds, but as we age many of us experience chronic, low-level inflammation. Such insidious inflammation is thought to be a major driver of fatal diseases of aging, including cancer, heart disease, and Alzheimer's disease, as well as of osteoporosis, loss of lean muscle mass after middle age, anemia in the elderly, and cognitive decline after 70. Just about everything that goes wrong with our bodies as we age appears to have an important inflammatory component, and low-level inflammation may well be a significant contributor to the overall aging process itself. As the underlying mechanisms of age-related inflammation are better understood, researchers should be able to identify interventions that can safely curtail its deleterious effects beginning in mid-life, broadly enhancing later-life, and with negligible risk of side effects.

While important advances have been made toward the goal of adding healthy years to life, it cannot be achieved in a timely way without significant financial support. In stark contrast to the rapidly rising costs of healthcare for the aging, we as a Nation are making a miniscule, and declining, investment in the prevention, treatment or cure of chronic diseases of aging. Out of each dollar appropriated to NIH only 3.6 cents goes toward supporting work of the NIA. Between fiscal year 2003 and fiscal year 2010, NIA-funded scientists saw a series of nominal increases and cuts that amounted to a 14.7 percent reduction in constant dollars. The November 11, 2010 issue of Nature notes that "[a]lthough the funding situation is tight all around for NIH-supported investigators, the NIA is in an exceptional predicament . . . . As both the United States and global populations age, the prevalence of chronic diseases such as cancer, heart disease and diabetes will also grow, along with neurodegenerative ailments . . . The NIA deals with age-related aspects of all of these."

An increase in funding for aging research is urgently needed to enable scientists to capitalize on the field's recent exciting discoveries. Advocates for age-related diseases like Alzheimer's disease and cancer in the past have called for congressional appropriations of $2 billion annually in order to achieve major breakthroughs in treating and curing those diseases. Thus, a goal of $2 billion annually in Federal funding for aging research on the basic underpinnings of aging over the next 3 to 10 years seems modest considering its great potential to lower overall disease risk (including Alzheimer's, cancer, and more) and add healthy years to life. For the NIA

in particular, an increase in funding would enable flexibility in supporting high-quality grant proposals that fall within the 20th percentile of submitted grants. In recent years, the percent of grant applications receiving funding by the NIA has dropped precipitously and currently only the top 9 percent are being funded. This means that many valuable projects are being set aside due to budget constraints, and many talented scientists who might make major contributions to aging research are being dissuaded from making this their life's work.

In addition to increased resources, the field would also benefit greatly from the creation of a trans-NIH initiative that could improve the quality and pace of research that advances the understanding of aging, its impact on age-related diseases, and the development of interventions to extend human healthspan. The initiative would be most effective if it included the representatives from the National Institute on Aging (NIA) and the major-disease focused institutes that have some role in aging research such as the National Institute of Neurological Disorders and Stroke (NINDS), National Heart, Lung, and Blood Institute (NHLBI), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the National Cancer Institute (NCI).

The field of aging research is poised to make transformational gains in the near future. Few if any areas for investing research dollars offer greater potential returns for public health. The Alliance for Aging Research supports funding the NIH at $35 billion in fiscal year 2012 with a minimum of $1.4 billion in funding for the NIA specifically. This level of support would allow the NIH and the NIA to adequately fund new and existing research projects, accelerating progress toward findings which could prevent, treat, slow the progression or even possibly cure conditions related to aging. With a Silver Tsunami of age driven chronic ailments looming as our population grows older, an increased emphasis on NIH's aging research activities has never been more urgent, with potential to impact so many Americans.

The payoffs from such focused attention and investment would be large and lasting. Therapies that delay aging would lessen our healthcare system's dependence on the relatively inefficient strategy of trying to redress diseases of aging one at a time, often after it is too late for meaningful benefit. They would also address the fact that while advances in lowering mortality from heart attack and stroke have dramatically increased life expectancy, they have left us vulnerable to other age-related diseases and disorders that develop in parallel, such as Alzheimer's disease, diabetes, and frailty. Properly focused and funded research could benefit millions of people by adding active, healthy, and productive years to life. Furthermore, the research will provide insights into the causes of and strategies for reducing the periods of disability that generally occur at the end of life.

Mr. Chairman, the Alliance for Aging Research thanks you for the opportunity to outline the challenges posed by the aging population that lie ahead as you consider the fiscal year 2012 appropriations for the NIH and we would be happy to furnish additional information upon request.

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PREPARED STATEMENT OF THE ALLIANCE OF INFORMATION AND REFERRAL SYSTEMS

The Alliance of Information and Referral Systems (AIRS) thanks you for providing the opportunity to submit testimony as you consider an fiscal year 2012 Labor-HHS, Education Appropriations bill. AIRS is the national voice of Information and Referral/Assistance (I&R/A) services and we provide a professional umbrella for over 1,200 I&R/A providers in both public and private organizations. Our primary purpose for submitting this testimony is to urge you not to cut Title IIIB funding of the Older Americans Act (OAA) as this provides Federal funding to the States for I&R. President Obama's proposed fiscal year 2012 budget emphasizes an increase in funding of $48 million for Title IIIB of the OAA.

Information and Referral brings people and services together. When people don't know where to turn, I&R/A is there for them. Last year, AIRS members answered more than 20 million calls for help. Comprehensive and specialized I&R/A programs help people in every community and operate as a critical component of the health and human services delivery system. I&R/A organizations have databases of programs and services and disseminate information through a variety of channels to individuals and communities. People in search of critical services such as, food, shelter, child care, work and job training, mental health support often do not know where to begin. More often than not, I&R/A organizations provide the answers.

We encourage you to support a $48 million increase in funding for Title III of the Older Americans Act and at a very minimum, not cut funding for I&R/A services. Thank you for your consideration.

PREPARED STATEMENT OF ALLUVIAM LLC

As a small business, we're writing to you today to bring to your attention what we feel is an urgent issue regarding the National Library of Medicine (NLM) decision to enter and unfairly compete with private industry in the market for software for firefighters and other emergency responders.

It has come to our attention that NLM has been funding development of a software program ("WISER") that they then give away at no cost to first responders. Apparently, NLM has been funding this effort for the last several years; in spite of the fact that there are at least 6 other companies within this market segment that provide similar decision support tools for first responders, and have been doing so prior to NLM entering the marketplace.

Providing government funding to a program that competes with an established segment of private industry kills jobs, stifles innovation and seems inherently unfair and contrary to the long term best interest of the emergency response community and a poor use of taxpayer money. With NLM's continued practices, there will cease to be any private industry R&D, innovation or other commercial investment in this market segment, effectively killing innovative technologies like ours, and the other companies currently providing products to this market. We have attempted to raise this issue to the attention of NLM without success, even though OMB circular A–76 (revised), supra note 182 at A–3 articulates a "Red Light for On-Line and Informational Government Activity: Principle 10: The government should exercise substantial caution in entering markets in which private-sector firms are active."

We feel that NLM is acting far outside its charter as a library information service. While we certainly applaud their efforts to provide concise and useful chemical and health related information to emergency responders and the public, it seems clear that with the development of software that they then give away, NLM has crossed the line of what it has been chartered to do, and is in conflict with OMB A–76, whose basic tenets are that "in the process of governing, the Government should not compete with its citizens" and that "a commercial activity is not a governmental function." These principles provide fundamental policy direction to agencies that the Government should not be in the business of providing commercial goods and services in competition with private markets.

We've attempted to contact NLM directly, but their position has been that they are fulfilling their duty of publishing Government information. We feel that developing and distributing analytical software, running focus groups to solicit user feedback, then promoting the software at the same industry trade shows that we attend is not consistent with publishing Government data. In fact, it is quite disingenuous, as if their intent was to publish the information, they could make the information widely available in any number of portable document or html formats that would be accessible from a range of devices, from laptops to smartphones, and would not put them in direct competition with private industry.

The Government doesn't provide emergency responders free emergency response vehicles, protective clothing, respirators, radios or chemical detectors, and neither should the Government be competing with established private industry companies that are already providing decision support software to emergency responders. I'm sure that Microsoft would take umbrage with the Department of Commerce if Commerce decided to develop and then give away a free spreadsheet program simply because they thought it would benefit U.S. business.

We respectfully request that you look into defunding this NLM program and get NLM out of the business of competing with private industry for this type of software. Since NLM started promoting their software, we've had existing customers and potential clients wonder why they should pay for software that NLM makes available for free.

By way of background, as part of the Homeland Security Act of 2002, Public Law 107–296, known as the SAFETY ACT, Congress passed the Act as a mechanism to foster and support the development of innovative and effective anti-terrorism technology. Today, our company is one of a few companies in the United States that has a CBRNE/IED decision support system that has earned SAFETY ACT certification and designation as an approved anti-terrorism technology. We've spent over 5 years, and nearly 25,000 man hours—all at our own private expense, developing, fielding and deploying our technology. Today our technology, HazMasterG3® is deployed with the FBI, the Secret Service Presidential Protective Detail, every CST/WMD team in the country, the USMC's CBIRF, DHS, US Special Forces, and many civilian fire departments, HAZMAT teams and bomb squads throughout the United States.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

The American Academy of Family Physicians representing 97,600 family physicians, residents, and medical students nationwide, is pleased to submit this statement for the record in support of our funding priorities for inclusion in the fiscal year 2012 appropriations bill.

The AAFP urges the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education to make a robust fiscal year 2012 investment in our Nation's primary care physician workforce in order to ensure that it is adequate to provide efficient, effective healthcare delivery addressing access, quality and value.

We recognize the difficult decisions which our Nation's budgetary pressures present and remain confident that wise Federal investment will help to transform healthcare to achieve optimal, cost-efficient health for everyone. Specifically, we recommend that the Committee provide the Health Resources and Services Administration and the Agency for Healthcare Research and Quality with the fiscal year 2012 funding levels called for in the President's budget request.

*Health Resourses and Services Administration*

HRSA is the Federal agency chiefly responsible for improving access to healthcare services for Americans who are uninsured, isolated or medically vulnerable. HRSA's mission also calls for a skilled health workforce, and the AAFP supports their efforts to train the necessary primary care physician workforce. Primary care physicians will serve as a strong foundation for a more efficient and effective healthcare system.

The AAFP recommends that the Committee provide at least $449.5 million for all of the Health Professions Training Programs authorized by Title VII of the Public Health Service Act and administered by the Health Resources and Services Administration (HRSA) as requested in the President's fiscal year 2012 budget.

Within that line, we urge you to provide at least:

—$140 million for Health Professions Primary Care Training and Enhancement authorized under Title VII, Section 747 of the Public Health Service Act;

—$10 million for Teaching Health Centers development grants authorized by Title VII, Section 749A; and

—$4 million for Title VII, Section 749B Rural Physician Training Grants.

*Title VII Health Professions Training Programs*

As the only medical specialty society devoted entirely to primary care, the AAFP appreciates this Committee's commitment to a strong primary care physician workforce. We are concerned that a failure to provide adequate funding for the Title VII, Section 747, the Primary Care Training and Enhancement (PCTE) program, would destabilize ongoing efforts to increase education and training support for family physicians, exacerbating primary care shortages and further straining the Nation's healthcare system.

Title VII, Section 747 primary care training grants to medical schools and residency programs have for decades helped to increase the number of physicians who select primary care specialties and work in underserved areas. A study published in the Annals of Family Medicine on the impact of Title VII training programs on community health center staffing and national health service corps participation found that physicians who work with the underserved in CHCs and NHSC sites are more likely to have trained in Title VII-funded programs.[1] Title VII primary care training grants are vital to departments of family medicine, general internal medicine, and general pediatrics; strengthen primary care curricula; and offer incentives for training in underserved areas.

In the coming years, medical services utilization is likely to rise given the increasing and aging population as well as the insured status of more of the populace. These demographic trends will cause primary care physician shortages to worsen. We urge the Committee to increase the level of Federal funding for primary care training to reinvigorate medical education, residency programs, as well as academic and faculty development in primary care to prepare physicians to support the patient centered medical home.

*Teaching Health Centers*

The AAFP has long called for reforms to graduate medical education programs in order to encourage the training of primary care residents in non-hospital settings where most primary care is delivered. An excellent first step is the innovative

[1] Rittenhouse DR, et al. Impact of Title VII training programs on community health center staffing and National Health Service Corps participation. Ann Fam Med. 2008;6(5):397–405.

Teaching Health Centers program authorized under Title VII, Section 749A to increase primary care physician training capacity now administered by HRSA.

Federal financing of graduate medical education has led to training which occurs mainly in hospital inpatient settings in spite of the fact that most patient care is delivered outside of hospitals in ambulatory settings across the Nation. The Teaching Health Center program provides resources to any qualified community based ambulatory care setting that operates a primary care residency program including federally Qualified Health Centers or federally Qualified Health Centers Look Alikes, Rural Health Clinics, Community Mental Health Centers, a Health Center operated by the Indian Health Service, or a center receiving Title X grants.

We were pleased that the Patient Protection and Affordable Care Act authorized a mandatory appropriations trust fund of $230 million over 5 years to fund the operations of Teaching Health Centers. However, if this program is to be effective, there must be funds for the planning grants to establish newly accredited or expanded primary care residency programs.

*Rural Health Needs*

Another important HRSA Title VII grant program is the Rural Physician Training Grants program to help medical schools to recruit students most likely to practice medicine in rural communities. This modest program authorized by Title VII, Section 749B will help provide rural-focused training and experience and increase the number of recent medical school graduates who practice in underserved rural communities.

*National Health Service Corps*

The National Health Service Corps (NHSC) recruits and places medical professionals in Health Professional Shortage Areas to meet the need for healthcare in rural and medically underserved areas. The NHSC provides scholarships or loan repayment as incentives for practitioners to enter primary care and provide healthcare to Americans in Health Professional Shortage Areas. By addressing medical school debt burdens, the NHSC also helps to ensure wider access to medical education opportunities.

The Government Accountability Office (GAO–01–1042T) described the NHSC as "one safety-net program that directly places primary care physicians and other health professionals in these medically needy areas." Currently most of the more than 7 million people who rely on NHSC clinicians for their healthcare needs would not have access to care without the NHSC.

Since its inception in 1972, the NHSC has helped place 37,000 primary care health professionals in underserved communities across the country, many of whom remain in these areas following the completion of their service. According to the fiscal year 2009 Health Resources and Services Administration budget justification, over 75 percent of the clinicians placed by the NHSC in underserved areas continued to serve in their position for at least 1 year after the completion of their service obligation.

Today, there are over 9,000 vacancies at NHSC approved sites across the country with more added every day, yet funding is inadequate to fill all of these needed slots.

The AAFP recommends that Committee provide at least the President's requested level of $418.5 million for the National Health Service Corps for fiscal year 2012 to include $295 million in funds made available for NHSC operations, scholarships and loan repayments by the Affordable Care Act.

*Agency for Heatlhcare Research and Quality*

The mission of the Agency for Healthcare Research and Quality (AHRQ)—to improve the quality, safety, efficiency, and effectiveness of healthcare for all Americans—closely mirrors the AAFP's own mission. AHRQ is a small agency with a huge responsibility for research to support clinical decisionmaking, reduce costs, advance patient safety, decrease medical errors and improve healthcare quality and access. Family physicians recognize that AHRQ has a critical role to play in patient-centered outcomes research also known as comparative effectiveness research.

*Patient-Centered Outcomes Research*

AHRQ's investment in patient-centered outcomes research will help Americans make the informed decisions we must make to focus on paying for quality rather than quantity. By determining what has limited efficacy or does not work, this important research can spare patients from tests and treatments of little value. Today, patients and their physicians face a broad array of diagnostic and treatment options without the scientific evidence needed to know what procedure or which drug is most likely to succeed or how best to time a given therapy. AHRQ is supporting re-

search to answer those questions so that physicians and their patients can make the choices about care that are most likely to succeed. AHRQ also supports the essential research into the prevention of medical errors and reducing hospital-acquired infections.

*Medical Liability Demonstrations*

Solving the professional medical liability has long been one of the AAFP's highest priorities. Although the medical liability demonstrations announced by AHRQ in fiscal year 2010 are quite modest, we support the effort to find alternatives to the current medical tort system.

*Primary Care Extension Program*

The AAFP supports the Primary Care Extension Program to be administered by AHRQ to provide support and assistance to primary care providers about evidence-based therapies and techniques so that providers can incorporate them into their practice. As AHRQ develops more scientific evidence on best practices and effective clinical innovations, the Primary Care Extension Program will disseminate them to primary care practices across the Nation in much the same way as the Federal Cooperative Extension Service provides small farms with the most current information and guidance.

The AAFP recommends that the Committee provide at least $405 million for AHRQ in fiscal year 2012. In addition, we ask that the Primary Care Extension program receive the authorized level of $120 million in fiscal year 2012.

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PREPARED STATEMENT OF THE AMERICAN ACADEMY OF PHYSICIAN ASSISTANTS

On behalf of the nearly 80,000 clinically practicing physician assistants in the United States, the American Academy of Physician Assistants is pleased to submit comments on fiscal year 2012 appropriations for Physician Assistant (PA) educational programs that are authorized through Title VII of the Public Health Service Act.

AAPA believes that the Title VII Health Professions Programs are essential to placing health professionals in medically underserved communities. According to the Health Resources and Services Administration, an additional 301,000 healthcare practitioners are needed to alleviate existing professional shortages. One of three healthcare professions providing primary medical care in the United States, the PA profession is deemed by many economists to be among the fastest growing professions. Title VII will not only encourage greater numbers of students to enter PA educational programs; it will also help increase access to care for millions of Americans who live in medically underserved areas.

As a member of the Health Professions and Nursing Education Coalition (HPNEC), AAPA respectfully supports the coalition's request to fund Title VII health professions education program at the President's request of $449,454,000.

AAPA recommends that Congress continue its support to grow the PA primary care work force. The U.S. healthcare system will require a much-expanded primary healthcare workforce, both in the private and public healthcare markets. For example, the National Association of Community Health Centers' March 2009 report, Primary Care Access: An Essential Building Block of Health Reform, predicts that in order to reach 30 million patients by 2015, health centers will need at least an additional 15,585 primary care providers, just over one-third of whom are non-physician primary care professionals.

A review of PA graduates from 1990–2009 demonstrates that PAs who have graduated from PA educational programs supported by Title VII are 67 percent more likely to be from underrepresented minority populations and 47 percent more likely to work in a rural health clinic than graduates of programs that were not supported by Title VII. Additionally, a study by the UCSF Center for California Health Workforce Studies found a strong association between physician assistants exposed to Title VII during their PA educational preparation and those who reported working in a federally qualified health center or other community health center.

Title VII programs are essential to the development and training of primary healthcare professionals and, in turn, provide increased access to care by promoting healthcare delivery in medically underserved communities. Title VII funding is especially important for PA programs as it is the only Federal funding available on a competitive application basis to these programs.

We wish to thank the members of this subcommittee for your historical role in supporting funding for the health professions programs, and we hope that we can count on your support to maintain funding to these important programs in fiscal year 2011 at the President's request.

*Overview of Physician Assistant Education*

Physician assistant educational programs are located within schools of medicine or health sciences, universities, teaching hospitals, and the Armed Services. All PA educational programs are accredited by the Accreditation Review Commission on Education for the Physician Assistant.

The typical PA program consists of 26 months of instruction, and the typical student has a bachelor's degree and about 4 years of prior healthcare experience. The first phase of the program consists of intensive classroom and laboratory study. More than 400 hours in classroom and laboratory instruction are devoted to the basic sciences, with over 75 hours in pharmacology, approximately 175 hours in behavioral sciences, and nearly 580 hours of clinical medicine.

The second year of PA education consists of clinical rotations. On average, students devote more than 2,000 hours, or 50 to 55 weeks, to clinical education, divided between primary care medicine—family medicine, internal medicine, pediatrics, and obstetrics and gynecology—and various specialties, including surgery and surgical specialties, internal medicine subspecialties, emergency medicine, and psychiatry. During clinical rotations, PA students work directly under the supervision of physician preceptors, participating in the full range of patient care activities, including patient assessment and diagnosis, development of treatment plans, patient education, and counseling.

After graduation from an accredited PA program, physician assistants must pass a national certifying examination developed by the National Commission on Certification of Physician Assistants. To maintain certification, PAs must log 100 continuing medical education hours every 2 years, and they must take a recertification exam every 6 years.

*Physician Assistant Practice*

By design, PAs always practice in teams with physicians, extending the reach of medicine and the promise of improved health to the most remote and in-need communities in our Nation. The PA profession's patient-centered, team-based approach reflects the changing realities of healthcare delivery and fits well into the patient-centered medical home model of care, as well as other integrated models of care management.

PAs practice in various medical setting across the country and in a recent survey conducted by the AAPA it is estimated that:

—Nineteen percent of all PAs practice in non-metropolitan areas where they may be the only full-time providers of care (State laws stipulate the conditions for remote supervision by a physician);
—41 percent of PAs work in urban and inner city areas;
—40 percent of PAs are in primary care;
—44 percent of PAs worked in group practices or solo physician offices: and
—80 percent of PAs practice in outpatient settings.

Nearly 300 million patient visits were made to PAs in 2009. PAs often provide autonomous medical care, have their own patient panels, and are granted prescribing authority in all 50 States.

*Critical Role of Title VII Public Health Service Act Programs*

Title VII programs promote access to healthcare in rural and urban underserved communities by supporting educational programs that train health professionals in fields experiencing shortages, improve the geographic distribution of health professionals, increase access to care in underserved communities, and increase minority representation in the healthcare workforce.

Title VII programs are the only Federal educational programs that are designed to address the supply and distribution imbalances in the health professions. Since the establishment of Medicare, the costs of physician residencies, nurse training, and some allied health professions training have been paid through Graduate Medical Education (GME) funding. However, GME has never been available to support PA education. More importantly, GME was not intended to generate a supply of providers who are willing to work in the nation's medically underserved communities—the purpose of Title VII.

Furthermore, Title VII programs seek to recruit students who are from underserved minority and disadvantaged populations, which is a critical step toward reducing persistent health disparities among certain racial and ethnic U.S. populations. Studies have found that health professionals from disadvantaged regions of the country are three to five times more likely to return to underserved areas to provide care.

*Title VII Support of PA Educational Programs*

Federal support for Title VII is authorized through section 747 of the Public Health Service Act. It is the only Federal funding available to PA educational programs. This funding is specifically targeted for primary care education and training programs and is designed to train PAs for practice in urban or rural medically underserved areas. The program is essential to the development and training of the Nation's health workforce and is critical to providing continued health services to both underserved and minority communities. It also encourages PAs to return to these environments with the greatest need after they have completed their training, being one of the best recruitment tools to date.

Title VII was last reauthorized in 2010 under the Patient Protection and Affordable Care Act. Now there is a critical need to fund the Title VII program through the appropriations process to increase the supply, diversity, and distribution of PAs and primary care practitioners in medically underserved communities.

Support for educating PAs to practice in underserved communities is particularly important given the market demand for physician assistants. Without Title VII funding to expose students to underserved sites during their training, PA students are far more likely to practice in the communities where they were raised or attended school. Title VII funding is a critical link in addressing the natural geographic maldistribution of healthcare providers by exposing students to underserved sites during their training, where they frequently choose to practice following graduation. Currently, 36 percent of PAs met their first clinical employer through their clinical rotations.

Changes in the healthcare marketplace reflect a growing reliance on PAs as part of the healthcare team. Currently, the supply of physician assistants is inadequate to meet the needs of society, and the demand for PAs is expected to increase. A 2006 article in the Journal of the American Medical Association (JAMA) concluded that the Federal Government should augment the use of physician assistants as physician substitutes, particularly in urban Community Health Centers (CHCs) where the proportional use of physicians is higher. The article suggested that this could be accomplished by adequately funding Title VII programs. Additionally, the Bureau of Labor Statistics projects that the number of available PA jobs will increase 39 percent between 2008 and 2018.

Title VII funding has provided a crucial pipeline of trained PAs to underserved areas. Recognizing that the PA educational programs received significantly less funding than other programs in the cluster on primary care medicine and dentistry, the 111th Congress established a 15 percent set-aside for PA education within the section 747 cluster on primary care during reauthorization of the Title VII Programs.

*Recommendations on Fiscal Year 2012 Funding*

The American Academy of Physician Assistants urges members of the Appropriations Committee to consider the inter-dependency of all public health agencies and programs when determining funding for fiscal year 2012. For instance, while it is critical, now more than ever, to fund clinical research at the National Institutes of Health (NIH) and to have an infrastructure at the Centers for Disease Control and Prevention (CDC) that ensures a prompt response to an infectious disease outbreak or bioterrorist attack, the good work of both of these agencies will go unrealized if the Health Resources and Services Administration (HRSA) is inadequately funded.

HRSA administers the "people" programs, such as Title VII, that bring the results of cutting edge research at NIH to patients through providers such as PAs who have been educated in Title VII-funded programs. Likewise, the CDC is heavily dependent upon an adequate supply of healthcare providers to be sure that disease outbreaks are reported, tracked, and contained.

Thank you for the opportunity to present the American Academy of Physician Assistants' views on fiscal year 2012 appropriations.

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PREPARED STATEMENT OF THE AMERICAN ACADEMY OF SLEEP MEDICINE

Dear Chairman Harkin and Members of the Committee: The American Academy of Sleep Medicine (AASM), an organization composed of over 9,700 sleep care professionals and the accrediting agent for over 2,200 accredited sleep care centers, is pleased to provide our views on the HHS research budget for fiscal year 2012. As the leader in setting standards and promoting excellence in evidence-based sleep medicine healthcare, education, and research, we can attest to the fact that the work of the National Institutes of Health (NIH) has proven to be vital in allowing our members to provide effective sleep care services.

The AASM supports funding levels for the NIH that will allow the careful continuation of the current research agenda. Savings should be realized from speeding the research process, vigilant screening of new research proposals, and an honest examination of spending for ongoing research. Key criteria in reviewing ongoing research should include both the potential patient benefit and whether a stoppage today will result in a restart on some future tomorrow that will duplicate the initial research and correspondingly duplicate the previously incurred expenses.

Even in this economic climate, the value of the NIH as an incubator for advancing scientific and healthcare knowledge has to be recognized. Efforts need to be made to continue spending that: Enhances our ability to identify and provide beneficial patient care services; moves information from the white coats of the research laboratory to the white coats at the patient's bedside; and ensures a continual pipeline of research professionals.

Even with this realization, however, we are not blind to the reality of the need to pare the Federal budget. We accept the fact that the totality of NIH spending is not immune to budget cuts. The key in looking at this budget is to take steps that do not fall into the category of being unexamined cuts that are made without taking into account the repercussions of these budget-based actions. While across-the-board cuts provide a clean and arguably simple process for trimming the budget, taking a budget axe to the NIH has the very real counter-productive potential of stopping prominent, patient oriented research in mid-stream and creating a gap in the research field. These unintended consequences carry significant negative implications that our patients and our society can ill afford.

Examples of ongoing sleep related and other research recently funded by the NIH illustrate the difficulty of budget slashing that fails to take into account the three above noted bullet points. The sleep related research identified at this site (set out below) provides clear examples of ongoing research with indisputable patient care implications. This is the type of research that needs to be completed and not simply restarted at some future point with duplicated expenses. It also bears noting that the research funding on the connection between sleep apnea treatment and cardiovascular disease resulted in 12 new jobs. These are the types of jobs that build the cadre of future key researchers. The importance of this cannot go unnoticed. For the future vitality of our society, we can ill afford another "Sputnik moment" by failing to maintain the research pipeline and the personnel that are essential to its maintenance and growth.

The American Academy of Sleep Medicine urges careful consideration when addressing budget issues; the Academy is available as a resource on how those issues are connected with care for patients with sleep disorders. Please feel free to direct questions for the AASM to Bruce Blehart, Director of Health Policy and Government Relations, at BBlehart@aasmnet.org.

Nirinjini Naidoo, Ph.D.
Research Assistant Professor of Medicine, University of Pennsylvania, Philadelphia, PA
Biomarker for Sleep Loss: A Proteomic Determination
Administered by the NHLBI Division of Lung Diseases, Lung Biology and Disease Branch
Fiscal Year 2009 Recovery Act Funding: $500,000

*Additional Funding*

Biomarker for Sleep Loss: A Proteomic Determination
Administered by the NHLBI Division of Lung Diseases, Lung Biology and Disease Branch
Fiscal Year 2010 Recovery Act Funding: $500,000
Total funding: $1,000,000

Dr. Nirinjini Naidoo grew up in South Africa, where she drew daily inspiration from her family. Her father, a classical scholar, fed the young Dr. Naidoo's desire to read voraciously. Over time, she was drawn to books about energetic, creative women in science like Marie Curie and Rosalind Franklin. "Those stories really stuck with me," Dr. Naidoo said, noting that she is intensely curious and always "wants to know." The attributes suit her well as a frontier scientist in the world of sleep research. They may be at odds with her getting sleep, though, she admitted. "I sometimes wake up at 3 a.m. and send myself an e-mail about a newly hatched experiment."

*Research Focus*.—Humans spend about one-third of their lives asleep. But according to Dr. Naidoo, many of us do not appreciate that sleep is a vital part of healthy living and that our bodies accomplish several important tasks during that time. "Sleep is definitely not just an 'off' state," Dr. Naidoo said. "Research is telling us that our bodies are actually very busy when we sleep—re-stocking cellular compo-

nents, consolidating memories, and strengthening connections between nerve cells in the brain." Dr. Naidoo's research interest in sleep came fairly recently. A chemist who specializes in studying the structures and functions of proteins, she did postdoctoral research in the area of circadian rhythms—the 24-hour cycles that tune body systems with the light-and-dark cycle of our environment. Matching her scientific skills to what she saw as a fascinating question, Dr. Naidoo decided to look at the molecular features of sleep. What proteins are talking to each other? Which genes and molecules are active . . . or asleep themselves?

*Grant Close-Up*.—Dr. Naidoo's Recovery Act grant is a comprehensive search for "biomarkers" of sleep loss. Biomarkers are substances that indicate a particular state or process. They can be used to signify health problems—high cholesterol is one, for example. Or, biomarkers can denote a normal activity, like growth or sleep. But as useful as they sound, accurate biomarkers can be very difficult to find. That's because so many factors can affect how the body functions: our diet, whether we exercise, what medicines we take, and our genetic make-up. All these components can influence body systems independently of each other, which makes finding telltale biomarkers challenging.

You could think of Dr. Naidoo's approach as a variant on the childhood matching game "same and different." In earlier experiments, she and other researchers identified people who were different types of sleepers. Some recovered quickly and fully from sleep deprivation and could easily pass a question-and-answer knowledge test. Others, Dr. Naidoo explained, reacted very differently and made several mistakes on the same relatively simple test. In that earlier experiment, she and leading sleep researcher Allan I. Pack, Ph.D., also at the University of Pennyslvania, collected blood samples from all the study participants. They will now use a high-tech chemical analytical tool called mass spectrometry to search for molecules that differ between the two different types of sleepers.

After 2 years, Dr. Naidoo plans to have a profile of sleepiness—a snapshot of all the proteins and other molecules in blood that define sleepy or non-sleepy. In general, biomarkers can useful non-invasive tools for detecting illness and spotting disease risk. She hopes the sleep biomarkers will help researchers and physicians track sleep deprivation or the role of sleep loss in various diseases.

*Economic Impact*.—Dr. Naidoo used Recovery Act funds to buy several pieces of state-of-the-art scientific equipment, such as a powerful microscope and machines that screen blood and other fluids for their component proteins. She is especially excited about the fact that this funding is enabling her to bring new blood into the field of sleep research. "One of my new research specialists working on this project—a recent chemistry graduate—is now applying to graduate school to study sleep," said Dr. Naidoo. "It's so important that we get new thinking and new methods into understanding one of the most fundamental processes in our daily lives."

*By Alison Davis, Ph.D.—Last Updated: August 10, 2010*

Susan Redline, M.D., M.P.H.
Professor, Case Western Reserve University, Cleveland, Ohio
PHASE II Trial of Sleep Apnea Treatment to Reduce Cardiovascular Morbidity
Administered by the NHLBI Division of Lung Diseases, National Center on Sleep Disorders Research
Fiscal Year 2009 Recovery Act Funding: $2,190,865

*Research Focus*.—More than 12 million American adults have sleep apnea, a disorder where breathing repeatedly pauses or becomes shallow during sleep. The condition can double or even quadruple a person's risk of heart disease, high blood pressure, and stroke. Despite sleep apnea's prevalence and risks, an estimated 1 in 10 patients isn't diagnosed or treated. One reason for the low treatment rate is that doctors lack evidence about which sleep apnea therapies actually reduce cardiovascular disease risk. On top of that, some patients who do get diagnosed may not follow through with their prescribed treatment because they think it's uncomfortable or awkward-looking.

*Grant Up Close*.—Supported by an NHLBI Recovery Act funded Grand Opportunity grant, Susan Redline, M.D., M.P.H., is leading the first large-scale study in the United States to determine whether two common sleep apnea treatments reduce patients' risk of cardiovascular disease. Her team is recruiting 1,400 cardiovascular clinic patients who have moderate to severe sleep apnea and monitoring their sleep at home.

One group of patients will receive extra oxygen at night. Dr. Redline wants to know if this simple therapy reduces the health risks of sleep apnea by compensating for lost breaths, or raises the risks by not increasing patients' breath rates. A second group of patients will receive another common sleep apnea treatment, continuous positive airway pressure (CPAP), in which a machine blows air into the throat each

night through a mask worn over the nose and mouth. Although both CPAP and oxygen therapy are widely used, researchers haven't yet established whether using them to treat sleep apnea reduces cardiovascular disease risk. Dr. Redline's team will conduct comparative effectiveness research into the two treatments. A third group of patients will not undergo sleep apnea treatment.

All three groups will have their early signs of cardiovascular disease treated. Together, these groups will help Dr. Redline's team begin to determine whether treating sleep apnea can change patients' risk of cardiovascular disease. The results of the study will also set the stage for advanced clinical trials. Her goal is to help doctors integrate sleep medicine into routine cardiology care and develop evidence-based treatment guidelines, ultimately lowering deaths from sleep apnea-related heart disease.

*"A true multidisciplinary team".*—The study includes cardiologists and sleep medicine experts from four sites across the country. Some of them already collaborate through the NHLBI's Sleep Heart Health Study, a multi-center population study examining the cardiovascular effects of sleep apnea. "My colleagues include engineers, informaticians, physiologists, geneticists, epidemiologists and clinicians," said Dr. Redline. "I meet regularly with these diverse and talented people to review our common or overlapping goals."

*Economic Impact*.—Thanks to Recovery Act funds, the team was able to create 12 new jobs. They also bought new equipment, including portable devices to measure patients' blood pressure and other responses to sleep apnea treatments. Because the trial involves several sites, the team developed an advanced web-based data management platform. Researchers beyond the study can adapt it to their own needs so they can start new studies faster and manage them more efficiently.

*Broadening her Dream*.—"As a child, I wanted to be a general physician, with a shingle on my door, and simply help people feel better," said Dr. Redline. She was accepted into an accelerated 6-year medical honors program when she was just 15 years old. Then her dream began to evolve. "As I was exposed to academic medicine and powerful epidemiological methods, I realized that I wanted to work on broad issues that impact the health of the community, especially the underserved," she said. Learning about how the environment can impact people's lung health, and seeing how common but poorly understood sleep disorders were, Dr. Redline decided that researching sleep medicine was the way she could help improve public health.

*Outside the Lab*.—Dr. Redline likes to spend time reading, biking, and kayaking.

*Aiming High*.—Dr. Redline wants to find a practical treatment for sleep apnea that improves people's sleep quality and lowers their risk of heart disease; and to uncover genes that contribute to sleep apnea, so researchers can develop better targeted treatments.

*By Stephanie Dutchen—Last Updated: August 10, 2010.*

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## PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH

The American Association for Cancer Research (AACR) is the world's oldest and largest scientific organization focused on every aspect of high-quality, innovative cancer research. The mission of the AACR and its more than 33,000 members is to prevent and cure cancer through research, education, communication and collaboration. We thank the United States Congress for its longstanding, bipartisan support for the National Institutes of Health (NIH) and for its commitment to funding cancer research.

The AACR urges the Senate to continue this commitment to NIH in the coming fiscal year. To sustain the momentum generated through past investments in biomedical research and to improve the health of all Americans, the AACR recommends $35 billion for the NIH, including $5.795 billion for the National Cancer Institute (NCI) in fiscal year 2012. This level of funding is needed to sustain the momentum generated through regular appropriations and the additional funds from the American Recovery and Reinvestment Act of 2009.

*Cancer research saves lives*

The Nation's historical investment in cancer research is unquestionably having a remarkable impact. We are in a time of unprecedented scientific opportunity: we are now able to accelerate progress against cancer by translating a wealth of scientific discoveries, such as the mapping of the human genome, into new treatments and preventive strategies for cancer. We can continue to make significant advances—but only if we continue to allocate the required resources to do so. Reversing recent cuts and providing stable, increased funding will greatly aid a full-scale national effort to lessen the burden of the more than 200 diseases we collectively call cancer.

This year marks the 40th anniversary of the enactment of the National Cancer Act. In the four decades since President Richard M. Nixon signed this landmark legislation: Annual cancer death rates in the United States have declined steadily; the 5-year survival rate for all cancers combined has improved to more than 65 percent; the 5-year survival rate for all childhood cancers combined has increased from 30 percent in 1976 to 80 percent today; and 12 million Americans have become cancer survivors, compared with only 3 million in 1971.

These remarkable achievements are a direct result of our national commitment to funding cancer research, screening, and treatment programs at the NCI, NIH, and other agencies across the Federal Government. Yet this substantial progress will be slowed if the Federal commitment to funding for critical cancer research priorities is not maintained.

In the last 40 years, innumerable advances in basic science, cancer prevention and detection, therapeutic development and clinical cancer management have been achieved. While these advances are too numerous to list here, the following cancer research advancements occurred in 2010 alone, as a direct result of funding by the NIH:

—12 new cancer drugs or cancer drug uses were approved by the FDA, including the first-ever therapeutic vaccine, Provenge, which was approved for men with metastatic prostate cancer; and

—biological knowledge of tumor genes and the tumor microenvironment has led to the development of drugs that inhibit specific genetic targets, which may result in new treatments for multiple types of cancers, including melanoma and lymphoma.

The opportunities and the science currently underway promise many more successes in improved treatment and prevention of cancer. Currently, there are: More than 800 cancer therapies from industry in some step of the trial process; more than 2,000 clinical trials accepting children and young adults in progress; and more than 200 cancer prevention trials open.

Right now, we are facing a precipice with cancer. The biological knowledge and the technological advances have positioned scientists at an inflection point. To pull back from Federal investment is to abandon science in a time when scientists will be able to make quantum leaps in prevention and treatment of cancer. It is imperative that sustained appropriations be provided to the NIH so that these opportunities and other promising areas such as personalized medicine and cancer prevention do not slip from our grasp.

*Cancer remains a significant public health challenge*

We have made significant progress against cancer in recent years, but as long as cancer remains the leading cause of death for Americans under age 85 and the second-leading cause of death overall, we cannot afford to slow down. In 2011, 1.5 million new cancer cases will be diagnosed and more than half a million American lives will be lost to this terrible collection of diseases.

Moreover, the United States is facing what some have termed a "cancer tsunami" as the baby boom generation reaches age 65 this year. More than three-quarters of all cancers are diagnosed in individuals aged 55 and older, and the number of cancer cases is estimated to approach 2 million new cases per year by 2025. This will dramatically exacerbate the current problems with the healthcare system and it will undoubtedly hit those who can least afford it—elderly, medically underserved, and minority populations—the hardest.

Beyond the enormous toll cancer takes on the lives of affected individuals and their loved ones, cancer places a heavy burden on the U.S. economy, costing an estimated $228 billion in direct medical costs and indirect costs associated with lost productivity due to illness and premature death.

*Targeted therapies as the future of cancer treatment*

The future of cancer treatment lies in the ability to treat patients based on the specific characteristics of a patient and his or her cancer—often referred to as personalized medicine. Cancer research is leading the way toward the realization of personalized medicine, in no small part thanks to Federal investment in deciphering the fundamental biology of cells, such as the Human Genome Project and, more recently, The Cancer Genome Atlas, an NCI project that is identifying important genetic changes involved in cancer.

The NCI is investing in efforts that will facilitate the translation of this wealth of basic knowledge into new treatments, including validating cancer biomarkers for prognosis, metastasis, treatment response, and progression; accelerating the identification and validation of potential cancer molecular targets; minimizing the

toxicities of cancer therapy; and integrating the clinical trial infrastructure for speed and efficiency.

*Accelerating progress in cancer prevention*

The AACR has long been a supporter of cancer prevention research aimed at identifying effective strategies to prevent cancer through lifestyle changes, chemoprevention, and early detection and treatment. Prevention is the keystone to success in the battle against cancer because preventing the disease is far more desirable—and cost-effective—than treating it. More than half of all cancers are related to modifiable behavioral factors, including tobacco use, diet, physical inactivity and sun exposure. Furthermore, many cancers can be halted in the early stages if individuals have access to, and take advantage of, screening tests. Vaccination—one of the most successful approaches for preventing disease—is one of the most promising areas of ongoing cancer prevention research.

Research on cancer prevention at the NCI focuses on three main areas: Risk assessment, including understanding and modifying lifestyle factors that increase cancer risk; developing medical interventions (chemoprevention), such as drugs or vaccines, to prevent or disrupt the carcinogenic process; and developing early detection and screening strategies that result in the identification and removal of precancerous lesions and early-stage cancers.

Cancer biology intersects with several areas and disciplines of cancer prevention, pointing to opportunities for, and the importance of, integrative, interdisciplinary efforts to advance clinical cancer prevention through hard-won science. The breadth and excitement of these current opportunities have never been greater.

*Addressing and conquering cancer health disparities*

Certain minority and underserved population groups continue to suffer disproportionately from cancer. Conquering cancer health disparities will contribute significantly to reducing the Nation's overall cancer burden, and this issue has been an important focus of both the NCI and the AACR. The NCI's investments in this area include: studying the factors that cause cancer health disparities; working with underserved communities to develop targeted interventions; developing the knowledge base for integrating cancer services to the underserved; collaborating to implement culturally appropriate information and dissemination approaches to underserved populations; and examining the role of health policy in eliminating cancer health disparities.

One size does not fit all in cancer treatment and prevention—certain populations may require specialized approaches to achieve success. We must make every effort to reduce and equalize cancer rates across all populations. The AACR urges sustained funding for these programs to ensure that all people benefit from cancer research and that these disparities are eliminated.

*Fighting cancer in challenging fiscal times*

We are acutely aware of the difficult decisions Congress must make as it seeks to improve the Nation's fiscal stability. However, it is imperative that such efforts be grounded in the goal of securing the prosperity and well-being of the American people. It is not by chance that the United States is the world leader in cancer research and the development of lifesaving treatments. Our preeminence is a direct result of the steadfast determination of the American public and the U.S. Congress to reduce the burden of this devastating disease by supporting and investing in research through the NIH and NCI.

Consider the following:

—Biomedical research is essential to maintaining American global competitiveness. While our Nation has been the undisputed leader in research and innovation, other countries are catching up. According to the Organisation for Economic Co-operation and Development (OECD), national expenditures for research and development as a percentage of gross domestic product (GDP) remained static for the United States between 2001 and 2008 while growing nearly 60 percent in China and 34 percent in South Korea. If this trend continues, we risk losing our global preeminence in biomedical research.

—Biomedical research has a strong positive impact on State and local economies. NIH dollars are creating and preserving high-wage, high-tech jobs at a critical time for the U.S. economy. A recent report issued by United for Medical Research estimated that in fiscal year 2010, NIH awards led to the creation of 488,000 jobs across the country, producing $68 billion in new economic activity. The NCI alone funds more than 6,500 research grants at more than 150 cancer centers and specialized research facilities located in 49 States. In over half the States, grants and contracts to institutions exceed $15 million annually.

—Biomedical research is an effective and efficient use of public dollars. NIH funding does not stay inside the Beltway. More than 80 percent of the dollars appropriated to the NIH are distributed throughout the United States to research projects that have undergone rigorous review for scientific merit. NIH has consistently received the highest possible ranking of "effective" under the Office of Management and Budget's Program Assessment Rating Tool (PART), demonstrating that its programs set ambitious goals, achieve results, and are well-managed and efficient.

*Recent cuts to the NIH jeopardize scientific progress*

The $320 million in cuts to the NIH enacted in the full-year continuing appropriations of 2011, which included $45 million in cuts to the NCI, will yield harmful consequences for cancer research and cancer patients. This loss of funding will result in the following: a 10 percent reduction in the number of new grants that can be awarded this year; a 3 percent cut to existing grants; and as much as a 5 percent cut to funding for NCI-designated cancer centers. These cuts mean that success rates for grants could fall into the single digits, leaving numerous meritorious grant proposals, which could be the key to new therapies, unfunded at a time of unprecedented scientific opportunity. Furthermore, cancer centers and research laboratories may have to lay off workers as a result of reduced funding, which would negatively impact local economies across the Nation. Budget cuts and low success rates for grant proposals also discourage young scientists from entering the field, putting the future scientific workforce at risk.

*The NIH needs stable, predictable increases in funding*

Although cancer remains a costly burden in terms of its human and economic toll, previous investments have led to an abundance of promising research opportunities, and it is crucial that such possibilities are not lost. We thank Congress for its past support for the NIH and cancer research and urge Congress to continue its long-standing, bipartisan commitment. The American people are depending on Congress to ensure the Nation does not lose the health and economic benefits that result from our extraordinary commitment to medical research. The AACR looks forward to working with you to assure that our collective commitment to ending the pain and suffering inflicted by cancer is upheld and that researchers have the resources needed to continue to deliver hope and tangible progress.

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PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR DENTAL RESEARCH

*Introduction*

Mr. Chairman and Members of the Subcommittee, I am Jeff Ebersole, Director of the Center for Oral Health Research at the University of Kentucky College of Dentistry. My testimony is on behalf of the American Association for Dental Research, where I currently serve as President.

I thank the Subcommittee for this opportunity to testify about the exciting advances in oral health science. With the support of this Committee, the research funded by the National Institute of Dental and Craniofacial Research (NIDCR) has not only returned dividends in terms of improvements in oral health across the U.S. population, but also in a wide array of other health issues ranging from craniofacial birth defects to chronic orofacial pain to oral cancer. The investments we make today will create an exciting tomorrow for the treatment and prevention of oral health diseases and disorders.

*What is the American Association for Dental Research?*

The American Association for Dental Research is headquartered in Alexandria, Virginia. It is a nonprofit organization with more than 4,000 members in the United States. Its mission is to: (1) advance research and increase knowledge for the improvement of oral health; (2) support and represent the oral health research community; and (3) facilitate the dissemination and application of research findings. The AADR is the largest Division of the International Association for Dental Research.

*Why is Oral Health Important?*

Oral health is an essential component of health across the lifespan. Poor oral health and untreated oral diseases and conditions can have a significant impact on social development, economic accomplishment, and the quality of life. They can affect the most basic human needs including the ability to eat and drink, swallow, maintain proper nutrition, smile and communicate.

Over the past 50 years, there has been a dramatic improvement in oral health. Still oral diseases remain a major concern. Tooth decay and gum disease represent

the predominant infections facing the public, although complete tooth loss, oral cancer, trauma to the mouth, and congenital facial anomalies also contribute to the ongoing importance of oral health research and care.

Employed adults in the United States lose more than 164 million hours of work each year as a result of oral health problems and children are estimated to lose 54 million school hours.[1] Approximately 25 percent of adults over the age of 60 have lost all of their natural teeth.[2] Americans with the poorest oral health are usually those who are economically disadvantaged, lack insurance, or are members of racial and ethnic minorities. Moreover, as the Nation ages oral health issues, particularly gum disease and the oral health impact of medical treatments and medicines will continue to increase.

*Research Accomplishments*

*Salivary Diagnostics*.—For many decades researchers have known that saliva is important for more than chewing, tasting, swallowing, and as the first step in digestion. A multitude of proteins and other molecules in saliva also play vital roles in protecting us from bacteria and viruses that are constantly entering through the mouth and can cause disease.

Now, scientists are well on their way to understanding how saliva contributes to broader health functions. In 2008, an NIDCR supported team of biologists, chemists, engineers and computer scientists at five research institutions across the country mapped the salivary proteome—a "catalogue and dictionary" of proteins present in human saliva.

This saliva database is an important first step toward being able to use biomarkers in saliva to diagnose or predict oral and systemic diseases. Saliva tests based on these biomarkers offer many advantages over blood tests that require a needle stick and can pose contamination risks from blood-borne diseases. However, much effort is still required. It is crucial that the research community have the resources necessary to refine and enrich the "dictionary" of proteins present in human saliva. Saliva tests could prove to be a potentially lifesaving alternative to detect diseases where early diagnosis is critical— as in the case of oral cancer or heart attacks.

*Oral Cancer*.—Oral cancer affects approximately 38,000 Americans each year. Oral cancer is any cancerous tissue growth located in the mouth. The death rate associated with this cancer is especially high due to delayed diagnosis. Only 60 percent of those with this cancer will survive more than 5 years.

Researchers are developing a Point of Care diagnostic system (real-time) for rapid onsite detection of saliva-based tumor markers. Early detection of oral cancer will increase survival rates, improve the quality of care for patients, and it will result in a significant reduction in healthcare costs.

Resources must be available to permit researchers to complete work on the Point of Care diagnostic systems, and to develop new therapeutic approaches. It should also be noted that several new drug candidates are now becoming available to treat oral cancer. It is believed that at least one of these drugs will be ready for FDA approval in the very near future.

*Health Disparities*.—Health Disparities are the persistent gaps between the health status of minorities and non-minorities in the United States. Predicted causes of health disparities are related to educational, socioeconomic, and environmental characteristics of different ethnic and racial groups, and most recently recognized in historically underserved rural populations of the United States.

The NIDCR is one of the leading institutes at NIH supporting health disparities research. The program at NIDCR takes a multidisciplinary approach to solving the complex problem of health disparities by addressing it from a holistic health prospective. The institute funded investigations engage behavioral and social scientists, health policy experts, economists, and basic and clinical dental and medical researchers. NIDCR has supported new health centers which focus on numerous populations at risk, including African Americans, Hispanic/Latinos, Native Americans and rural communities. The centers partner with other academic health centers, State and local health agencies, community and migrant health centers, and institutions that serve these targeted populations.

The physical and economic burden due to health disparities is real and efforts must continue in order to eliminate them. I am proud to say that dental researchers are leading this charge.

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[1] Centers for Disease Control Publication, "Oral Health for Adults," December 2006.
[2] Ibid.

*Conclusion*

As you can see Mr. Chairman, much has been accomplished with the resources provided by this committee; however, there is much yet to be done. Science is advancing rapidly and the next generation of technological innovation may greatly accelerate the next breakthroughs in oral, dental and craniofacial research. Researchers have already created prototypes for "labs-on-a-chip," bioengineered tissue replacements, and developed powerful molecular imaging tools that provide a new window into complex biological systems about which we continue to learn. This emerging wave of knowledge and tools will accelerate the development of molecular-based oral healthcare. As importantly, the NIDCR provides the resources for training the next generation of biomedical scientists focusing or oral health issues as well as the future academics to train the next generation of dentists for the United States. Thus, it is vital that NIDCR have the resources to support a diverse portfolio of research and training. The AADR representing each of these constituencies respectfully requests a fiscal year 2012 budget of $468 million for NIDCR.

Thank you.

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PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR GERIATRIC PSYCHIATRY

The American Association for Geriatric Psychiatry (AAGP) appreciates this opportunity to comment on issues related to fiscal year 2012 appropriations for mental health research and services. AAGP is a professional membership organization dedicated to promoting the mental health and well-being of older Americans and improving the care of those with late-life mental disorders. AAGP's membership consists of geriatric psychiatrists as well as other health professionals who focus on the mental health problems faced by aging adults. Although we generally agree with others in the mental health community about the importance of sustained and adequate Federal funding for mental health research and treatment, AAGP brings a unique perspective to these issues because of the elderly patient population served by our members.

*A National Health Crisis: Demographic Projections and the Mental Disorders of Aging*

The aging of the baby boomer generation will result in an increase in the proportion of persons over 65 from 12.7 percent currently to 20 percent in 2030, with the fastest growing segment of the population consisting of age 85 and older. During the same period, the number of older adults with major psychiatric illnesses will more than double, from an estimated 7 million to 15 million individuals, meeting or exceeding the number of consumers in discrete, younger age groups.

*Center for Mental Health Services*

It is critical that there be adequate funding for the mental health initiatives under the jurisdiction of the Center for Mental Health Services (CMHS) within the Substance Abuse and Mental Health Services Administration (SAMHSA). While research is of critical importance to a better future, today's patients must also receive appropriate treatment for their mental health problems.

*Evidence-based Mental Health Outreach and Treatment for the Elderly*

AAGP was pleased that the final budgets for the last 9 years have included $5 million for evidence-based mental health outreach and treatment to the elderly, the only federally funded services program dedicated specifically to the mental healthcare of older adults. AAGP is concerned that this program was eliminated in the President's fiscal year 2012 budget proposal. It is critical that SAMHSA and CMHS ensure that, as they design programs to promote prevention and recovery from mental illness, the senior citizen cohort not be ignored. AAGP asks the Committee to restore the funding for this critical program as well as ensure that all of CMHS's programs assure a life-span approach by specifically including the older adult population as a targeted population.

*Centers of Excellence for Depressive and Bipolar Disorders*

PPACA also included authorization for a new national network of centers of excellence for depressive and bipolar disorders, which will enhance the coordination and integration of physical, mental and social care that are critical to the identification and treatment of depression and other mental disorders across the lifespan. The work of these centers will help to disseminate and implement evidence-based practices in clinical settings throughout the country. AAGP strongly supports funding for the centers authorized by this legislation and is disappointed that the Administration has not recommended funding them. With respect to older adults, these cen-

ters would be able to focus on new models of care that integrate evidenced-based depression care into real world primary care and home care to improve the outcomes; specific combinations of medications and talk therapy that successfully treat depression and prevent relapse in older adults; specific clinical and biological factors that link depression and risk of Alzheimer's disease in some older depressed patients; and prevention of depression in older people at risk. AAGP recommends that these centers be funded at $10 million for fiscal year 2012.

*Preparing a Workforce to meet the Mental Health Needs of the Aging Population*

In 2008, the Institute of Medicine (IOM) released a study of the readiness of the Nation's healthcare workforce to meet the needs of its aging population. The Re-tooling for an Aging America: Building the Health Care Workforce called for immediate investments in preparing our healthcare system to care for older Americans and their families. AAGP is deeply grateful to this subcommittee and its House counterpart for providing, in the appropriations bill for fiscal year 2010, funding for a follow-up study of the current and projected mental and behavioral healthcare needs for aging Americans. This study, which is now underway, will complement the 2008 IOM study in providing in-depth consideration of the mental health needs of geriatric and ethnic minority populations that were precluded by the broad scope of the earlier one.

Virtually all healthcare providers need to be fully prepared to manage the common medical and mental health problems of old age. In addition, the number of geriatric health specialists, including mental health providers, needs to be increased both to provide care for those older adults with the most complex issues and to train the rest of the workforce in the common medical and mental health problems of old age. The small numbers of specialists in geriatric mental health, combined with increases in life expectancy and the growing population of the Nation's elderly, foretells a crisis in healthcare that will impact older adults and their families nationwide.

Already, there are programs administered by the Bureau of Health Professions in the HHS Health Resources and Services Administration (HRSA) administers that are aimed to help to assure adequate numbers of healthcare practitioners for the Nation's geriatric population, especially in underserved areas. These are the only Federal programs that seek to increase the number of faculty with geriatrics expertise in a variety of disciplines, and the breadth of the programs has been strengthened by provisions included in the Patient Protection and Affordable Care Act (PPACA).

The geriatric health professions program supports these important initiatives:

—The Geriatric Education Center (GEC) program provides interdisciplinary training for healthcare professionals in assessment, chronic disease syndromes, care planning, emergency preparedness, and cultural competence unique to older Americans. PPACA authorizes $10.8 million in supplemental grants for the GEC Program to support training in geriatrics, chronic care management, and long-term care for faculty in a broad array of health professions schools, as well as direct care workers and family caregivers. GECs receiving these grants are required to develop and include material on depression and other mental disorders common among older adults, medication safety issues for older adults, and management of the psychological and behavioral aspects of dementia in all appropriate training courses.

—The Geriatric Training for Physicians, Dentists, and Behavioral and Mental Health Professionals (GTPD Program) provides fellows with exposure to older adult patients in various levels of wellness and functioning and from a range of socioeconomic and racial/ethnic backgrounds.

—The Geriatric Academic Career Awards (GACA) support the academic career development of geriatric specialists in junior faculty positions who are committed to teaching geriatrics in professional schools. PPACA expands the disciplines eligible for the awards. GACA recipients are required to provide training in clinical geriatrics, including the training of interdisciplinary teams of healthcare professionals.

—PPACA authorized a new Geriatric Career Incentive Awards Program in Title VIII of the Public Health Service Act for grants to foster great interest among a variety of health professionals in entering the field of geriatrics, long-term care, and chronic care management. This program was authorized for $10 million over 3 years.

—A new program, authorized by PPACA at $10 million for 3 years, will provide advanced training opportunities for direct care workers in the field of geriatrics, long term-care or chronic care management.

AAGP strongly supports increased funding for the existing programs, particularly as the disciplines included have been expanded, and funding to fully authorized levels for the new programs.

*National Institutes of Health (NIH) and National Institute of Mental Health (NIMH)*

With the graying of the population, mental disorders of aging represent a growing crisis that will require a greater investment in research to understand age-related brain disorders and to develop new approaches to prevention and treatment. Even in the years in which funding was increased for NIH and the NIMH, these increases did not always translate into comparable increases in funding that specifically address problems of older adults. For instance, according to figures provided by NIMH, NIMH total aging research amounts decreased from $106,090,000 in 2002 to $85,164,000 in 2006 (dollars in thousands: $106,090 in 2002, $100,055 in 2003, $97,418 in 2004, $91,686 in 2005, $85,164 in 2006).

The critical disparity between federally funded research on mental health and aging and the projected mental health needs of older adults is continuing. If the mental health research budget for older adults is not substantially increased immediately, progress to reduce mental illness among the growing elderly population will be severely compromised. While many different types of mental and behavioral disorders occur in late life, they are not an inevitable part of the aging process, and continued and expanded research holds the promise of improving the mental health and quality of life for older Americans. This trend must be immediately reversed to ensure that our next generation of elders is able to access effective treatment for mental illness. Federal funding of research must be broad-based and should include basic, translational, clinical, and health services research on mental disorders in late life.

AAGP believes that it is critical that NIH begin to invest increased funding in future evidence-based treatments for our Nation's elders. Annual increases of funds targeted for geriatric mental health research at NIH should be used to: (1) identify the causes of age-related brain and mental disorders to prevent mental disorders before they devastate lives; (2) speed the search for effective treatments and efficient methods of treatment delivery; and (3) improve the quality of life for older adults with mental disorders.

*Participation of Older Adults in Clinical Trials*

Federal approval for most new drugs is based on research demonstrating safety and efficacy in young and middle-aged adults. These studies typically exclude people who are old, who have more than one health problem, or who take multiple medications. As the population ages, that is the very profile of many people who seek treatment. Thus, there is little available scientific information on the safety of drugs approved by the Food and Drug Administration (FDA) in substantial numbers of older adults who are likely to take those drugs. Pivotal regulatory trials never address the special efficacy and safety concerns that arise specifically in the care of the Nation's mentally ill elderly. This is a critical public health obligation of the Nation's health agencies. Just as the FDA has begun to require inclusion of children in appropriate studies, the agency should work closely with the geriatric research community, healthcare consumers, pharmaceutical manufacturers, and other stakeholders to develop innovative, fair mechanisms to encourage the inclusion of older adults in clinical trials. Clinical research must also include elders from diverse ethnic and cultural groups. In addition, AAGP urges that Federal funds be made available each year for support of clinical trials involving older adults.

*Study on NIH Funding for Mental Disorders among Older Adults*

As little emphasis has been placed on the development of new treatments for geriatric mental disorders, AAGP encourages NIH to promote the development of new medications specifically targeted at brain-based mental disorders of the elderly. AAGP urges this Committee to request a GAO study on spending by NIH on conditions and illnesses related to the mental health of older individuals. NIH is already working to enhance cooperative activities among NIH Institutes and Centers that support research on the nervous system. A GAO study of the work being done by these institutes in areas that predominately involve older adults could provide crucial insights into possible new areas of cooperative research, which in turn will lead to advances in prevention and treatment for these devastating illnesses.

*Conclusion*

AAGP recommends:

—Increased funding for the geriatric health professions education programs under Title VII of the Public Health Service Act and full funding for new programs authorized by the PPACA;

—Funding to support clinical trials involving older adults;
—A GAO study on spending by NIH on conditions and illnesses related to the mental health of older individuals;
—$5 million in funding to continue evidence-based geriatric mental health outreach and treatment programs at CMHS;
—$10 million in funding for Centers of Excellence for Depressive and Bipolar Disorders.

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PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF NURSING

The American Association of Colleges of Nursing (AACN) respectfully submits this testimony highlighting funding priorities for nursing education and research programs in fiscal year 2012. AACN represents 667 schools of nursing with baccalaureate and graduate nursing programs that educate over 337,000 students and employ more than 15,000 full-time faculty members. These institutions educate approximately half of our Nation's Registered Nurses (RNs) and all of the Advanced Practice Registered Nurses (APRNs), nurse faculty, and researchers.

The programs outlined in this testimony play an integral role in continuing to shape, advance, and promote a professional nursing workforce to meet the needs of America's patients. An emphasis on two key components of the profession—education and research—will be necessary to sustain and enhance the quality of nursing care in the United States. The release of the landmark Institute of Medicine's (IOM) report, The Future of Nursing: Leading Change, Advancing Health, outlines specific priorities for the profession and identifies expanded Federal support to meet the goals of preparing a more highly educated nursing workforce, removing barriers so all nurses can practice to the full scope of their education, and enabling nurses to serve as equal partners in the redesign of the healthcare system.

The ongoing reform of our healthcare system will continue to increase access to care, requiring a surge in the number of nurses and other health professionals. RNs and APRNs will be in high demand given the needs of an aging population, the increased complexity of care, and significant growth in the number of patients with chronic diseases. More specifically, the U.S. Bureau of Labor Statistics projects a demand on our delivery system that will necessitate the creation of 581,000 new positions by 2018, a 22 percent increase in the nursing workforce. Without increased attention to the challenges facing nursing education, schools of nursing will be unable to meet this demand, further jeopardizing access to quality care.

The current supply and demand of nurses demonstrates two distinct challenges. First, due to the present and looming need for healthcare by American consumers, the supply of nurses is not growing at a pace that will adequately meet long-term projections, including the demand for primary care provided by APRNs. This issue is further compounded by the number of nurses who will retire or leave the profession in the near future, ultimately reducing the nursing workforce. Currently, over 1 million of the total 2.6 million practicing nurses are over the age of 50. More striking yet, over 275,000 RNs are over the age of 60 according to the 2008 National Sample Survey of Registered Nurses.

Second, the supply of nurses nationwide is stretched thin due, in large part, to capacity barriers in schools of nursing. According to AACN, 67,563 qualified applications were turned away from baccalaureate and graduate nursing programs in 2010, primarily due to budget constraints which impact the insufficient number of faculty, clinical sites, classroom space, and clinical preceptors. As the ability of most States to support the needs of higher education has decreased, Federal support for nursing education has become even more critical. National reform goals cannot be met without an adequate number of nurses to provide the cost-effective and quality care associated with the nursing discipline.

NURSING WORKFORCE DEVELOPMENT PROGRAMS: A PROVEN SOLUTION

For nearly 50 years, the Title VIII Nursing Workforce Development Programs (42 U.S.C. 296 et seq.) have supported hundreds of thousands of nurses and nursing students. Between fiscal year 2006 and 2009, the Title VIII programs supported over 347,000 nurses and nursing students as well as numerous academic nursing institutions and healthcare facilities. As the largest source of dedicated funding for nursing, the Title VIII programs award grants to nursing education programs, as well as provide direct support through loans, scholarships, traineeships, and programmatic grants. The programs also favor institutions that educate nurses for practice in rural and medically underserved communities and help to develop a more diverse nursing workforce to meet the cultural healthcare needs of our Nation's population. Additionally, programs funded through Title VIII contribute to the

promotion of academic progression, a major goal highlighted in the IOM's Future of Nursing report.

Of specific interest to AACN, the Title VIII programs support future nurse faculty, a significant barrier to addressing the nursing care needs in the United States. The nurse faculty shortage has grown critical as the national vacancy rate is 6.9 percent for schools offering baccalaureate and graduate nursing programs according to an AACN Survey on Vacant Faculty Positions for Academic Year 2010–2011. Of those schools reporting vacancies, the number of positions left unfilled was 803. Regionally, schools of nursing are struggling to recruit and hire faculty. Compared to the North Atlantic (9.2 percent), Southern (9.5 percent), and Mid-Western (9.2 percent) regions of the country, the West Coast (11.7 percent) has the highest faculty vacancy rate.

*Title VIII Effectiveness*

The Nursing Workforce Development Programs are effective and meet their authorized mission. AACN's 2010–2011 Title VIII Student Recipient Survey included responses from 1,459 students who noted that these programs played a critical role in funding their nursing education, which will ultimately help them to achieve future career goals. The students responding to the Title VIII survey have career aspirations that meet the direct needs of the healthcare system and the profession. Nearly one-third (32.8 percent) of the respondents reported that their career goal is to become a nurse practitioner. Given the demand for primary care providers, the Title VIII funds are helping to support the next generation of these essential practitioners. Moreover, the nurse faculty shortage continues to inhibit the ability of nursing schools to increase student capacity. Of the students who responded to the survey, an additional 33.2 percent stated their ultimate career goal was to become nurse faculty. Providing support for Title VIII is the key to help schools expand student capacity, fill vacant nursing positions, and, in turn, improve healthcare quality.

*Demand for Title VIII*

While millions of Americans are struggling during this economic downturn and thousands of students need loans to finance their education, Federal support is necessary. Nursing students depend on Federal loans like Title VIII to pay for their education. AACN's Title VIII Student Recipient Survey also indicated that 73 percent of the undergraduate and 62.6 percent of the master's students responding to the question regarding funding for nursing education noted that they will pay for their education through Federal loans. The average loan amount that students reported they would take (private/Federal) to support their education was $19,336 for undergraduate students and $55,698 for master's students. These students also noted that the total amount they will pay for their education is $32,307 for undergraduates and $64,734 for master's. Given this information, it is interesting to note that 65.6 percent of the students reported that the amount of support they received from Title VIII was $3,000 or less in one fiscal year.

Over the last 47 years, Congress has used the Title VIII authorities as a mechanism to address past nursing shortages. When the need for nurses was great, such as in the 1970s, appropriations were higher. Congress provided $160.61 million to the Title VIII programs in 1973. Adjusting for inflation, $160.61 million in 1973 dollars would be equivalent to $841.371 million in 2011 dollars. The fiscal year 2011 investment of $242.387 million represents a 70 percent reduction in buying power for the Title VIII programs, at a time when our Nation faces historic demands on our nursing workforce.

AACN respectfully requests $313.075 million for the Nursing Workforce Development Programs authorized under Title VIII of the Public Health Service Act in fiscal year 2012 as recommended in the President's budget proposal.

NURSING RESEARCH: SUPPORTING HEALTH PROMOTION AND DISEASE PREVENTION

The National Institute of Nursing Research (NINR) is one of the 27 Institutes and Centers at the National Institutes of Health (NIH). As the Nation's nucleus for nursing science, NINR funds research that establishes the scientific basis for health promotion, disease prevention, and high quality nursing care to individuals, families, and populations. Often working collaboratively with physicians and other researchers, nurse scientists are vital in setting the national research agenda. NINR focuses on four strategic areas which include promoting health and preventing disease, eliminating health disparities, improving quality of life, and setting directions for end-of-life research.

NINR's fiscal year 2011 funding level of $144.381 million is approximately 0.47 percent of the overall $30 billion NIH budget. Spending for nursing research is a modest amount relative to the allocations for other health science institutes and for

major disease category funding. For NINR to adequately continue and further its mission, the institute must receive additional funding. Cuts in funding have impeded the institute from supporting larger comprehensive studies needed to advance nursing science and improve the quality of patient care. With increased appropriations for NINR, more comprehensive, complex, and longitudinal studies could be funded in the critical areas of their mission while maintaining their portfolio of current goals, projects, and priorities of the institute.

Additionally, considering that NINR presently allocates 6 percent of its budget to training that helps develop the pool of nurse researchers, increased funding would support NINR's efforts to prepare faculty researchers desperately needed to educate new nurses. AACN respectfully requests $163 million for the National Institute of Nursing Research in fiscal year 2012.

NURSE-LED PRACTICE MODELS: INVESTING IN NURSE-MANAGED HEALTH CLINICS

The Affordable Care Act amended Sec. 330 of the Public Health Service Act, allowing Nurse- Managed Health Clinics (NMHCs) to apply for grant funds to help cover the costs of operating these unique community-based settings. NMHCs are nurse-practice arrangements and are managed by APRNs who provide primary care or wellness services to underserved or vulnerable populations through clinics located in places like public housing, churches, Native American reservations, rural communities, senior citizen centers, elementary schools, and storefronts. Each of these clinics is associated with a school, college, university or department of nursing, federally qualified health center, or independent nonprofit health or social services agency, and serves as safety net of providers for vulnerable populations. Moreover, NMHCs play a valuable role as teaching and practice sites for nursing students. AACN respectfully requests $20 million for the Nurse-Managed Health Clinics authorized under Title III of the Public Health Service Act in fiscal year 2012 as recommended in the President's budget proposal.

CAPACITY GRANTS: SOLUTIONS TO GROW ENROLLMENT

According to AACN's latest enrollment and graduation survey, the major barriers to increasing student capacity in nursing schools are insufficient numbers of faculty, admission seats, clinical sites, classroom space, and clinical preceptors, as well as budget constraints. The Capacity for Nursing Students and Faculty Program, a section of the Higher Education Opportunity Act of 2008, offers capitation grants (formula grants based on the number of students enrolled/or matriculated) to nursing schools allowing them to increase the number of students. Schools of nursing continue to face budget cuts at the State level, and capacity grants are a proven method for meeting the needs of nursing education. AACN respectfully requests $25 million for this program in fiscal year 2012.

CONCLUSION

AACN acknowledges the fiscal challenges facing this Subcommittee and Congress, but would be remiss in not highlighting the benefits of these programs. Title VIII has a long and successful record of providing dedicated support for the nursing workforce. The National Institute of Nursing Research invests in developing the scientific basis for quality nursing care. Nurse-Managed Health Clinics provide services to the underserved and training and practice settings for nursing students. The Capacity for Nursing Students and Faculty Program would allow schools to increase student capacity.

To be effective in meeting the critical goals outlined in the IOM's report, The Future of Nursing: Leading Change, Advancing Health, and the larger health reform goals of the Nation, these programs must receive additional funding. AACN respectfully requests $313.075 million for Title VIII programs, $163 million for NINR, $20 million for Nurse-Managed Health Clinics, and $25 million for the Capacity for Nursing Students and Faculty Program in fiscal year 2012. Additional funding for these programs will assist schools of nursing to expand their educational and research programs, educate more nurse faculty, increase the number of practicing RNs, and ultimately improve the patient care provided in our healthcare system.

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## PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF OSTEOPATHIC MEDICINE

On behalf of the American Association of Colleges of Osteopathic Medicine (AACOM), I am pleased to submit this testimony in support of increased funding in fiscal year 2012 for programs at the Health Resources Services Administration

(HRSA), the National Institutes of Health (NIH), and the Agency for Healthcare Research and Quality (AHRQ). AACOM represents the administrations, faculty, and students of the Nation's 26 colleges of osteopathic medicine at 34 locations in 26 States. Today, more than 19,000 students are enrolled in osteopathic medical schools. Nearly one in five U.S. medical students is training to be an osteopathic physician.

*Title VII*

The health professions education programs, authorized under Title VII of the Public Health Service Act and administered through HRSA, support the training and education of health practitioners to enhance the supply, diversity, and distribution of the healthcare workforce, acting as an essential part of the healthcare safety net and filling the gaps in the supply of health professionals not met by traditional market forces. Title VII and Title VIII nurse education programs are the only Federal programs designed to train clinicians in interdisciplinary settings to meet the needs of special and underserved populations, as well as increase minority representation in the healthcare workforce.

According to HRSA, an additional 33,000 health practitioners are needed to alleviate existing health professional shortages. Combined with faculty shortages across health professions disciplines, racial and ethnic disparities in healthcare, a growing, aging population and the anticipated demand for access to care, these needs strain an already fragile healthcare system. While AACOM appreciates the investments that have been made in these programs, we recommend increasing funding to $449.4 million, the same funding level requested by the President, in fiscal year 2012 for the Title VII programs. Investment in these programs, including the Primary Care Training and Enhancement Program, the Health Careers Opportunity Program, and the Centers of Excellence, is necessary to address the primary care workforce shortage. Strengthening the workforce has been recognized as a national priority, and the investment in these programs recommended by AACOM will help meet the demand for a well-trained, diverse workforce that this country will witness as a result of healthcare reform.

*Teaching Health Centers*

The Teaching Health Center Graduate Medical Education Program (THCGME) is the first of its kind to shift graduate medical education (GME) training to community-based care settings that emphasize primary care and prevention. It is uniquely positioned to provide much needed primary care training in underserved populations. However, because the program is the first of its kind, most community-based settings do not have existing infrastructure to provide this training. AACOM strongly supports the President's budget request of $10 million to fund the THC Development Grants. This funding would allow potential THC training sites to develop the infrastructure needed to administer residency training programs.

*National Health Service Corps*

Approximately 50 million Americans live in communities with a shortage of health professionals, lacking adequate access to primary care. Through scholarships and loan repayment, the National Health Service Corps (NHSC) supports the recruitment and retention of primary care clinicians to practice in underserved communities. At the close of fiscal year 2010, the NHSC provided a network of 7,500 primary healthcare professionals in 10,000 sites in underserved communities. However, this still fell approximately 20,000 practitioners short of fulfilling the need for primary care, dental and mental health practitioners in Health Professional Shortage Areas (HPSAs). Growth in HRSA's Community Health Center Program must be complemented with increases in the recruitment and retention of primary care clinicians to ensure adequate staffing, which the NHSC provides. AACOM supports the President's budget request of $418 million for this program. This includes $295 million from the Affordable Care Act (ACA) fund for the NHSC and $24.695 million in appropriated dollars for field placements and $98.7 million in appropriated dollars for recruitment.

*National Institutes of Health*

Research funded by the NIH leads to important medical discoveries regarding the causes, treatments, and cures for common and rare diseases, as well as disease prevention. These efforts improve our Nation's health and save lives. To maintain a robust research agenda, further investment will be needed. AACOM recommends $32 billion in fiscal year 2012 for the NIH. While the need is significantly greater, approximately $35.0 billion, anything less than the President's request will result in a reduction in real dollars dedicated to research.

With today's increasingly demanding and evolving medical curriculum, there is a critical need for more research geared toward evidence-based osteopathic medicine. AACOM believes that it is vitally important to maintain and increase funding for biomedical and clinical research in a variety of areas related to osteopathic principles and practice, including osteopathic manipulative medicine and comparative effectiveness. In this regard, AACOM supports the President's budget request of $131.002 million for NIH's National Center for Complementary and Alternative Medicine to continue fulfilling this essential research role.

*Agency for Healthcare Research and Quality*

AHRQ supports research to improve healthcare quality, reduce costs, advance patient safety, decrease medical errors, and broaden access to essential services. AHRQ plays an important role in producing the evidence base needed to improve our Nation's health and healthcare. The incremental increases for AHRQ's Patient Centered Health Research Program in recent years, as well as the funding provided to AHRQ in the ARRA, will help AHRQ generate more of this research and expand the infrastructure needed to increase capacity to produce this evidence. More investment is needed, however, to fulfill AHRQ's mission and broader research agenda, especially research in patient safety and prevention and care management research. AACOM recommends $405 million in fiscal year 2012 for AHRQ. This investment will preserve AHRQ's current programs while helping to restore its critical healthcare safety, quality, and efficiency initiatives.

AACOM is grateful for the opportunity to submit its views and looks forward to continuing to work with the Subcommittee on these important matters.

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## PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY

AACP and its member colleges and schools of pharmacy appreciate the continued support of the U.S. House of Representatives Appropriations Subcommittee on Labor, Health and Human Services, and Education. Our Nation's 124 accredited colleges and schools of pharmacy are engaged in a wide-range of programs supported by grants and funding administered through the agencies of the Department of Health and Human Services (HHS) and the Department of Education. We also understand the difficult task you face annually in your deliberations to do the most good for the Nation and remain fiscally responsible to the same. AACP respectfully offers the following recommendations for your consideration as you undertake your deliberations.

### U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES SUPPORTED PROGRAMS AT COLLEGES AND SCHOOLS OF PHARMACY

*Agency for Healthcare Research and Quality (AHRQ)*

AACP supports the Friends of AHRQ recommendation of $405 million for AHRQ programs in fiscal year 2012.

Pharmacy faculty are strong partners with the Agency for Healthcare Research and Quality (AHRQ).

—Vincent J. Willey, Associate Professor at the University of the Sciences in Philadelphia, was appointed to the Comparative Effectiveness Research Pharmacy Workgroup.

—AHRQ Effective Healthcare programs including the Center for Education and Research on Therapeutics (CERTs) and the Developing Evidence to Inform Decisions about Effectiveness ( DEcIDE) support pharmacy faculty researchers focused on improving the effectiveness of healthcare services.

—Researcher faculty at The University of Arizona College of Pharmacy's Center for Health Outcomes and PharmacoEconomic Research, support the Arizona CERT and its mission to improve therapeutic outcomes and reduce adverse events caused by drug interactions and drugs that prolong the QT interval, especially those affecting women. Researchers determined that certain drug combinations increased the risk of death. Published research from this CERT includes the 2010 Women's Health Research: Progress, Pitfalls and Promise, for the Institute of Medicine and a comparison study on the U.S. Department of Veterans Affairs drug-drug interactions compared to two standard compendia. #U18 HS17001

—Almut G. Winterstein, University of Florida, has received a 2-year $482,000 award from the Agency for Healthcare Research and Quality for "Comparative Safety and Effectiveness of Stimulants in Medicaid Youth with ADHD." #5R01HS018506–02

—Sean D. Sullivan, University of Washington, received a $2.45 million grant from AHRQ to implement the multidisciplinary Mentored Clinical Scientist Comparative Effectiveness Research Career Development (K12) Program in collaboration with research partners at Group Health Research Institute, the Fred Hutchinson Cancer Research Center, and the Veterans' Administration Health Services Research and Development Center of Excellence. #1K12HS019482–01

—Daniel C. Malone, University of Arizona, received a 3-year grant from AHRQ for $1.25 million, to evaluate awareness of CER guides by pharmacists and physicians and identify critical skills needed to use these reviews to support and encourage safe and effective prescribing of medications. #1R18HS019220–01

*Centers for Disease Control and Prevention (CDC)*

AACP supports the CDC Coalition recommendation of $7.7 billion for CDC core programs in fiscal year 2012 and the Friends of NCHS recommendation of $162 million for the National Center for Health Statistics.

The educational outcomes of a pharmacist's education include those related to public health. When in community-based positions, pharmacists are frequently providers of first contact. The opportunity to identify potential public health threats through regular interaction with patients provides public health agencies such as the CDC with on-the-ground epidemiologists. Pharmacy faculty are engaged in CDC-supported research in areas such as immunization delivery, integration of pharmacogenetics in the pharmacy curriculum and inclusion of pharmacists in emergency preparedness. Information from the National Center for Health Statistics (NCHS) is essential for faculty engaged in health services research and for the professional education of the pharmacist.

—Katie J. Suda, faculty member at the University of Tennessee, was supported by CDC funding to conduct a national analysis of outpatient anti-infective prescribing patterns. She also prepared a continuing education program in partnership with the CDC entitled, "Weighing in on Antibiotic Resistance: Community Pharmacists Tip the Scale," featured on the CDC Web site: http://www.cdc.gov/getsmart/specific-groups/hcp/ce-course.html. The program details the CDC's Get Smart program, focused on decreasing the amount of unnecessary antibiotics in the community.

—Grace Kuo, Associate Professor of Clinical Pharmacy at the University of California San Diego, founded PharmGenEd™, an evidence-based pharmacogenomics education program designed for pharmacists and physicians, pharmacy and medical students, and other healthcare professionals and is supported by funding from CDC. #IU38GD000070

*Health Resources and Services Administration (HRSA)*

AACP supports the Friends of HRSA recommendation of $7.65 billion for fiscal year 2012.

HRSA is a Federal agency with a wide-range of policy and service components. Faculty at colleges and schools of pharmacy are integral to the success of many of these. Colleges and schools of pharmacy are the administrative units for interprofessional and community-based linkages programs including geriatric education centers and area health education centers. Pharmacy faculty research issues related to rural health delivery. Student pharmacists benefit from diversity program funding including Scholarships for Disadvantaged Students.

*Office of Pharmacy Affairs*

AACP recommends a program funding of $5 million for fiscal year 2012 for the Office of Pharmacy Affairs.

AACP member institutions are actively engaged in Office of Pharmacy Affairs (OPA) efforts to improve the quality of care for patients in federally qualified health centers and entities eligible to participate in the 340B drug discount program. The success of the HRSA Patient Safety and Clinical Pharmacy Collaborative is a direct result of past OPA actions linking colleges and schools of pharmacy with federally qualified health centers. The result of these links has been the establishment of medical homes that improve health outcomes for underserved and disadvantaged patients through the integration of clinical pharmacy services.

*Office of Telehealth Advancement*

Technology is an important component for improving healthcare quality and maintaining or increasing access to care. Colleges and schools of pharmacy utilize technology to increase access to care, improve care quality and to increase the reach of education to student and practicing pharmacists.

—Keri H. Naglosky, Marcia M. Worley, Timothy P. Stratton and Randall D. Seifert University of Minnesota, received a $63,000 grant for their study, "Pilot

Study to Determine the Effectiveness of Pharmacist Provided MTM Using Face-to-Face and TeleMTM in the Treatment of Long-Haul Drivers with Hypertension Department of Transportation Classifications Stage 1, 2 and 3."

—Leigh Ann Ross and Sarah Fontenot, faculty at the University of Mississippi, work with The Delta Health Alliance on many projects including its HRSA telehealth grant and as members of the HRSA Patient Safety Collaborative, receiving the Clinical Pharmacy Services Improvement Award in 2010. Five Delta hospitals have telemedicine capabilities as a result of its funding and 86,083 individuals received medical or health education services during the 2009–2010 fiscal year. #H2AIT16626

*Poison Control Centers*

HRSA grant funding supports the management of 10 of the 57 poison control centers by pharmacy faculty.

—In 2010, the Maryland Poison Center, headed by Bruce Anderson, faculty at the University of Maryland, answered ~36,000 human exposure calls, ~2,000 animal exposures and ~25,000 requests for poison or drug information and over 70 percent of the human exposure calls were managed on site, avoiding treatment at a healthcare facility. This year, Paul Starr, also at the University of Maryland, was recognized for his 20 years as a certified specialist in poison information. #H4BHS15526

*Bureau of Health Professions (BHPr)*

AACP supports the Health Professions and Nursing Education Coalition (HPNEC) recommendation of $762.5 million for Title VII and VIII programs in fiscal year 2012.

AACP member institutions are active participants in BHPr programs. Two colleges of pharmacy are current grantees in the Centers of Excellence program (Xavier University School of Pharmacy). This program focuses on increasing the number of underserved individuals attending health professions institutions. Colleges and schools of pharmacy are also part of Title VII interprofessional and community-based linkages programs including Geriatric Education Centers and Area Health Education Centers. These programs are essential for creating the educational approaches necessary for the Institute of Medicine's recommendations of improving quality through team-based, patient-centered care and serve as valuable experiential education sites for student pharmacists.

—Gayle A. Hudgins, faculty at the University of Montana, was awarded an ARRA supplement of $132,446 from HRSA, Bureau of Health Professions, for equipment to enhance training for health professionals.

*Food and Drug Administration (FDA)*

AACP recommends a funding level of $3.7 billion for FDA programs in fiscal year 2012.

The FDA sees the colleges and schools of pharmacy as essential partners in assuring the public has access to a healthcare professional well versed in the science of safety. Pharmacy faculty partner with the FDA to improve the drug manufacturing process through the National Institute for Pharmaceutical Technology and Education (NIPTE) and increase the science-base for decisions regarding drug and device safety and effectiveness.

—Dianne M. Cappelletty, Associate Professor at The University of Toledo, was recently appointed to serve on the advisory committee to the Division of Anti-Infective and Ophthalmology Products.

—James E. Polli, University of Maryland, received $1,099,990 from the FDA for "Pharmacokinetic Studies of Epileptic Drugs: Evaluation of Brand & Generic Antiepileptic Drug Products in Patients."

*National Institutes of Health (NIH)*

AACP supports the Ad Hoc Group for Medical Research recommendation of $35 billion for fiscal year 2012.

Pharmacy faculty are supported in their research by nearly every institute at the NIH. The NIH-supported research at AACP member institutions spans theresearch spectrum from the creation of new knowledge through the translation of that new knowledge to providers and patients. In 2010, pharmacy faculty researchers received more than $358 million in grant support from the NIH. AACP member institutions are concerned, as are other health professions education organizations, of the need to increase the number of biomedical researchers.

—At the University of California, San Francisco, Kathleen M. Giacomini and co-lead Deanna L. Kroetz received $15.1 million in funding over the next 5 years from the NIH for research into the genetics behind membrane transporters and

a branch project from that research that will focus on the genetic factors that determine responses to the anti-diabetic drug, metformin in African American patients with type 2 diabetes. #2U19GM061390–11

—Alice M. Clark and Ameeta K. Agarwal, University of Mississippi, received $388,221 from the National Institute of Allergy and Infectious Diseases to study New Drugs for Opportunistic Infections. #5R01AI027094–21

—Eugene D. Morse, the University at Buffalo, received two grants: $952,000 in funding for, "Clinical Pharmacology Quality Assurance and Quality Control" funded by the National Institute of Allergies and Infectious Diseases/Division of AIDS and $2.3 Million for, "Clinical Pharmacology Lab from NIH to Promote HIV Research in Africa." #272200800019C–4-0–1

—Jordan K. Zjawiony and Charles L. Burandt, the University of North Carolina, received $71,500 from the NIH to study Chemistry and Pharmacology of Newly Emerging Psychoactive Plants-Year 2. #5R03DA023491–02

U.S. DEPARTMENT OF EDUCATION SUPPORTED PROGRAMS AT COLLEGES AND SCHOOLS OF PHARMACY

AACP supports the Student Aid Alliance's recommendations for:

—Pell Grant maximum be maintained at $5,550;

—Gaining Early Awareness and Readiness for Undergraduate Programs (GEAR UP) should be funded at $333 million; and

—Maintaining the in-school interest subsidy for graduate program loans.

AACP recommends a funding level of $160 million for the Fund for the Improvement of Post Secondary Education (FIPSE).

The Department of Education supports the education of healthcare professionals by:

—assuring access to education through student financial aid programs;

—supporting educational research allows faculty to determine improvements in educational approaches; and

—maintaining the oversight of higher education through the approval of accrediting agencies.

AACP actively supports increased funding for undergraduate student financial assistance programs. Admission to into the pharmacy professional degree program requires at least 2 years of undergraduate preparation. Student financial assistance programs are essential to assuring colleges and schools of pharmacy are accessible to qualified students. Likewise, financial assistance programs that support graduate education are an important component meeting our Nation's need for scientists and educators.

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PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

The American Association of Immunologists (AAI), a not-for-profit professional association representing more than 7,000 of the world's leading experts on the immune system, appreciates having this opportunity to submit testimony regarding fiscal year 2012 appropriations for the National Institutes of Health (NIH). The vast majority of AAI members, whose crucially important discoveries help to prevent, treat and cure disease, depends on NIH funding to support their work.[1]

For more than 50 years, NIH has been envy of the world and has been instrumental in promoting science, better health, and discovery. Unlike many Federal agencies, NIH distributes most of its funding to scientists working in all 50 States. In fact, about 80 percent of the $31.2 billion NIH budget is awarded to scientists working at research institutions throughout the United States, making NIH funding the foundation of our Nation's biomedical research infrastructure and a key factor in local and national economic growth.[2] In addition to its positive economic impact on a community, NIH funding supports highly skilled jobs that focus on improving

[1] AAI members work in academia, government, and industry. Many members receive grants from the National Institute of Allergy and Infectious Diseases, the National Cancer Institute, the National Institute on Aging, and the National Institute of Arthritis and Musculoskeletal and Skin Diseases, as well as other NIH Institutes and Centers.

[2] NIH funding supports "almost 50,000 competitive grants to more than 325,000 researchers at over 3,000 universities, medical schools, and other research institutions in every State and around the world." See http://www.nih.gov/about/budget.htm (3/9/11). According to NIH Director Francis Collins M.D., Ph.D., "every dollar that NIH gives out in a grant returns over $2 in investments in terms of economic goods and services that are produced within just 1 year." "Francis S. Collins," April 26, 2010, http://pubs.acs.org/cen/coverstory/88/8817cover.html.

human health.[3] NIH funding also helps train the next generation of inventors and innovators, crucial to the nation's future job creation and pipeline of new therapeutics.

*The role of the immune system*

The immune system's job is to protect its human or animal host from a wide range of infectious and chronic diseases. When the immune system works, the host remains healthy. But many infectious diseases, including influenza, HIV/AIDS, malaria, tuberculosis, salmonella, and the common cold, challenge and sometimes overcome the defenses mounted by the immune system. And many chronic diseases, including cancer, diabetes, multiple sclerosis, rheumatoid arthritis, asthma, inflammatory bowel disease, and lupus, are either caused by—or due in large part to—an overactive (autoimmune) or underactive immune response.[4] Advances in immunological research have already yielded progress in preventing, diagnosing, and treating some of these diseases, but further progress depends on increased knowledge in the field of immunology.

A young and evolving discipline,[5] immunology has already answered many key questions and is now needed to explore urgent new challenges to community and global health, including understanding the human and animal immune response to: (1) pathogens that threaten to become the next pandemic, (2) man-made and natural infectious organisms that are potential agents of bioterrorism (including plague, smallpox, and anthrax),[6] (3) environmental threats, and (4) cancer. While researchers and public health professionals must respond quickly to these emergent threats, AAI believes that the best preparation is to support consistent, ongoing research rather than to "ramp up" research in times of emergency.[7]

*Recent advances in immunological research*

Immunological research has led to unprecedented medical advances in recent years, including new treatments for lupus and malignant melanoma, and new vaccines against influenza and cervical cancer.

The value of vaccination against disease and the importance of continued research and evaluation cannot be overstated. Recent expansion of the influenza vaccine to all U.S. children "may induce herd immunity against influenza for older adults and has the potential to be more beneficial to older adults than the existing policy of preventing influenza by vaccinating older adults themselves."[8] A recent study has shown the efficacy of vaccinating older adults, whether healthy or with chronic diseases, against shingles, a painful blistering skin rash caused by the varicella-zoster virus, the virus that causes chickenpox.[9] Most recently, a new vaccine against rotavirus has greatly reduced hospital admissions in the United States in babies with infectious diarrhea and markedly decreased deaths in infants in the developing

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[3] "[E]very grant that NIH gives creates seven high-quality, high-paying jobs that sustain American leadership in science." "Francis S. Collins," April 26,2010, http://pubs.acs.org/cen/coverstory/88/8817cover.html.

[4] The immune system works by recognizing and attacking bacteria and viruses inside the body and by controlling the growth of tumor cells. A healthy immune system can protect its human or animal host from illness or disease either entirely—by destroying the virus, bacterium, or tumor cell—or partially, resulting in a less serious illness. It is also responsible for the rejection response following transplantation of organs or bone marrow. The immune system can also malfunction, causing the body to attack itself, resulting in an "autoimmune" disease, such as Type 1 diabetes, multiple sclerosis, lupus or rheumatoid arthritis.

[5] 5 Although the first vaccine (against smallpox) was developed in 1798, most of our basic understanding of the immune system has developed in the last 50 years, and the pace of discovery is rapidly increasing.

[6] To best protect against bioterrorism, scientists should focus on basic research, including working to understand the immune response, identifying new and potentially modified pathogens, and developing tools (including new and more potent vaccines) to protect against these pathogens.

[7] For example, to best protect against a pandemic, scientists should focus on basic research to combat seasonal flu, including building capacity, pursuing new production methods, and seeking optimized flu vaccines and delivery methods.

[8] Cohen SA, Chui K, Naumova E, "Influenza Vaccination in Young Children Reduces Influenza-associated Hospitalizations in Older Adults, 2002–2006," Journal of the American Geriatrics Society, 2011; 59(2):327–332.

[9] Tseng HF, Smith N, Harpaz R, Bialek SR, Sy LS, Jacobsen SJ, "Herpes zoster vaccine in older adults and the risk of subsequent herpes zoster disease," Journal of the American Medical Association, 2011 Jan 12; 305(2):160–166.

world.[10] Thousands of children will not die due to the results of immunological and infectious disease research originally funded by the NIH on this killer virus.

Recently, immunologists have advanced the understanding of the exquisitely precise regulation of the immune system and are very hopeful that this understanding will allow for therapeutic manipulation of the immune system. This important discovery about immune-system regulation could lead to new approaches for the prevention and treatment of numerous autoimmune diseases, including lupus (systemic lupus erythematosus),[11] a serious chronic autoimmune disease affecting about 1.5 million Americans. Finally, new monoclonal antibodies (highly specific immune molecules) that block the immune response of people with autoimmune diseases (in which one's immune system attacks one's own body) show enormous promise in improving these debilitating diseases.

*Sustaining NIH Funding in a Difficult Fiscal Climate*

AAI greatly appreciates the strong historical support of this subcommittee for biomedical research, from doubling the NIH budget (fiscal year 1999 to fiscal year 2003), to passing the Appropriations Acts for fiscal year 2009 and 2010, to including in the American Recovery and Reinvestment Act of 2009 ("ARRA") a $10.4 billion supplemental appropriation for NIH. As a result of this generous support, NIH has been able to fund many excellent, innovative projects with great promise for advancing human health, and to invest in the Nation's research infrastructure. AAI—and the entire biomedical research community—are deeply grateful for this support and for the subcommittee's strong bipartisan commitment to advancing medical research. And yet, AAI comes to you this year deeply concerned about efforts to cut, rather than invest in, the NIH budget. Imminent advances may not come to fruition if the fiscal year 2012 appropriations level is unable to support NIH's current functional capacity (~$34.4 billion), made possible in large part by this subcommittee's prior support. AAI remains concerned that investment in biomedical research continues unfettered by our global competitors, while our challenged budget makes it difficult for us to attract the best and brightest to these crucial scientific fields. The AAI funding recommendation for fiscal year 2012 is premised on these concerns.

*NIH Funding for Fiscal Year 2012*

AAI greatly appreciates the President's proposed increase for NIH for fiscal year 2012 ($31.98 billion, or 4 percent increase over the regular fiscal year 2011 appropriations level). More is required, however, for NIH to be able to support existing research projects and fund a reasonable number of excellent new ones. AAI therefore urges the subcommittee to provide NIH with a fiscal year 2012 budget of $35 billion to enable NIH to maintain its current functional capacity and to provide a small funding boost for important new research. Sustained funding, particularly in this challenging fiscal climate, would not only stabilize ongoing research projects and the overall research enterprise, but also inspire confidence in the system among many of our brightest young students who are considering (but due to such limited grant funding, are fearful to begin) careers in biomedical research.

*NIH priorities for Fiscal Year 2012*

AAI believes strongly that the engine for biomedical innovation and discovery is individual investigator-initiated research. Researchers working in laboratories around the country, with their scientific collaborators around the world, are the best source of scientific advancement and progress. "Top-down" science, where Government directives force the research in specified directions, is less likely to achieve the desired goals than funding the best, most promising, ripest grant applications.

AAI strongly supports the President's request for a $436 million increase in funding for individual research project grants (RPGs) that fund individual scientists. Unfortunately, this increase will only support approximately 43 additional RPGs. AAI notes that the President's budget includes $100 million to establish the Cures Acceleration Network (CAN). AAI recommends a significantly smaller appropriation for the first year of this program, with the remainder going to support additional RPGs.

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[10] Esposito DH, Tate JE, Kang G, Parashar UD, "Projected impact and cost-effectiveness of a rotavirus vaccination program in India, 2008," Clinical Infectious Diseases, 2011; 52 (2):171–177. Gagneur A, Nowak E, Lemaitre T, Segura JF, Delaperrière N, Abalea L, Poulhazan E, Jossens A, Auzanneau L, Tran A, Payan C, Jay N, de Parscau L, Oger E, "Impact of rotavirus vaccination on hospitalizations for rotavirus diarrhea: The IVANHOE study," Vaccine, 2011 March 25, doi:10.1016/j.vaccine.2011.03.035.

[11] Kim HJ, Verbinnen B, Tang X, Linrong L, Cantor H, "Inhibition of follicular T-helper cells by CD8+ regulatory T cells is essential for self tolerance," Nature, 2010 July 22; 467: 328–322.

AAI supports the President's request for $300 million for the Global Fund to Fight AIDS, Tuberculosis, and Malaria—infectious diseases which devastate people and communities around the world.

AAI supports the President's proposed 4 percent increase for the National Research Service Awards, a long-needed training stipend increase for young scientists who are the next generation of research leaders.

AAI urges this subcommittee to do all it can to reduce the time-consuming, distracting, and unnecessary administrative burden that too often accompanies the receipt of Government funds.

AAI recommends strongly against any legislative effort to determine the size and number of NIH grants. Such a decision should be a scientific one made by NIH.

AAI supports the President's request for $1.538 billion for NIH Research, Management, and Services (RM&S) to fund the management, monitoring, and oversight of all research activities. Only through adequate funding of this account will NIH be able to supervise and oversee its large and complex portfolio.

*The NIH Public Access Policy*

AAI requests that the subcommittee require NIH to publicly report on the current and historical cost of the NIH Public Access Policy ("Policy"), and receive the response of private scientific publishers to this information. AAI continues to believe that the Policy duplicates publications and services which are already provided cost-effectively and well by the private sector, including not-for-profit scientific societies. AAI and other private sector publishers already publish—and make publicly available—thousands of scientific journals with millions of articles that report cutting-edge research funded by NIH and other entities. AAI urges that the subcommittee require NIH to partner with, rather than compete with, private publishers to enhance public access while addressing publishers' key concerns, including respecting copyright law and ensuring journals' continued ability to provide quality, independent peer review of NIH-funded research.

*Conclusion*

AAI thanks the subcommittee for its strong support for biomedical research, the NIH, and the biomedical researchers who devote their lives to scientific discovery and the prevention, treatment, and cure of disease.

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PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF NURSE ANESTHETISTS

FISCAL YEAR 2012 APPROPRIATIONS REQUEST SUMMARY

| | Fiscal year— | | | AANA fiscal year 2012 request |
|---|---|---|---|---|
| | 2010 actual | 2011 budget | 2012 budget | |
| HHS/HRSA/BHPr Title VIII Advanced Education Nursing, Nurse Anesthetist Education Reserve | [1] $3,500,000 | ([2]) | ([2]) | [3] $4,000,000 |
| Total for Advanced Education Nursing, from Title VIII | 64,440,000 | 64,440,000 | 104,438,000 | 104,438,000 |
| Title VIII HRSA BHPr Nursing Education Programs | 243,872,000 | 243,872,000 | 313,075,000 | 313,075,000 |
| CDC/Division of Healthcare Quality and Promotion | ..... | ..... | ([4]) | ([4]) |

[1] Awards amounted to approximately.
[2] Grant allocations not specified.
[3] For nurse anesthesia education.
[4] Maintain level funding.

The American Association of Nurse Anesthetists (AANA) is the professional association for the 44,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists practicing today, representing over 90 percent of the nurse anesthetists in the United States. Today, CRNAs deliver approximately 32 million anesthetics to patients each year in the United States. CRNA services include administering the anesthetic, monitoring the patient's vital signs, staying with the patient throughout the surgery, and providing acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and in some States are the sole anesthesia providers in 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, and trauma stabilization, and pain management capabilities. CRNAs work in every setting in which anesthesia is delivered, including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management units and the offices of dentists, podiatrists and plastic surgeons. Nurse anesthetists are experienced and highly trained anesthesia professionals whose record of patient safety in the field of anesthesia was bolstered by the Institute of Medicine report in 2000, which found that anesthesia is

50 times safer than in the 1980s. (Kohn L, Corrigan J, Donaldson M, ed. To Err is Human. Institute of Medicine, National Academy Press, Washington DC, 2000.) Nurse anesthetists continue to set for themselves the most rigorous continuing education and re-certification requirements in the field of anesthesia. Relative anesthesia patient safety outcomes are comparable among nurse anesthetists and anesthesiologists, with a recent Health Affairs article, "No Harm Found When Nurse Anesthetists Work without Supervision by Physicians" finding that adverse outcomes were no more prevalent in States that opted out of the Medicare physician supervision requirement of nurse anesthetists than those States that didn't opt-out (Dulisse B, Cromwell J. No Harm Found When Nurse Anesthetists Work Without Supervision By Physicians. Health Aff. 2010;29(8):1469–1475).

In addition, a study published in Nursing Research indicates that obstetrical anesthesia, whether provided by CRNAs or anesthesiologists, is extremely safe, and there is no difference in safety between hospitals that use only CRNAs compared with those that use only anesthesiologists. (Simonson, Daniel C et al. Anesthesia Staffing and Anesthetic Complications During Cesarean Delivery: A Retrospective Analysis. Nursing Research, Vol. 56, No. 1, pp. 9–17. January/February 2007). In addition, a recent AANA workforce study showed that CRNAs and anesthesiologists are substitutes in the production of surgeries. Through continual improvements in research, education, and practice, nurse anesthetists are vigilant in our efforts to ensure patient safety.

CRNAs provide the lion's share of anesthesia care required by our U.S. Armed Forces through active duty and the reserves. For decades, CRNAs have staffed ships, remote U.S. military bases, and forward surgical teams without physician anesthesiologist support. In addition, CRNAs predominate in rural and medically underserved areas, and where more Medicare patients live.

*Importance of Title VIII Nurse Anesthesia Education Funding*

The nurse anesthesia profession's chief request of the Subcommittee is for $4 million to be reserved for nurse anesthesia education and $104.438 million for advanced education nursing from the Title VIII program. We feel that this funding request is well justified, as we know that more baby boomers retiring will not only reduce our nurse workforce from retirements but will increase the demand from an aging population requiring care. The Title VIII program is an effective means to help address the nurse anesthesia workforce demand.

Increasing funding for advanced education nursing from $64.44 million in fiscal year 2010 to $104.438 million is necessary to meet the continuing demand for nursing faculty and other advanced education nursing services throughout the United Staes. The program provides for competitive grants that help enhance advanced nursing education and practice and traineeships for individuals in advanced nursing education programs. This funding is critical to meet the nursing workforce needs of Americans who require healthcare, particularly as we see more patients enter the system with health reform. More APRNs will be needed to fill the gap to ensure access to care. In addition, this funding provides a two-fold benefit for the nurse workforce. It not only seeks to increase the number of providers in rural and underserved America but also prepares providers at the master's and doctoral levels, increasing the number of clinicians who are eligible to serve as faculty.

There continues to be high demand for CRNA workforce in clinical and educational settings. The supply of clinical providers has increased in recent years, stimulated by increases in the number of CRNAs trained. Between 2000–2009, the number of nurse anesthesia educational program graduates doubled, with the Council on Certification of Nurse Anesthetists (CCNA) reporting 1,075 graduates in 2000 and 2,375 graduates in 2010. This growth is leveling off somewhat, but is expected to continue. However, even though the number of graduates has doubled in 8 years, the demand for nurse anesthetists continues to rise as the population ages, the number of clinical sites requiring anesthesia services grows, and CRNA retirements increase.

The problem is not that our 111 accredited programs of nurse anesthesia are failing to attract qualified applicants. It is that they have to turn them away by the hundreds. The capacity of nurse anesthesia educational programs to educate qualified applicants is limited by the number of faculty, the number and characteristics of clinical practice educational sites, and other factors. A qualified applicant to a CRNA program is a bachelor's educated registered nurse who has spent at least 1 year serving in an acute care healthcare practice environment.

Recognizing the important role nurse anesthetists play in providing quality healthcare, the AANA has been working with the 111 accredited nurse anesthesia educational programs to increase the number of qualified graduates. In addition, the AANA has worked with nursing and allied health deans to develop new CRNA pro-

grams. To truly meet the nurse anesthesia workforce challenge, the capacity and number of CRNA schools must continue to grow. With the help of competitively awarded grants supported by Title VIII funding, the nurse anesthesia profession is making significant progress, expanding both the number of clinical practice sites and the number of graduates.

The AANA is pleased to report that this progress is extremely cost-effective from the standpoint of Federal funding. Anesthesia can be provided by nurse anesthetists, physician anesthesiologists, or by CRNAs and anesthesiologists working together. As mentioned earlier, the Health Affairs study by Dulisse and Cromwell indicates the safety of CRNA care. Another study published recently in Nursing Economic$ indicates that costs of educating and training a CRNA from undergraduate education through graduate education is roughly 15 percent of the cost of educating and training an anesthesiologist (Hogan, PF, Seifert RF, Moore CS, Simonson BE, Cost Effectiveness Analysis of Anesthesia Providers, Nurs Econ. 2010;28(3): 150–169.) This study also found that among anesthesia delivery models, CRNAs acting independently provide anesthesia services at the lowest economic cost; costs for this model are 25 percent less than the second lowest cost model in which an anesthesiologist supervises six CRNAs. Nurse anesthesia education represents a significant educational cost-benefit for supporting CRNA educational programs with Federal dollars vs. supporting other, more costly, models of anesthesia education.

To further demonstrate the effectiveness of the Title VIII investment in nurse anesthesia education, the AANA surveyed its CRNA program directors to gauge the impact of the Title VIII funding. Of the eleven schools that had reported receiving competitive Title VIII Nurse Education and Practice Grants funding from 1998 to 2003, the programs indicated an average increase of at least 15 CRNAs graduated per year. They also reported on average more than doubling their number of graduates. Moreover, they reported producing additional CRNAs that went to serve in rural or medically underserved areas.

We believe the Subcommittee should allocate $4 million for nurse anesthesia education for several reasons. First, as this testimony has documented, the funding is cost-effective and needed. Second, this particular funding meets a distinct need not met elsewhere; nurse anesthesia for rural and medically underserved America is not affected by increases in the budget for the National Health Service Corps and community health centers, since those initiatives are for delivering primary and not surgical healthcare. Third, this funding meets an overall objective to increase access to quality healthcare in medically underserved America.

*Title VIII Funding for Strengthening the Nursing Workforce*

The AANA joins The Nursing Community and the Americans for Nursing Shortage Relief (ANSR) Alliance in support of the Subcommittee providing a total of $313.075 million in fiscal year 2012 for nursing shortage relief through Title VIII. AANA asks that of the $313.075 million, $104.438 million go to Advanced Education Nursing and $4 million go to nurse anesthesia education to help increase clinicians in underserved communities and those eligible to serve as faculty. The AANA appreciates the support for nurse education funding in fiscal year 2010 and past fiscal years from this Subcommittee and from the Congress.

In the interest of patients past and present, particularly those in rural and medically underserved parts of this country, we ask Congress to invest in CRNA and nursing educational funding programs and to provide these programs the sustained increases required to help ensure Americans get the healthcare that they need and deserve. Quality anesthesia care provided by CRNAs saves lives, promotes quality of life, and makes fiscal sense. This Federal support for Title VIII and advanced education nurses will improve patient access to quality services and strengthen the Nation's healthcare delivery system.

*Safe Injection Practices*

As a leader in patient safety, the AANA has been playing a vigorous role in the development and projects of the Safe Injection Practices Coalition, intended to reduce and eventually eliminate the incidence of healthcare facility acquired infections. Provider education and awareness, detection, tracking and response are all extremely important to preventing healthcare-associated infections. In the interest of promoting safe injection practice and reducing the incidence of healthcare facility acquired infections, we recommend the Committee maintain its level of funding for CDC's Division of Healthcare Quality and Promotion so they can address outbreaks and promote innovative ways to adhere to injection safety and infection control guidelines. We also hope the committee will support the CDC's efforts around provider education and patient awareness activities, as this issue transcends provider

type and it's important to educate all types of providers and patients alike. In light of the recent healthcare-associated transmission of blood-borne pathogens in California, North Carolina, Florida, Colorado, and Nevada, the CDC needs resources to use the knowledge they have gained on detection and be able to develop new strategies to prevent healthcare associated transmission of blood borne pathogens.

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PREPARED STATEMENT OF THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

The American Congress of Obstetricians and Gynecologists, representing 54,000 physicians and partners in women's healthcare, is pleased to offer this statement to the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education. We thank Chairman Harkin, and the entire Subcommittee for the opportunity to provide comments on important programs to women's health. Today, the United States lags behind other nations in healthy births, yet remains high in birth costs. ACOG's Making Obstetrics and Maternity Safer (MOMS) Initiative seeks to improve maternal outcomes through more research and better data, and we urge you to make this a top priority in fiscal year 2012.

Research is critically needed to understand why our maternal and infant mortality rate remains comparatively high. Having better data collection methods and comprehensive maternal mortality reviews has shown maternal mortality rates in some States, such as California, to be higher than previously thought. States without these resources are likely underreporting maternal and infant deaths and complications from childbirth. Without accurate data, the full range of causes of these deaths remains unknown. Effective research based on comprehensive data is a key MOMS element to developing and implementing evidence-based interventions.

The President's budget for fiscal year 2012 takes a positive first step toward this goal, including a $1 billion increase for NIH, and ACOG requests the Subcommittee build on these increases to sustain the investment for women's health. Please note that given the current fiscal climate, our requests are more conservative this year and do not reflect the actual need in the health community. ACOG asks for a 1.7 percent increase over fiscal year 2010 to the NICHD within NIH to $1.352 billion, a 2.3 percent increase for HRSA to $7.65 billion, a 19 percent increase for CDC to $7.7 billion, and a 2 percent increase for AHRQ to $405 million.

Funding of research and programs in the following areas are vital to the MOMS Initiative:

*Maternal Mortality Reviews at HHS*

National data on maternal mortality is inconsistent and incomplete due to the lack of standardized reporting definitions and mechanisms. To capture the accurate number of maternal deaths and plan effective interventions, maternal mortality should be addressed through multiple, complementary strategies. ACOG recommends that HHS fund States in implementing maternal mortality reviews that would allow them to conduct regular reviews of all deaths within the State to identify causes, factors in the communities, and strategies to address the issues. Combined with adoption of the recommended birth and death certificates in all States and territories, CDC could then collect uniform data to calculate an accurate national maternal mortality rate. Results of maternal mortality reviews will inform research needed to identify evidence based interventions addressing causes and factors of maternal mortality and morbidity.

ACOG urges Congress to provide $10 million to Health and Human Services to assist States in setting up maternal mortality reviews. ACOG also urges Congress to provide $50,000 to NIH to hold a workshop to identify definitions for severe maternal morbidity and $100,000 to HHS to develop a research plan to identify and monitor severe maternal morbidity.

*Maternal/Child Health Research at the NIH*

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) conducts the majority of women's health research. Despite the NIH's critical advancements, reduced funding levels have made it difficult for research to continue.

ACOG supports a 1.7 percent increase in funds over fiscal year 2010 to $1.352 billion for the NICHD. A modest increase, these funds will assist the following research areas critical to the MOMS Initiative:

*Reducing the Prevalence of Premature Births*.—There is a known link between pre-term birth and infant mortality, and women of color are at increased risk for delivering pre-term. NICHD is helping our Nation understand how adverse conditions and health disparities increase the risks of premature birth in high-risk racial

groups, and how to reduce these risks. Prematurity rates have increased almost 35 percent since 1981, accounting for 12.5 percent of all births, yet the causes are unknown in 25 percent of cases. Preterm births cost the Nation $26 billion annually, $51,600 for every infant born prematurely. Direct healthcare costs to employers for a premature baby average $41,610, 15 times higher than the $2,830 for a healthy, full-term delivery.

Additional research is critically needed to understand how we can drive down our prematurity rates and NICHD conducts the majority of this research. For example, a 2003 NICHD study showed that progesterone supplementation reduces preterm birth in a select group of women, paving the way for its widespread clinical use. Today, around 139,000 (3.3 percent) women are candidates for this therapy. Among these women, 22 percent, or about 30,500, are likely to have a recurrent preterm birth without this treatment. With treatment, about one-third, or 10,000, of these preterm births can be prevented. The prevention of all 10,000 preterm births would result in direct medical cost savings of $334 million and total medical cost savings of $519 million. However, further studies are needed to determine if progesterone therapy can be designed to help prevent preterm delivery in other ways, including optimal preparation, dosage, and route of administration. The high cost of prematurity and past successful research at NICH highlights the need to sustain investments to reduce the rate of prematurity.

ACOG supports the Surgeon General's effort to make the prevention of pre-term birth a national public health priority, and urges Congress to allocate $1 million to NICHD to create a Trans-disciplinary Research Center on Prematurity to help streamline efforts to reduce pre-term births.

*Obesity Research, Treatment and Prevention*.—Obese pregnant women are at higher risk for poor maternal and neonatal outcomes. Additional research and interventions are needed to address the increased risk for poor outcomes in obese women receiving infertility treatment, the increased incidence of birth defects and stillbirths in obese pregnant women, ways to optimize outcomes in obese women who become pregnant after bariatric surgery, and the increased future risk of childhood obesity in their offspring.

ACOG is grateful to the NIH for making obesity a priority and initiating transdisciplinary approaches to combat obesity. The recent release of the Strategic Plan for NIH Obesity Research offers some innovative and promising directions for obesity research, and sustained funding is critical to implement the plan.

*Training Programs*.—The average investigator is in his/her forties before receiving their first NIH grant, a huge dis-incentive for students considering bio-medical research as a career. Complicating matters, there is a gap between the number of women's reproductive health researchers being trained and the need for such research. The NICHD-coordinated Women's Reproductive Health Research (WRHR) Career Development program seeks to increase the number of ob-gyns conducting scientific research in women's health in order to address this gap. To date 170 WRHR Scholars have received faculty positions, and 7 new and competing WRHR sites were added in 2010.

Additional funding to add new sites can help sustain this low-dollar, large impact training program while at the same time shoring up the women's reproductive research workforce.

*Maternal/Child Health Programs at CDC*

CDC funds programs that are critical to providing resources to mothers and children in need. Where NIH conducts research to identify causes of pre-term birth, CDC funds programs that provide resources to mothers to help prevent pre-term birth, and help identify factors contributing to pre-term birth and poor maternal outcomes.

ACOG supports a 19 percent increase in funds over fiscal year 2010 to $7.7 billion to increase CDC's ability to bring prevention, treatment and interventions to more women and children in need, and to help enact some of the important provisions within healthcare reform. This funding will help the following programs important to the MOMS Initiative:

*Electronic Birth Records and Death Records, National Center for Health Statistics (NCHS), National Vital Statistics System (NVSS)*.—NCHS is the Nation's principal health statistics agency; it collects, analyzes and reports on data critical to all aspects of our healthcare system. NCHS collects State data needed to monitor maternal and infant health, such as use of prenatal care, and smoking during pregnancy. This data allows investigators to monitor maternal and child health objectives, and develop efficient prevention and treatment strategies.

Uniform consistent data from birth and death records is critical to conducting research and directing public programs to combat maternal and infant death. Only 75

percent of States and territories use the 2003 recommended birth certificates and 65 percent have adopted the 2003 recommended death certificate. The President recently issued a Memorandum to all departments and agencies encouraging expanded data collection on maternal mortality by using the 2003 U.S. standard birth certificate and updating to electronic systems, noting that until all States adopt the same data standards it will be difficult to formulate national maternal mortality ratios.

ACOG urges Congress to allocate $11 million for States to modernize their birth and death records systems to the 2003 recommended guidelines. It is a low cost that will yield enormous gains in CDC's ability to collect accurate data nationally and better direct medical research and best practice for physicians.

*Safe Motherhood/Infant Health.*—Two to three women a day die from delivery complications. The Safe Motherhood Program supports CDC's work to identify and gather information on pregnancy-related deaths; collect and provide information about women's health and health behaviors around pregnancy; and expand the use of guidelines on preconception care into everyday practice and healthcare policy.

Safe Motherhood also tracks infant morbidity and mortality associated with preterm birth. ACOG is concerned with recent trends particularly among rates of late pre-term births. Increased funding is needed for CDC to improve national data systems to track pre-term birth rates and expand epidemiological research that focuses especially on the causes and prevention of preterm birth and births at 37–38 weeks gestation.

ACOG urges Congress to include a 23.7 percent increase in funds to $55.4 million for Safe Motherhood, consistent with the President's fiscal year 2011 budget.

*Maternal/Child Health Programs at HRSA*

HRSA delivers critical resources to communities to improve the health of mothers and children. ACOG urges a 2.3 percent increase in funds over fiscal year 2010 to $7.65 billion to increase the scope of HRSA programs, ultimately bringing more resources to more mothers and children. This funding will help expand the following programs important to the MOMS Initiative:

*Fetal Infant Mortality Reviews, Healthy Start Program.*—The U.S. infant mortality rate is again on the rise and is particularly severe among minority and low-income women. The infant mortality rate among African-American women has been increasing since 2001 and reached 14.2 deaths per 1,000 births in 2004. There also has been a startling rise in infant mortality in the South in the past few years.

The Healthy Start Program through HRSA promotes community-based programs that focus on infant mortality and racial disparities in perinatal outcomes. These programs are encouraged to use the Fetal and Infant Mortality Review (FIMR) which brings together ob-gyn experts and local health departments to help solve problems related to infant mortality. Today more than 220 local programs in 42 States find FIMR a powerful tool to help solve infant mortality.

ACOG urges Congress to include $.5 million for Healthy Start Programs to include FIMR.

*Maternal Child Health Block Grant (MCH)*

The MCH is the only Federal program that exclusively focuses on improving the health of mothers and children. State and territorial health agencies and their partners use MCH Block Grant funds to reduce infant mortality, deliver services to children and youth with special healthcare needs, support comprehensive prenatal and postnatal care, screen newborns for genetic and hereditary health conditions, deliver childhood immunizations, and prevent childhood injuries.

These early healthcare services help keep women and children healthy, eliminating the need for later costly care. For example, every $1 spent on preconception care programs for women with diabetes can reduce health costs by up to $5.19 by preventing costly complications in both mothers and babies. Studies also suggest that every $1 spent on smoking cessation counseling for pregnant women saves $3 in neonatal intensive care costs.

ACOG urges Congress to increase funding for MCH $700 million, a 5.74 percent increase over fiscal year 2010.

*Title X Family Planning*

The Title X program provides contraceptive services, immunizations and other preventive healthcare, including screenings for STDs, HIV, breast cancer, cervical cancer, high blood pressure, and anemia to more than 5 million low-income men and women at more than 4,500 service delivery sites. These programs improve maternal and child health outcomes, prevent unintended pregnancies, and reduce the rate of abortions. Every $1 spent on family planning results in a $4 savings to Medicaid.

Services provided at Title X clinics accounted for $3.4 billion in healthcare savings in 2008 alone.

ACOG supports a 3.15 percent increase in funds for Title X to $327 million, consistent with the President's budget.

Again, we would like to thank the Committee for its consideration of funding for programs to improve women's health, and we urge you to consider our MOMS Initiative in fiscal year 2012.

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PREPARED STATEMENT OF THE AMERICAN DENTAL EDUCATION ASSOCIATION

The American Dental Education Association (ADEA)[1] respectfully submits this statement for the record and for your consideration as you begin to prioritize fiscal year 2012 appropriation requests. ADEA urges you to preserve the funding and fundamental structure of Federal programs that provide prevention of dental disease, access to oral healthcare for underserved populations, and access to careers in dentistry and oral health services.

As you know, ADEA's membership is comprised of all 61 dental schools in the United States. These academic dental institutions make substantial contributions to the oral health and well-being of the Nation. Services are provided through campus and offsite dental clinics where students and faculty provide patient care as dental homes to the uninsured and underserved populations. However, in order to continue to provide these services, there must be adequate funding. Therefore, it is critical that funding for oral healthcare, delivery of services, and research be preserved in order to ensure the level of care that is necessary for all segments of the population.

ADEA's requests build upon funding from the American Economic Recovery and Reinvestment Act (ARRA), the Labor, Health and Human Services and Education fiscal year 2010 Appropriations, and the Continuing Resolution for fiscal year 2011. We are asking the committee to maintain adequate funding for the dental programs in Title VII of the Public Health Service Act; the National Institutes of Health and the National Institute of Dental and Craniofacial Research; the Dental Health Improvement Act; Part F of the Ryan White HIV/AIDS Treatment and Modernization Act: the Dental Reimbursement Program and the Community-Based Dental Partnerships Program; and State-Based Oral Health Programs at the Centers for Disease Control and Prevention. These programs enhance and sustain State oral health departments, fund public health programs proven to prevent oral disease, fund research to eradicate dental disease, and fund programs to develop an adequate workforce of dentists with advanced training to serve all segments of the population including children, the elderly, and those suffering from chronic and life-threatening diseases.

*$30 million for Primary Oral Healthcare Workforce Improvements (HHS)*

The dental programs in Title VII, Section 748 of the Public Health Service Act that provide training in general, pediatric, and public health dentistry and dental hygiene are critical. Support for these programs will help to ensure there will be an adequate oral healthcare workforce to care for the American public. The funding supports predoctoral oral health education and postdoctoral pediatric, general, and public health dentistry training. The investment that Title VII makes not only helps to educate dentists and dental hygienists, but also expands access to care for underserved communities.

Additionally, Section 748 addresses the shortage of professors in dental schools with the dental faculty loan repayment program and faculty development courses for those who teach pediatric, general, or public health dentistry or dental hygiene. There are currently almost 400 open faculty positions in dental schools. These two programs provide schools with assistance in recruiting and retaining faculty.

*$35 billion for the National Institutes of Health, including $468 million for the National Institute of Dental and Craniofacial Research (NIDCR)*

Discoveries stemming from dental research have reduced the burden of oral diseases, led to better oral health for millions of Americans, and uncovered important associations between oral and systemic health. Dental researchers are poised to make breakthroughs that can result in dramatic progress in medicine and health,

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[1] The American Dental Education Association represents all 61 U.S. dental schools, 700 dental residency training programs, nearly 600 allied dental programs, as well as more than 12,000 faculty who educate and train the nearly 50,000 students and residents attending these institutions. It is at these academic dental institutions that future practitioners and researchers gain their knowledge, where the majority of dental research is conducted, and where significant dental care is provided.

such as repairing natural form and function to faces destroyed by disease, accident, or war injuries; diagnosing systemic disease from saliva instead of blood samples; and deciphering the complex interactions and causes of oral health disparities involving social, economic, cultural, environmental, racial, ethnic, and biological factors. Dental research is the underpinning of the profession of dentistry. With grants from NIDCR, dental researchers in academic dental institutions have built a base of scientific and clinical knowledge that has been used to enhance the quality of the nation's oral health and overall health.

Also, dental scientists are putting science to work for the benefit of the healthcare system through translational research, comparative effectiveness research, health information technology, health research economics, and further research on health disparities. NIDCR continues to make disparities a priority with continued funding for the Centers for Research to Reduce Disparities in Oral Health at Boston University, the University of California, San Francisco, and the University of Colorado at Denver, the University of Florida, and the University of Washington.

*$20 million for the Dental Health Improvement Act (DHIA)*

Section 340G of the Public Health Service Act created the Grants to States to Support Oral Health Workforce Activities as authorized by the Dental Health Improvement Act. This program supports the development of innovative dental workforce programs specific to the State's dental workforce needs and increases access to dental care for underserved populations.

In 2010, Congress provided at total of $17.5 million to assist States in developing flexible dental workforce programs tailored to meet States' individual workforce needs. Grants are being used to support a variety of initiatives including, but not limited to: loan repayment programs to recruit culturally and linguistically competent dentists to work in underserved communities; rotating residents and students in rural areas; recruiting dental school faculty; training pediatricians and family medicine physicians to provide oral health services (screening exams, risk assessments, fluoride varnish application, parental counseling, and referral of high-risk patients to dentists); and supporting tele-dentistry. We expect fiscal year 2011 appropriations to continue to fund the fiscal year 2010 awarded grants, many of which are 3-year projects.

*$19 million for Part F of the Ryan White HIV/AIDS Treatment and Modernization Act: Dental Reimbursement Program (DRP) and the Community-Based Dental Partnerships Program*

Patients with compromised immune systems are more prone to oral infections like periodontal disease and tooth decay. By providing reimbursement to dental schools and schools of dental hygiene, the Dental Reimbursement Program (DRP) provides access to quality dental care for people living with HIV/AIDS while simultaneously providing educational and training opportunities to dental residents, dental students, and dental hygiene students who deliver the care. DRP is a cost-effective Federal/institutional partnership that provides partial reimbursement to academic dental institutions for costs incurred in providing dental care to people living with HIV/AIDS. Congress, recognizing that dental care is a "core medical service" needed by HIV patients provided $13.6 million to fund Part F in 2010.

*$107 million for Diversity and Student Aid*

$24 million for Centers of Excellence (COE)
$60 million for Scholarships for Disadvantaged Students (SDS)
$22 million for Health Careers Opportunity Program (HCOP)
$1.2 million for Faculty Loan Repayment Program (FLRP)

Title VII Diversity and Student Aid programs play a critical role in helping to diversify the health profession's student body and thereby the healthcare workforce. For the last several years, these programs have not enjoyed adequate funding to sustain the progress that is necessary to meet the challenges of an increasingly diverse U.S. population.

*$25 million for Oral Health Programs at the Centers for Disease Control and Prevention (CDC)*

The CDC Oral Health Program expands the coverage of effective prevention programs. The program increases the basic capacity of State oral health programs to accurately assess the needs of the State, organize and evaluate prevention programs, develop coalitions, address oral health in state health plans, and effectively allocate resources to the programs. This strong public health response is needed to meet the challenges of oral disease affecting children, and vulnerable populations.

As the oral health programs at the CDC are so important, we have serious concerns about the proposal to downgrade the status of the Division of Oral Health

(DOH) at the CDC to a branch. We request that you do everything you can to prevent this move.

Thank you for your consideration of this request. ADEA looks forward to working with you to ensure the continuation of congressional support for these critical programs. Please feel free to use us a resource on any issue affecting the oral healthcare of the nation.

If you should have any questions regarding the aforementioned, please contact Deborah Darcy, ADEA Director of Congressional Affairs at (202) 289–7201 x 163.

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PREPARED STATEMENT OF THE AMERICAN DENTAL HYGIENISTS' ASSOCIATION

On behalf of the American Dental Hygienists' Association (ADHA), thank you for the opportunity to submit testimony regarding appropriations for fiscal year 2012. ADHA appreciates the Subcommittee's past support of programs that seek to improve the oral health of Americans and to bolster the oral health workforce. Oral health is a part of total health and authorized oral healthcare programs require appropriations support in order to increase the accessibility of oral health services, particularly for the underserved.

ADHA is the largest national organization representing the professional interests of more than 152,000 licensed dental hygienists across the country. Dental hygienists are primary care providers of oral health services and are licensed in each of the 50 States. Hygienists are committed to improving the Nation's oral health, a fundamental part of overall health and general well-being. In order to become licensed as a dental hygienist, an individual must graduate from an accredited dental hygiene education program and successfully complete a national written and a State or regional clinical examination.

In the past decade, the link between oral health and total health has become more apparent and the significant disparities in access to oral healthcare services have been well documented. At the State and local level, policymakers and consumer advocates have been pioneering innovations to extend the reach of the oral healthcare delivery system and improve oral health infrastructure. At this time, when tens of millions of Americans struggle to obtain the oral healthcare required to remain healthy, Congress has a great opportunity to support oral health prevention, infrastructure and workforce efforts that will make care more accessible and cost-effective.

ADHA urges full funding of all authorized oral health programs and describes some of the key oral health programs below:

*Title VII Program Grants to Expand and Educate the Dental Workforce—Fund at a level of $25 million in fiscal year 2012*

A number of existing grant programs offered under Title VII support health professions education programs, students, and faculty. ADHA is pleased that dental hygienists are now recognized as primary care providers of oral health services and are included as eligible to apply for several grants offered under the "General, Pediatric, and Public Health Dentistry" grants.

With millions more Americans eligible for dental coverage in coming years, it is critical that the oral health workforce is bolstered. Dental and dental hygiene education programs currently struggle with significant shortages in faculty and there is a dearth of providers pursuing careers in public health dentistry and pediatric dentistry. Securing appropriations to expand the Title VII grant offerings to additional dental hygienists and dentists will provide much needed support to programs, faculty, and students in the future.

ADHA recommends funding at a level of $25 million for fiscal year 2012.

*Alternative Dental Health Care Provider Demonstration Project Grants—Fund at a level of $30 million in fiscal year 2012*

States have increasingly been pioneering new dental delivery models to extend access to oral healthcare services to those currently unable to access needed care. The Alternative Dental Health Care Provider Demonstration Project grants support State-level efforts to better utilize the existing oral health workforce as well as develop new provider models.

A number of dental hygiene-based models are listed as eligible for the grants, including advanced practice hygienists, public health hygienists, and independent dental hygienists.

Grants could also be awarded to dental therapist models, programs where physicians/other medical providers deliver basic dental services and other models deemed appropriate by the Secretary of Health and Human Services. Funding would also

allow HRSA to fulfill its statutory requirement to contract with the Institute of Medicine to conduct a study of the demonstration projects.

Currently, more than 30 States have statutes and rules that allow dental hygienists to work in community-based settings (like public health clinics, schools, and nursing homes) to provide oral health services without the presence or direct supervision of a dentist. These models extend the reach of dental professionals beyond the private dental office.

The American Dental Education Association supports funding of this program. The PEW Charitable Trusts Children's Dental Campaign also supports funding of this program. Indeed, more than 60 organizations have called for funding this important program. Without the appropriate supply, diversity and distribution of the oral health workforce, the current oral health access crisis will only be exacerbated.

ADHA recommends funding at a level of $30 million for fiscal year 2012 to support these vital demonstration projects.

*Oral Health Prevention and Education Campaign—Fund at a level of $5 million in fiscal year 2012*

A targeted national campaign led by the Centers for Disease Control to educate the public, particularly those who are underserved, about the benefits of oral health prevention could vastly improve oral health literacy in the country. While significant data has emerged over the past decade drawing the link between oral health and systemic diseases like diabetes, heart disease, and stroke, many remain unaware that neglected oral health can have serious ramifications to their overall health. Data is also emerging to highlight the role that poor oral health in pregnant women has on their children, including a link between periodontal disease and low-birth weight babies.

ADHA advocates an allocation of $5 million in fiscal year 2012 for a national oral health prevention and education campaign.

*School-Based Sealant Programs—Fund at a level sufficient to ensure school-based sealant programs in all 50 States*

Sealants have long-proven to be low-cost and effective in preventing dental caries (cavities), particularly in children. While most dental disease is fully preventable, dental caries remains the most common childhood disease, five times more common than asthma, and more than half of all children age 5–9 have a cavity or filling.

The CDC has noted that data collected in evaluations of school-based sealant programs indicates the programs are effective in stopping and preventing dental decay. Significant progress has been made in developing best practices for school-based sealant programs, yet most States lack well developed programs as a result of funding shortfalls. ADHA encourages the transfer of funding from the Public Health and Prevention Fund sufficient to allow CDC to meaningfully fund school-based sealant programs in all 50 States in fiscal year 2012.

*Oral Health Programming within the Centers for Disease Control—Fund at a level of $25 million in fiscal year 2012*

ADHA joins with others in the dental community in urging $25 million for oral health programming within the Centers for Disease Control. This funding level will enable CDC to continue its vital work to control and prevent oral disease, including vital work in community water fluoridation. Federal grants to facilitate improved oral health leadership at the State level, support the collection and synthesis of data regarding oral health coverage and access, promote the integrated delivery of oral health and other medical services, enable States to innovate new types of oral health programs and promote a data-driven approach to oral health programming.

ADHA joins with others in the oral health community to express concern with plans to fold the Division of Oral Health at CDC into the Division of Adult and Community Health, and asks the subcommittee to urge CDC to maintain the Division of Oral Health as a separate entity within the chronic disease center so that the Division of Oral Health can continue to improve the oral health of Americans from inception to old age.

ADHA advocates for $25 million in funding for grants to improve and support oral health infrastructure and surveillance.

*Dental Health Improvement Grants—Fund at a level of $20 million in fiscal year 2012*

HRSA administered dental health improvement grants are an important resource for States to have available to develop and carry out State oral health plans and related programs. Past grantees have used funds to better utilize the existing oral health workforce to achieve greater access to care. Previously awarded grants have funded efforts to increase diversity among oral health providers in Wisconsin, pro-

mote better utilization of the existing workforce including the extended care permit (ECP) dental hygienist in Kansas, and in Virginia implement a legislatively directed pilot program to allow patients to directly access dental hygiene services.

ADHA supports funding of HRSA dental health improvement grants at a level of $20 million for fiscal year 2012.

*National Institute of Dental and Craniofacial Research—Fund at a level of $468 million in fiscal year 2012*

The National Institute of Dental and Craniofacial Research (NIDCR) cultivates oral health research that has led to a greater understanding of oral diseases and their treatments and the link between oral health and overall health. Research breeds innovation and efficiency, both of which are vital to improving access to oral healthcare services and improved oral status of Americans in the future.

ADHA joins with others in the oral health community to support NIDCR funding at a level of $468 million in fiscal year 2012.

*Conclusion*

ADHA appreciates the difficult task Appropriators face in prioritizing and funding the many meritorious programs and grants offered by the Federal Government. In addition to the items listed, ADHA joins other oral health organizations in support for continued funding of the Dental Reimbursement Program (DRP) and the Community-Based Dental Partnerships Program established under the Ryan White HIV/AIDS Treatment and Modernization Act ($19 million for fiscal year 2012) as well as block grants offered by HRSA's Maternal Child Health Bureau ($8 million for fiscal year 2012).

ADHA remains a committed partner in advocating for meaningful oral health programming that makes efficient use of the existing oral health workforce and delivers high quality, cost-effective care.

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## PREPARED STATEMENT OF THE AMERICAN DIABETES ASSOCIATION

Thank you for the opportunity to submit this testimony on behalf of the American Diabetes Association. As someone who has lived with diabetes for over thirty years, I am proud to be a representative of the nearly 105 million American adults and children living with diabetes or prediabetes.

Every minute, three more people are diagnosed with diabetes. While nearly 26 million Americans have diabetes today, this number is expected to grow to 44 million in the next 25 years if present trends continue. Every 24 hours, 230 people with diabetes will undergo an amputation, 120 people will enter end-stage kidney disease programs and 55 people will go blind from diabetes. Every single day, diabetes costs our country over a half a billion dollars, yet, that is but a fraction of the costs we face unless we immediately take action to stop the march of this epidemic.

Given the toll the diabetes epidemic imposes on the Nation's health and economy and the promise of public diabetes research and public health initiatives, the American Diabetes Association (Association) respectfully requests programs at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) and the Division of Diabetes Translation (DDT) at the Centers for Disease Control and Prevention (CDC) be top priorities in fiscal year 2012. As the Nation's leading non-profit health organization providing diabetes research, information and advocacy, the Association believes Federal funding for diabetes prevention and research is critical, not only for the 26 million American adults and children (8 percent of the population) who currently have diabetes, but for the 79 million more with prediabetes, a condition placing them at high risk for developing diabetes.

The Association acknowledges the challenging fiscal climate and supports fiscal responsibility, but not at the expense of America's health and well-being. Simply put, our country cannot afford the consequences of failing to adequately fund diabetes research and programs, a cost paid in expensive complications and death. We cannot afford to turn our backs on the promising research which provides tools to prevent diabetes, better manage it and prevent complications, and bring us closer to a cure.

Therefore, the Association urges the Senate LHHS Subcommittee to invest in research and prevention proportionate to the magnitude of the burden diabetes has on our country and, by doing so, to change the future of diabetes in America.

Diabetes is a chronic disease that impairs the body's ability to use food for energy. The hormone insulin, which is made in the pancreas, is needed for the body to change food into energy. In people with diabetes, either the pancreas does not create insulin, which is type 1 diabetes, or the body does not create enough insulin and/

or cells are resistant to insulin, which is type 2 diabetes. If left untreated, diabetes results in too much glucose in the blood stream. The majority of diabetes cases, 90 to 95 percent, are type 2, while type 1 diabetes accounts for 5 percent of diagnosed cases. Additionally, based on new diagnostic criteria, it is now estimated that 18 percent of pregnancies are affected by gestational diabetes. In the short term, blood glucose levels that are too high or too low (as a result of medication to treat diabetes) can be life threatening. The long-term complications of diabetes are widespread, serious—and deadly. In those with prediabetes, blood glucose levels are higher than normal and taking action to reduce their risk of developing diabetes is essential.

The Centers for Disease Control and Prevention (CDC) has identified diabetes as a disabling, deadly epidemic, which is on the rise. Between 1990 and 2001, the prevalence of diabetes increased by 60 percent. According to the CDC, one in three adults will have diabetes in 2050 if present trends continue. This number is even greater among minority populations, where nearly one in two adults will have diabetes in 2050.

Additionally, type 2 diabetes, traditionally seen in older patients, is beginning to reach a younger population, due in part to the surge in childhood obesity. Approximately one in every 400 children and adolescents has diabetes, and an alarming 2 million adolescents (or 1 in 6 overweight adolescents) aged 12–19 have prediabetes. The impact diabetes has on individuals and the healthcare system is enormous and continues to grow at a shocking rate. Diabetes is the leading cause of kidney failure, new cases of adult-onset blindness and non-traumatic lower limb amputations as well as a significant cause of heart disease and stroke.

In addition to the physical toll, diabetes also attacks our pocketbooks. A study by the Lewin Group found when factoring in the additional costs of undiagnosed diabetes, prediabetes, and gestational diabetes, the total cost of diabetes and related conditions in the United States in 2007 was $218 billion ($18 billion for undiagnosed diabetes; $25 billion for prediabetes; $623 million for gestational diabetes). In 2007, medical expenditures due to diabetes totaled $116 billion, including $27 billion for diabetes care, $58 billion for chronic diabetes-related complications, and $31 billion for excess general medical costs. Indirect costs resulting from increased absenteeism, reduced productivity, disease-related unemployment disability and loss of productive capacity due to early mortality totaled $58 billion. Approximately one out of every five healthcare dollars is spent caring for someone with diagnosed diabetes, while one in ten healthcare dollars is directly attributed to diabetes. Further, one-third of Medicare expenses are associated with treating diabetes and its complications.

Despite these numbers, there is hope. A greater Federal investment in diabetes research at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH), and prevention, surveillance, control, and research work currently being done at the Division of Diabetes Translation (DDT) at the CDC is crucial for finding a cure and improving the lives of those living with, or at risk for, diabetes. Additionally, the National Diabetes Prevention Program is poised to dramatically cut the number of new diabetes cases in high-risk individuals. Accordingly, for fiscal year 2012, the American Diabetes Association is requesting:

—$2.209 billion for the NIDDK, an increase of $267 million over the fiscal year 2011 level. This additional funding will act to offset years of decreased or flat funding combined with inflation that has lead to cutbacks in promising research. It will also demonstrate Congress's commitment to science and research in the face of this deadly epidemic.

—$86.1 million for the DDT, which represents a total increase of $21.3 million over the fiscal year 2011 level for the DDT's critical prevention, surveillance and control programs. Even as proposals to consolidate the CDC's chronic disease programs including DDT circulate, expanded investment in the DDT will produce much larger savings in reduced acute, chronic, and emergency care spending.

—$80 million for the implementation of the National Diabetes Prevention Program through the Prevention and Public Health Fund.

*NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)*

The NIDDK is poised to make major discoveries to prevent diabetes, better treat its complications, and—ultimately—find a cure. Researchers supported by the NIH are working on a variety of projects representing hope for the millions of individuals with both type 1 and type 2 diabetes. While the list of advances in treatment and prevention is long, much more can be achieved for people with diabetes with an increased investment in scientific research at the NIDDK.

Thanks to research at the NIDDK, people with diabetes now manage their disease with a variety of insulin formulations and regimens far superior to those used in decades past. The result is the ability to live healthier lives with diabetes. Because of these advances, my hemoglobin A1C, which provides a snapshot of an individual's blood glucose, went from 12.9 percent, a very dangerous level, to 5.9 percent, an accomplishment that provides me with hope of avoiding diabetes's devastating complications. This is a dramatic development for me and proof of the importance of NIDDK's work.

Recent discoveries at the NIDDK include the ability to predict type 1 diabetes risk, new drug therapies for type 2 diabetes, and the discovery of genetic markers explaining the increased burden of kidney disease among African Americans. The NIDDK funded the Diabetes Prevention Program, a multicenter clinical research trial, which found modest weight loss through dietary changes and increased physical activity could prevent or delay the onset of type 2 diabetes by 58 percent. While great strides have been made in diabetes research, there are many unanswered questions about the disease meriting further study. Diabetes researchers across the country are poised to expand the base of knowledge of diabetes in order to make new discoveries transforming diabetes prevention and care.

Increased fiscal year 2012 funding would allow the NIDDK to support additional research in order to build upon past successes, improve prevention and treatment, and close in on a cure. For example, additional funding will support a new comparative effectiveness clinical trial testing different medications for type 2 diabetes, a process that is instrumental in finding the most effective treatments for type 2 diabetes. fiscal year 2012 funding will also support researchers who are studying how insulin-producing beta cells develop and function, with an ultimate goal of creating therapies for replacing damaged or destroyed beta cells in people with diabetes. Finally, additional funding will support ongoing studies outlining environmental triggers of disease, which could identify an infectious cause of type 1 diabetes and lead to a vaccine.

*CDC's Division of Diabetes Translation (DDT)*

The Senate Appropriations Committee's fiscal year 2011 bill provided increased resources to address chronic diseases through the creation of the Chronic Disease Initiative (CDI) at CDC. In approving the fiscal year 2011 LHHS bill, the full Committee acknowledged chronic disease programs, including the diabetes programs traditionally operated through the DDT, have been woefully underfunded to adequately address the trajectory and scope of diabetes and other diseases including heart disease, stroke and arthritis.

This year, ideas continue to circulate to consolidate programs at CDC, including DDT. While we think coordination across chronic disease programs at CDC is an important endeavor, Congress must ensure the needs of people with, and at risk for, diabetes are adequately addressed. Given DDT funding has not kept pace with the magnitude of the growing diabetes epidemic, the Federal investment in DDT programs should be substantially increased—at a minimum to $86.1 million in fiscal year 2012—regardless of the organization of chronic disease programs at CDC or in any consolidation plan. As the dialogue continues about how best to address chronic disease prevention, DDT should be the centerpiece in the Federal Government's efforts in this regard and its State and national expertise should be maintained.

Preserving the DDT's expertise is vital. The Division works to eliminate the preventable burden of diabetes through proven educational programs, best practice guidelines and applied research. It performs vital work in both primary prevention of diabetes and in preventing its complications. Both key missions must continue. Funds appropriated to DDT focus on developing and maintaining State-based Diabetes Prevention and Control Programs (DPCPs), supporting the National Diabetes Education Program (NDEP), defining the diabetes burden through the use of public health surveillance, and translating research findings into clinical and public health practice. Our request of an additional $21.3 million will allow these programs at DDT to reach more at-risk Americans and help to prevent or delay this destructive disease and its complications.

DDT's Diabetes Prevention and Control Programs, located in all 50 States, the District of Columbia, and U.S. territories, work to prevent diabetes, to lower blood glucose and cholesterol levels and to reduce diabetes-related emergency room visits and hospitalizations. DDT also plays a leadership role in the dissemination of diabetes prevention and treatment information through the National Diabetes Education Program, a joint effort of DDT and NIDDK. Funding for the DDT also supports vital and groundbreaking translational research like the Search for Diabetes in Youth study, collaboration between DDT and NIDDK designed to determine the impact of type 2 diabetes in youth in order to improve prevention efforts aimed at young peo-

ple. DDT is also engaged in efforts to eliminate diabetes related disparities in vulnerable populations that bear a disproportionate burden of the disease in urban and rural areas. Finally, DDT maintains vital diabetes data at the State and national levels through the National Diabetes Surveillance System, which helps determine how best to deploy resources in the most appropriate and cost-effective way.

Although DDT has played an instrumental role in fighting the diabetes epidemic, the reach of the Division could be significantly broader with additional fiscal year 2012 funding. With an additional $21.3 million, the DDT will be able to expand the reach of DPCPs in every State and territory. Given the dramatic decreases in funding for State and local health departments, supporting the work of the DPCPs is more critical than ever to ensure access to diabetes care and services.

Increased funding for DDT is needed to allow the Division to build upon its work in reducing health disparities through vital programs such as the Native Diabetes Wellness Program, furthering the development of effective health promotion activities and messages tailored to American Indian/Native Alaskan communities. Additional resources will enable the DDT to expand its translational research studies, leading to improved public health interventions.

*The National Diabetes Prevention Program*

Further studies of the Diabetes Prevention Program by the CDC have shown this groundbreaking intervention can be replicated in community settings for a cost of less than $300 per participant. With this in mind, the National Diabetes Prevention Program was authorized by the Patient Protection and Affordable Care Act of 2010. This program will provide funding to the CDC to expand such evidence-based programs across the country. We ask the Committee to direct $80 million from the Fund for the National Diabetes Prevention Program.

The National Diabetes Prevention Program supports the creation of community-based sites where trained staff will provide those at high risk for diabetes with cost-effective, group-based lifestyle intervention programs. Local sites will be required to provide detailed program plans, ensure adequate training, and be rigorously evaluated based on the achievement of required standards and goals. The program also includes applied research grants, which will advance the national strategy for community-based programs and improve communication strategies for high-risk communities.

The Fund seeks to make a national investment in prevention and public health programs, both to improve the health of Americans and to rein in healthcare costs. The National Diabetes Prevention Program is exactly the program the Fund should be supporting. The NIH did research in the clinical setting—it worked. The CDC translated this research to the community setting—it worked. It is an amazingly inexpensive proven means of combating a growing epidemic. Indeed, the Urban Institute has estimated a nationwide expansion of this type of diabetes prevention program will save a total of $190 billion over 10 years. Based on estimates that a large portion of burden of chronic disease falls on the poor and elderly, the Institute's report assumes 75 percent of this savings would be savings to Medicare or Medicaid.

*Conclusion*

As you consider the fiscal year 2012 appropriation for NIDDK, and DDT, and the National Diabetes Prevention Program, we ask you to consider diabetes is an epidemic growing at an astonishing rate, which will overwhelm the healthcare system with tragic consequences unless we take action. To change this future, we must increase our commitment to research and prevention to reflect the burden diabetes poses both for us and for our children. Our fight against diabetes must be significantly expanded. Your leadership in combating this growing epidemic is essential. Thank you for your commitment to the diabetes community and for the opportunity to submit this testimony. The Association is prepared to answer any questions you might have on these important issues.

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## PREPARED STATEMENT OF THE AMERICAN FOUNDATION FOR SUICIDE PREVENTION

Chairman Harkin, Ranking Member Shelby and members of the Committee. The American Foundation for Suicide Prevention (AFSP) thanks you for the opportunity to provide testimony on the funding needs of Federal Agencies and programs that play a critical role in suicide prevention efforts.

AFSP is the leading national not-for-profit organization exclusively dedicated to understanding and preventing suicide through research, education and advocacy, and to reaching out to people with mental disorders and those impacted by suicide. You can find more information at www.asfp.org and www.spanusa.org.

Preliminary data from the Centers for Disease Control for 2009 shows that suicide is the 10th leading cause of death in the United States (36,547) and the third leading cause of death in teens and young adults from ages 15–24. Nearly 1.1 million Americans attempt suicide each year and another 8 million have suicidal thoughts. Suicide in 1 year costs the United States $13 billion in lost earnings, 1 million years of lost life and suicide attempts requiring hospitalization amount to $3.54 billion in lost medical and work-loss costs.

In order to more effectively combat this public health crisis, AFSP urges the Committee approve funding at the levels requested for the following programs/agencies for fiscal year 2012:

*Garrett Lee Smith Memorial Act Programs*

We respectfully request that Garrett Lee Smith Memorial Act (GLSMA) youth suicide prevention grant programs receive $53.2 million for fiscal year 2012.

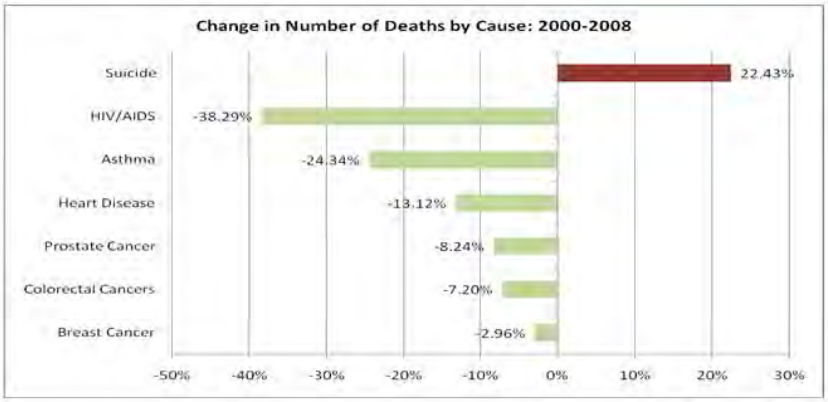
Since 2005, the Substance Abuse and Mental Health Services Administration (SAMHSA) has awarded GLSMA grants to 45 State programs, 12 tribal programs, and 78 colleges and universities for programs to help reduce youth suicides rates. State grantees include: Alaska, Arizona, Colorado, Connecticut, District of Columbia, Delaware, Florida, Georgia, Guam, Hawaii, Iowa, Idaho, Indiana, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Missouri, Mississippi, North Carolina, North Dakota, Nebraska, New Hampshire, New Mexico, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, and Wyoming.

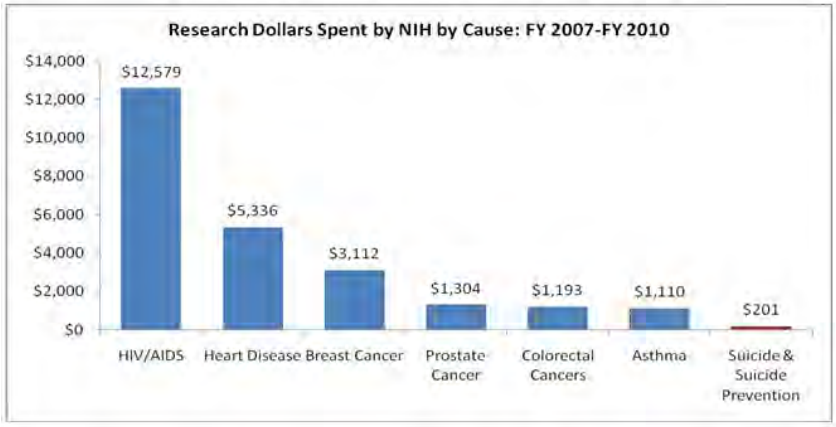
Funding for the Act is directed to three programs administered by SAMHSA. We request $5 million for the Suicide Prevention Technical Assistance Center to support its mission of providing technical assistance and support to grantees. We request $42 million for the Youth Suicide Early Intervention and Prevention Strategies grant program. These grants help States and tribes develop and implement statewide youth suicide early intervention and prevention strategies that will raise awareness and educate people about mental illness and the risk of suicide, help young people at risk of suicide take the first step toward seeking help, and allow States to expand access to treatment options. Finally, we request $6.2 million to fund the Mental and Behavioral Health Services on Campus matching-grant program for colleges and universities to help raise awareness about youth suicide, as well as enable those institutions to train students and faculty to identify and intervene when youth are in crisis, and develop a system to refer students for care.

*Support Federal Investment in Suicide Prevention Research at NIMH for Fiscal Year 2012*

Strategic investments in disease research have produced declines in deaths, and the same types of investments are necessary to reduce deaths by suicide. In fiscal year 2010 (latest data) only $41 million was devoted directly to suicide research. AFSP urges Congress to increase the investment in suicide prevention research at the National Institutes of Mental Health by 15 percent, or $6.15 million.

It is illuminating to compare the number of suicide deaths with the number of deaths in several major disease categories against the direct dollars spent on research in those areas (see below). In fact, the Institute of Medicine, in their 2002 report "Reducing Suicide: A National Imperative," stated the following: "There is every reason to expect that a national consensus to declare war on suicide and to fund research and prevention at a level commensurate with the severity of the problem will be successful, and will lead to highly significant discoveries as have the wars on cancer, Alzheimer's disease, and AIDS."




*Maintain Vital Funding for SAMHSA Suicide Prevention Programs and Mental Health Services*

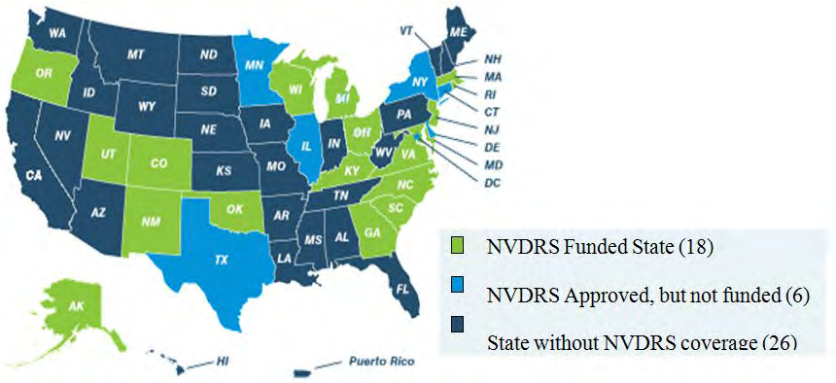
As the lead Government agency charged with implementation of suicide prevention initiatives, AFSP urges this Committee to provide $3.387 billion for SAMHSA in fiscal year 2012. By this action Congress will recognize the important role SAMHSA plays in healthcare delivery and mental health services.

As the lead Government agency charged with implementation of suicide prevention initiatives, SAMHSA has supported the establishment of a national toll-free hotline (the National Suicide Prevention Lifeline), a technical assistance center (the Suicide Prevention Resource Center), and a youth suicide prevention grant program for States and colleges (authorized and funded under the Garrett Lee Smith Memorial Act). Since its launch in January 2005, the Suicide Prevention Lifeline has answered more than 1 million calls and has 140 active crisis centers in 48 States. Beginning in 2008, SAMHSA's National Survey on Drug Use and Health asked respondents about suicide attempts and whether or not they had previously acknowledged major depression. This was an important first step forward in suicide surveillance, promoting greater attention to the interrelationship of suicide, substance abuse and depression. Moreover, the Agency also has been supporting the identification, development and promotion of best practices in suicide prevention, focusing on risk and protective factors related to suicide, with particular attention to mental health and substance abuse issues affecting suicide risk.

*Support Federal Investment in Data Collection in Fiscal Year 2012*

To design effective suicide prevention strategies, we must first have complete, accurate and timely information about deaths by suicide. The National Violent Death Reporting System (NVDRS) provides this information, which is essential to improve

State and Federal suicide prevention activities. Current funding of $3.5 million allows only 18 States to participate in this program. This Committee approved an additional $1.5 million in fiscal year 2011; however, the bill never got signed into law. AFSP urges this Committee to appropriate the full $5 million for the NVDRS in fiscal year 2012.




*Provide Funding for Depression Centers of Excellence (DCOE)*

This Committee included $10 million for the DCOE in the fiscal year 2011 mark up as a down payment toward studying Depression, the most common psychiatric diagnosis associated with suicide. AFSP urges Congress to appropriate funds to the DCOE at the highest levels possible in fiscal year 2012.

Depression Centers of Excellence would increase access to the most appropriate and evidence-based depression care and develop and disseminate evidence-based treatment standards to improve accurate and timely diagnosis of depression and bipolar disorders. Additionally, they would create a national database for large-sample effectiveness studies and a repository of evidence-based interventions and programs for depression and bipolar disorders. They would also utilize the network of centers as an ongoing national resource for public and professional education and training, with the goal of advancing knowledge and eradicating stigma of these mental disorders.

Chairman Harkin, Ranking Member Shelby and Members of the Committee. AFSP once again thanks you for the opportunity to provide testimony on the funding needs of Federal Agencies and programs that play a critical role in suicide prevention efforts.

Suicide robs families, communities and societies of tens of thousands of its citizens. In a single year, in the United States alone, suicide is responsible for the deaths of over 36,000 people of all ages and costs an estimated $13 billion in lost income. With your help, we can assure those tasked with leading the Federal Government's response to this public health crisis will have the resources necessary to effectively prevent suicide.

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## PREPARED STATEMENT OF THE AMERICAN GERIATRICS SOCIETY

Mr. Chairman and Members of the Subcommittee: We are writing on behalf of the American Geriatrics Society (AGS), a nonprofit organization of over 6,000 geriatrics healthcare professionals dedicated to improving the health, independence and quality of life of all older Americans. As the Subcommittee begins to work on its Labor-HHS-Education Appropriations bill, we ask that you prioritize funding for the geriatrics education and training programs under Title VII and Title VIII of the Public Health Service Act and for research funding within the National Institute on Aging in fiscal year 2012.

Continued Federal investments are needed to support the training of the healthcare workforce and to foster groundbreaking medical research so that our Nation is prepared to meet the unique healthcare needs of the rapidly growing population of seniors. While we fully recognize the fiscal challenges facing our Nation, we also recognize that sustained and enhanced Federal investments in these initiatives are essential to fulfilling the promise of health reform to deliver higher quality and better coordinated care to our Nation's seniors.

We ask that the subcommittee consider the following recommended funding levels for these programs in fiscal year 2012 $46.5 million for Title VII Geriatrics Health Professions Programs, $5 million for Title VIII Comprehensive Geriatric Education Nursing Program, and $1.4 billion for the National Institute on Aging.

Summarized and broken down below are the American Geriatrics Society's funding priorities in these areas for fiscal year 2012.

*Programs to Train Geriatrics Health Care Professionals*

This year, the first wave of baby boomers turn 65, signaling the start of a significant demographic shift in America's population. According to the Institute of Medicine's (IOM) ground-breaking 2008 report, Retooling for an Aging America: Building the Healthcare Workforce, America's healthcare workforce is woefully ill-prepared to care for the growing and unprecedented number of seniors, especially those with multiple chronic and complex medical conditions.

The increase in the older adult population is expected to be even greater in rural America, which are more likely to experience poor health and a shortage of healthcare resources. Not only are geriatricians few in number, but they are largely concentrated in urban areas. Of further concern, our Nation is facing a critical shortage of geriatrics faculty and healthcare professionals across disciplines. At the same time, the Title VII and VIII geriatrics programs under the Public Health Service Act have remained essentially level-funded since fiscal year 2007 and in each subsequent year the geriatrics programs have received an even smaller percentage of funding provided to Title VII and VIII programs.

This trend must be reversed if we are to provide our seniors with the quality care they need and deserve. AGS believes it is critical that Congress increase the percentage of Title VII and VIII funding that is devoted to supporting increasing the capacity of America's healthcare workforce to care for older adults. Care provided by geriatric healthcare professionals, who understand the most complex cases and the most frail elderly, has shown to reduce those common and costly conditions that are often preventable with appropriate care, such as falls, polypharmacy, and delirium.

*Title VII Geriatrics Health Professions Programs ($46.5 million)*

Funding for Title VII Geriatrics Health Professions Programs is a proven investment in ensuring that older adults receive high quality healthcare now and in the future. These programs support three initiatives: the Geriatric Academic Career Awards (GACAs), the Geriatric Education Center (GEC) program, and geriatric faculty fellowships, the only programs specifically designed to address the evident shortage of geriatrics healthcare professionals in the United States. Strong and sustained investments are important to reversing the chronic under-funding of these essential programs at a time when our Nation is facing a critical shortage of geriatrics healthcare professionals across disciplines. We ask the subcommittee to provide a fiscal year 2012 appropriation of $46.5 million for Title VII Geriatrics Health Professions Programs.

Our funding request of $46.5 million breaks down as follows:

—*Geriatric Academic Career Awards (GACAs) ($5.3 million).*—GACAs support the development of newly trained geriatric physicians in academic medicine who are committed to teaching geriatrics in medical schools across the country. GACA recipients are required to provide training in clinical geriatrics, including the training of interdisciplinary teams of healthcare professionals. Under ACA, GACAs have been expanded to a variety of new disciplines beyond physicians, including those in nursing, social work, psychology, dentistry, and pharmacy. AGS has long advocated for this change. We must now ensure that there is adequate funding to meet the increased demand given the greater number of disciplines eligible for the award. A budget of $5.3 million would support 68 awardees at $78,000 per award.

*Program Accomplishments.*—In Academic Year 2009–2010, there were 84 non-competing continuation awards. GACA awardees provided interdisciplinary training in geriatrics training to about 60,000 health professionals. These awardees provided culturally competent quality healthcare to over 525,000 underserved and uninsured patients in acute care services, geriatric ambulatory care, long-term care, and geriatric consultation services settings.

—*Geriatric Education Centers (GECs) ($22.7 million).*—GECs provide grants to support collaborative arrangements involving several health professions, schools and healthcare facilities to provide multidisciplinary training in geriatrics, including assessment, chronic disease syndromes, care planning, emergency preparedness, and cultural competence unique to older Americans. Under ACA, Congress authorized $10.8 million over 3 years for a supplemental grant award

program that will train additional faculty through an intensive short-term fellowship program and also requires faculty to provide training to family caregivers and direct-care workers. Our funding request of $22.7 million includes continued support for the core work of 45 GECs and for up to 24 GECs to be funded to undertake the work through the supplemental grant program.

*Program Accomplishments*.—In Academic Year 2009–2010, the GEC grantees provided clinical training to 54,167 health professional students and to 20,791 interdisciplinary teams in multiple settings.

—*Geriatric Training Program for Physicians, Dentists, and Behavioral and Mental Health Professions ($8.5 million)*.—This program is designed to train physicians, dentists, and behavioral and mental health professionals who choose to teach geriatric medicine, dentistry or psychiatry. The program provides fellows with exposure to older adult patients in various levels of wellness and functioning, and from a range of socioeconomic and racial/ethnic backgrounds. Our funding request of $8.5 million will allow 13 institutions to continue this important faculty development program.

*Program Accomplishments*.—In Academic Year 2009–2010, 11 non-competing continuation grants were supported. Forty-nine physicians, dentists, and psychiatric fellows provided geriatric care to 20,078 older adults across the care continuum. Geriatric physician fellows provided healthcare to 12, 254 older adults. Geriatric dental fellows provided healthcare to 4,073 older adults. Geriatric psychiatry fellows provided healthcare to 3,751 older adults.

—*Geriatric Career Incentive Awards Program ($10 million)*.—This is a new grant award program created under ACA to foster greater interest among a variety of health professionals in entering the field of geriatrics, long-term care, and chronic care management. AGS supports the President's fiscal year 2012 request of $10 million to implement this new program.

*Title VIII Comprehensive Geriatric Education Nursing Program ($5 million)*

The American healthcare delivery system for older adults will be further strengthened by Federal investments in Title VIII Nursing Workforce Development Programs, specifically the comprehensive geriatric education grants, as nurses provide cost-effective, quality care. Increasing funding for the nursing comprehensive geriatric education program would be highly cost effective. This program supports additional training for nurses who care for the elderly, development and dissemination of curricula relating to geriatric care, and training of faculty in geriatrics. It also provides continuing education for nurses practicing in geriatrics.

Under the new health reform law, this program is being expanded to include advanced practice nurses who are pursuing long-term care, geropsychiatric nursing or other nursing areas that specialize in the care of older adults. Our funding request of $5 million includes funds to continue the training of nurses caring for older Americans offer 200 traineeships to nurses under this newly expanded program.

*Program Accomplishments*.—In Academic Year 2009–2010, 27 CGEP grantees provided education and training to 3,030 Registered Nurses/Registered Nursing Students; 260 Advanced Practice Nurses; 221 Faculty; 110 Home Health Aides; 483 Licensed Practical/Vocational Nurses & LPN students; 730 Nurse Assistants/Patient Care Associates; 810 Allied Health Professionals and 929 lay persons, guardians, activity directors. The CGEP grantees provided 459 educational course offerings in the care of the elderly on a variety of topics to 6,846 participants.

*Research Funding Initiatives*

*National Institute on Aging ($1.4 billion)*

The NIA leads a broad scientific effort to understand the nature of aging and to extend the healthy, active years of life. Robust medical research in aging is critical to the development of medical advances which will ultimately lead to higher quality and more efficient healthcare. Continued Federal investments in scientific research, including comparative effectiveness initiatives, will ensure that the NIA has the resources to succeed in its mission to establish research networks, assess clinical interventions and disseminate credible research findings to patients, providers and payers of healthcare.

As a member of the Friends of the NIA, a broad-based coalition of more than 45 aging, disease, research, and patient groups committed to the advancement of medical research that affects millions of older Americans, AGS asks that NIA receive $1.4 billion in fiscal year 2012. Alternatively, in light of our Nation's immediate budget constraints, we request that that the NIA be funded at no less than the $1.29 billion, as requested in the President's fiscal year 2012 budget.

According to the Congressional Research Service, in fiscal year 2003, NIH reached the peak of its purchasing power from regular appropriations when Congress com-

pleted a 5-year doubling of the NIH budget. In each year since then, NIH's buying power has declined because its annual appropriations have grown at a lower rate than the inflation rate for medical research.

Essentially flat funding of NIH since 2003 has additionally led to declining numbers of young investigators choosing research careers, given the scarcity of funding to support their career development. We must provide the resources and tools to support the next generation of investigators and expand the pool of clinical researchers focused on advancing aging research.

The ongoing Federal commitment to investments in science, research, and technology lead to cutting-edge breakthroughs in medicine and improved patient care. AGS urges Congress to maintain this commitment in fiscal year 2012 and beyond, so that we may continue to advance medicine to improve the quality of care of our Nation's older adults and the long-term goals of health reform can be fully achieved.

In closing, geriatrics is at a critical juncture, with our Nation facing an unprecedented increase in the number of older patients with complex health needs. Strong support such as yours will help ensure that the promise of health reform is fulfilled and every older American is able to receive high-quality healthcare.

Thank you for your consideration.

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PREPARED STATEMENT OF THE AMERICAN HEART ASSOCIATION

Over the past 50 years, major progress has been made in the battle against heart disease, stroke and other forms of cardiovascular disease (CVD). Improved diagnosis and treatment have been remarkable—as has the survival rate. According to the National Institutes of Health (NIH), since the 1960s, 1.6 million lives have been saved that would have been lost to CVD. Americans can now expect to live on average 4 years longer due to the reduction in heart-related deaths.

Yet, one startling fact remains. Heart disease and stroke are still respectively the No. 1 and No. 3 killers in the United States. Nearly 2,200 people die of CVD each day—one death every 39 seconds. CVD is a major cause of disability and costs our Nation more than any disease—a projected $287 billion in medical expenses and lost productivity for 2007. Today, an estimated 83 million adults suffer from CVD. Moreover, CVD risk factors such as obesity and high blood pressure are on the rise. At age 40, the lifetime risk for CVD is 2 in 3 for men and over 1 in 2 for women.

Moreover, a new study projects that more than 40 percent of adults in the United States will live with the consequences of CVD at a cost to exceed $1 trillion annually by the year 2030. The graying of Americans combined with the explosive growth in medical spending are the main drivers of increased costs. Our country is truly facing a crisis. Without prevention on a nationwide scale, managing CVD will be an enormous challenge. Clearly, there must be a greater emphasis on prevention and evidence-based approaches to healthy behaviors. This will require strategies to reach people where they live, work and play. Prevention must be an integral part of our toolkit to promote heart healthy and stroke-free habits and wellness at an early age.

Yet, in the face of these statistics, heart disease and stroke research, treatment and prevention programs remain woefully underfunded and money for NIH is unpredictable for the continuity of effort needed for key advances to redefine disease, ramp up prevention and promote best care.

Given CVD is the No. 1 killer in each State and preventable and treatable risk factors continue to rise, many are surprised that the Centers for Disease Control and Prevention (CDC) invests on average only 16 cents per person on heart disease and stroke prevention. Also, only 20 States are funded for WISEWOMAN—a proven heart disease and stroke prevention program that serves uninsured and under-insured low-income women with a high prevalence of CVD risk factors.

Where you live could also affect if you survive a very deadly form of heart disease—sudden cardiac arrest (SCA). Only 21 States received funding in fiscal year 2010 for the Health Resources and Services Administration's (HRSA) Rural and Community Access to Emergency Devices Program designed to save lives from sudden cardiac death.

The American Heart Association applauds the administration and Congress for providing hope to the 1 in 3 adults in the United States who live with CVD by wisely investing in the NIH and in the Prevention and Public Health Fund. These resources have provided a much needed boost to improve our Nation's physical and fiscal health. However, stable and sustained funding is critical for fiscal year 2012 to advance heart disease and stroke research, prevention and treatment.

FUNDING RECOMMENDATIONS: INVESTING IN THE HEALTH OF OUR NATION

Heart disease and stroke risk factors continue to rise, yet promising research to stem this tide goes unfunded. Too many Americans die from CVD, while proven prevention efforts beg for resources for widespread implementation. Now is the time to boost research, prevention and treatment of America's No. 1 and most costly killer. If Congress fails to build on progress of the past half century, Americans will pay more in lives lost and higher healthcare costs. Our recommendations address these issues in a comprehensive and fiscally responsible manner.

*Capitalize on Investment for the National Institutes of Health (NIH)*

NIH research has revolutionized patient care and holds the key to finding new ways to prevent, treat and even cure CVD, resulting in longer, healthier lives and reduced healthcare costs. NIH invests resources in every State and in 90 percent of congressional districts. According to a 2008 study, the typical NIH grant paid the salaries of about 7 mainly high-tech full-time or part-time jobs in fiscal year 2007. Further, every dollar that NIH distributes in a grant returns $2.21 in goods and services to the local community in 1 year.

*American Heart Association Advocates*.—We advocate for a fiscal year 2012 appropriation of $35 billion for NIH to capitalize on the investment to save lives, advance better health, spur our economy and spark innovation. NIH research prevents and cures disease, generates economic growth and preserves the U.S. role as the world leader in pharmaceuticals and biotechnology.

*Enhance Funding for NIH Heart and Stroke Research: A Proven and Wise Investment*

From 1997 to 2007, death rates for coronary heart disease and stroke fell nearly 28 percent and 45 percent, respectively. However, there is still much more to be done to improve the lives of heart disease and stroke patients—and more importantly to prevent CVD and stroke in the first place. Research will help lead the way. These declines in mortality are directly related to NIH heart and stroke research, with scientists on the verge of exciting discoveries that could lead to new treatments and even cures. For example, the biggest U.S. stroke rehabilitation study showed that patients who receive home physical therapy improve walking skills just as effectively as those treated in a program and that the progress continued up to 1 year post-stroke. NIH research has also demonstrated that over-zealous blood pressure lowering and combination lipid drugs did not cut cardiovascular disease in adult diabetics more than standard evidence-based care. Moreover, studies have defined the genetic basis of risky responses to vital blood-thinners.

In addition to saving lives, NIH-funded research can cut healthcare costs. For example, the original NIH tPA drug trial resulted in a 10-year net $6.47 billion reduction in stroke healthcare costs. Also, the Stroke Prevention in Atrial Fibrillation Trial 1 produced a 10-year net savings of $1.27 billion. Yet, in the face of such solid returns on investments and other successes, NIH still invests a meager 4 percent of its budget on heart research, and a mere 1 percent on stroke research.

*Cardiovascular Disease Research: National Heart, Lung, and Blood Institute (NHLBI)*

Even in the face of progress and promising research opportunities, there is no cure for CVD. As our population ages, demand will only increase to find better ways for Americans to live healthy and productive lives despite CVD. Stable and sustained funding is needed to allow NHLBI to build on investments that provided grants to use genetics to identify and treat those at greatest risk from heart disease; hasten drug development to treat high cholesterol and high blood pressure; and create tailored strategies to treat, slow or prevent heart failure. Other key studies include an analysis of whether maintaining a lower blood pressure than currently recommended further reduces risk of heart disease, stroke, and cognitive decline. This information is vital to manage the burden of heart disease and stroke. Sustained critical funding will allow for aggressive implementation of other initiatives in the NHLBI and cardiovascular strategic plans.

*Stroke Research: National Institute of Neurological Disorders and Stroke (NINDS)*

An estimated 795,000 people in this country will suffer a stroke this year, and more than 135,950 will die. Many of the 7 million survivors face severe physical and mental disabilities, emotional distress and huge costs—a projected $41 billion in medical expenses and lost productivity for 2007. A new study projects stroke prevalence will increase 25 percent over the next 20 years, striking more than 10 million individuals. Over the same time period, direct medical costs will rise 238 percent.

Stable and sustained funding is required for NINDS to capitalize on investments to prevent stroke, protect the brain from damage and enhance rehabilitation. This includes initiatives to: (1) determine if MRI brain imaging can assist in selecting stroke victims who could benefit from the clot busting drug tPA beyond the 3-hour treatment window; (2) assess chemical compounds that might shield brain cells during a stroke; and (3) advance stroke rehabilitation by studying if the brain can be helped to "rewire" itself after a stroke. Enhanced funding will also allow for proactive initiation and implementation of the NINDS' novel stroke planning process (a result of its Stroke Progress Review Group) to assess the stroke research field and develop priorities to advance the most promising prevention, treatment, recovery and rehabilitation research.

*The American Heart Association Advocates*.—While AHA supports increased funding for the 18 Institutes and centers that conduct heart and stroke research, including the National Institute of Diabetes, and Digestive and Kidney Diseases; and the National Institute on Aging, we have specific funding recommendations for the NHLBI and the NINDS. AHA advocates for an fiscal year 2012 appropriation of $3.514 billion for NHLBI; and $1.857 billion for NINDS.

*Increase Funding for the Centers for Disease Control and Prevention (CDC)*

Prevention is the best way to protect the health of all Americans and reduce the economic burden of CVD. Yet, effective prevention strategies and programs are not being implemented due to insufficient resources. The President's 2012 budget proposes a Coordinated Chronic Disease Prevention and Health Promotion Grant Program. AHA supports some consolidation of chronic disease programs, but with some important modifications and caveats. First, CDC must preserve the Division for Heart Disease and Stroke Prevention. A consolidation must ensure more predictable and adequate funding to all 50 States, including an annual share of the Prevention and Public Health Fund, with resources allocated by formula on the basis of burden, including cost, mortality, morbidity, and prevalence. These programs must be evidence-based and targeted, with a focus on capacity, evaluation and surveillance, including measurable outcomes and a higher level of accountability. To preserve the best elements of existing programs, funding should preserve evidenced-based outcomes work across the full spectrum of prevention and clinical care, including primary and secondary prevention, acute treatment, rehabilitation and continuous quality improvement (CQI). Each State must retain staff expertise to effectively address heart disease and stroke. State-based advisory groups of stakeholders from each constituency should be formed to help with plan implementation. A national advisory committee of constituencies should be created to foster stakeholder involvement. Matches, including in-kind, should be required when possible to build support in State health departments. Plans should use some funding for at least one program on common risk factors to consolidated diseases that can show a measurable, population-based impact. The rest of the funds should be spent on effective, evidence-based projects aimed at secondary prevention, acute treatment, rehabilitation, and CQI.

This CDC division administers WISEWOMAN that serves uninsured and underinsured low-income women ages 40 to 64 in 20 States. This program helps them avoid heart disease and stroke by providing preventive health services, referrals to local healthcare providers, as needed, and lifestyle counseling and interventions tailored to their identified risk factors to promote lasting, healthy behavior modifications. From July 2008 to June 2010, WISEWOMAN reached more than 70,000 low-income women. During this time period, 89 percent of them had a least one risk factor and 28 percent had three or more risk factors for heart disease and stroke. However, more than 43,000 of these women participated in at least one lifestyle intervention session.

*The American Heart Association Advocates*.—AHA joins with the CDC Coalition in advocating for $7.7 billion for the CDC's "core programs," including increases for the Division of Heart Disease and Stroke Prevention and WISEWOMAN. AHA recommends $37 million to expand WISEWOMAN to more States and serve more eligible women in already funded States. We join the Friends of the NCHS in asking for $162 million for the National Center for Health Statistics.

*Restore Funding for Rural and Community Access to Emergency Devices (AED) Program*

About 92 percent of sudden cardiac arrest (SCA) victims die outside of a hospital. But, prompt CPR and defibrillation, with an automated external defibrillator (AED), can more than double their chances of survival. Communities with comprehensive AED programs have reached survival rates of about 40 percent. HRSA's Rural and Community AED Program provides grants to States, competitively, to buy AEDs,

train lay rescuers and first responders in their use and place AEDs where SCA is likely to occur. From September 2007 to August 2008, 3,051 AEDs were bought and 10,287 people were trained. And, 795 patients were saved between August 1, 2009 and July 31, 2010. Due to insufficient budgets, only 21 states received funds for this program in fiscal year 2010.

*The American Heart Association Advocates*.—For fiscal year 2012, AHA advocates restoring HRSA's Rural and Community AED Program to its fiscal year 2005 level of $8.927 million.

*Increase Funding for the Agency for Healthcare Research and Quality (AHRQ)*

AHRQ develops scientific evidence to improve healthcare for Americans. AHRQ provides patients and caregivers with valuable scientific evidence to make the right healthcare decisions. AHRQ's research also enhances quality and efficiency of healthcare, providing the basis for protocols that prevent medical errors and reduce hospital-acquired infections, and improve patient confidence, experiences, and outcomes.

*The American Heart Association Advocates*.—AHA joins Friends of AHRQ in advocating for $405 million for AHRQ to preserve its vital initiatives, boost the research infrastructure, spur innovation, nurture the next generation of scientists and help reinvent health and healthcare.

CONCLUSION

Cardiovascular disease continues to inflict a deadly, disabling and costly toll on Americans. Yet, our funding recommendations for NIH, CDC and HRSA outlined above will save lives and cut rising healthcare costs. The American Heart Association urges Congress to seriously consider our suggestions during the fiscal year 2012 appropriations process. These proposed resources represent a wise investment for our nation and for the health and well-being of this and future generations.

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PREPARED STATEMENT OF THE AMERICAN INDIAN HIGHER EDUCATION CONSORTIUM

*Summary of Requests*.—Summarized below are the fiscal year 2012 recommendations of the Nation's Tribal Colleges and Universities (TCUs), covering three areas within the Department of Education and one in the Department of Health and Human Services, Administration for Children and Families' Head Start Program.

DEPARTMENT OF EDUCATION PROGRAMS

*Higher Education Act Programs*

*Strengthening Developing Institutions*.—Section 316 of HEA Title III–A, specifically supports TCUs' grant programs. The TCUs request that the Subcommittee appropriate $30 million for this critically important program, the same level included in the President's fiscal year 2012 budget request.

*TRIO Programs*.—Retention and support services are vital to achieving the national goal of having the highest percentage of college graduates globally by 2020. The President's fiscal year 2012 budget request includes funding for TRIO programs at fiscal year 2010 levels, which is not enough to sustain even the current level of program services. The TCUs support building on the President's fiscal year 2012 budget request for TRIO programs and technical assistance funding so that these essential program services can be, at a minimum, maintained at current levels.

*Pell Grants*.—TCUs urge the Subcommittee to sustain the current Pell Grant maximum.

*Perkins Career and Technical Education Programs*

Section 117 of the Carl D. Perkins Career and Technical Education Act provides a competitively awarded grant opportunity for tribally chartered and controlled career and technical institutions. AIHEC requests $8,200,000 to fund grants under Section 117 of the Perkins Act. Additionally, TCUs strongly support the Native American Career and Technical Education Program (NACTEP) authorized under Sec tion 116 of the Perkins Act.

*Elementary and Secondary Education Act and Workforce Investment Act Programs*

*American Indian Teacher and Administrator Corps*.—Authorized in Title IX of the Elementary and Secondary Education Act (ESEA) the American Indian Teacher Corps and the American Indian Administrator Corps offer professional development grants designed to increase the number of American Indian teachers and administrators serving their reservation communities. The TCUs request that the Subcommittee maintain funding for these programs at the fiscal year 2010 level.

*Adult and Basic Education*.—Despite the loss of Federal funding for tribal adult basic education (ABE) in fiscal year 1996, there remains an extremely high demand for ABE programs in the communities that are home to the TCUs. While TCUs continue to offer adult education; GED; remediation and literacy services for American Indians, without dedicated funding these efforts cannot begin to meet demand. The TCUs request that the Subcommittee direct that $5 million of the funds appropriated each year for the Adult Education State Grants be made available to make competitive awards to TCUs to support the vitally needed reservation-based adult and basic education programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES PROGRAM

*Tribal Colleges and Universities Head Start Partnership Program (DHHS–ACF)*

Tribal Colleges and Universities are ideal partners to help achieve the goals of Head Start in Indian Country. The TCUs request that the Subcommittee direct the Head Start Bureau to make available $5 million, of the more than $8.1 billion for Head Start included in the President's fiscal year 2012 budget request or of the amount ultimately appropriated in fiscal year 2012, for the TCU-Head Start Partnership program grants. These funds will help to ensure that each of the TCUs has the opportunity to compete for these much-needed partnership funds, thereby giving a jump start to the education successes of more American Indian children growing up in poor and isolated tribal communities.

BACKGROUND ON TRIBAL COLLEGES AND UNIVERSITIES

The Nation's 36 Tribal Colleges and Universities, operating over 75 sites, provide access to quality higher education to 80 percent of Indian Country. TCUs are accredited by independent, regional accreditation agencies and like all institutions of higher education, must undergo stringent performance reviews on a periodic basis to retain their accreditation status. In addition to college level programming, they provide high school completion (GED), basic remediation, job training, college preparatory courses, and adult education and literacy programs. TCUs fulfill additional roles within their respective reservation communities functioning as community centers, libraries, tribal archives, career and business centers, economic development centers, public meeting places, and child and elder care centers. Each TCU is committed to improving the lives of its students through higher education and to moving American Indians toward self-sufficiency.

Tribal Colleges and Universities, chartered by their respective tribal governments, were established in response to the recognition by tribal leaders that local, culturally based institutions are best suited to help American Indians succeed in higher education. TCUs effectively blend traditional teachings with conventional postsecondary curricula. They have developed innovative ways to address the needs of tribal populations and are overcoming long-standing barriers to success in higher education for American Indians. Since the first TCU was established on the Navajo Nation just over 40 years ago, these vital institutions have come to represent the most significant development in the history of American Indian higher education, providing access to, and promoting achievement among, students who may otherwise never have known postsecondary education success.

JUSTIFICATIONS FOR FISCAL YEAR 2012 APPROPRIATIONS REQUESTS FOR TCUS

Tribal colleges and our students are already disproportionately impacted by efforts to reduce the Federal budget deficit and control Federal spending. The final fiscal year 2011 continuing resolution eliminated all of the Department of Housing and Urban Development's MSI community-based programs, including a critical TCU–HUD facilities program. TCUs were able to maximize leveraging potential, often securing even greater non-Federal funding to construct and equip Head Start and early childhood centers; student and community computer laboratories and public libraries; and student and faculty housing in rural and remote communities where few or none of these facilities existed. Important STEM program operated by the National Science Foundation and NASA were cut and for the first time since the program was established in fiscal year 2001, no new TCU–STEM awards, our sole STEM education program, are scheduled to be made in fiscal year 2011. Additionally, TCUs and our students suffer the impact of cuts to programs such as GEAR–UP, TRIO, SEOG, and year-round Pell more profoundly than do mainstream institutions of higher education, which have large endowments, alternative funding sources, including the ability to charge higher tuition rates, enroll more financially stable students, and affluent alumnae. The loss of opportunity that cuts to DoEd, HUD, and NSF programs represent to TCUs, and to other MSIs, is magnified by

cuts to workforce development programs within the Department of Labor, nursing and allied health professions tuition forgiveness and scholarship programs operated by the Department of Health and Human Services, and an important TCU-based nutrition education program planned by USDA. Combined, these cuts strike at the most economically disadvantaged and health-challenged Americans.

*Higher Education Act*

In 1998, section 316 within Title III–A of the Higher Education Act launched a new program specifically for the Nation's Tribal Colleges and Universities. Programs under Titles III and V of the Act support institutions that enroll large proportions of financially disadvantaged students and that have low per-student expenditures. TCUs, which are truly developing institutions, are providing access to quality higher education opportunities to some of the most rural, impoverished, and historically underserved areas of the country. Seven of the Nation's 10 poorest counties are served by TCUs. A stated goal of the Higher Education Act Title III programs is "to improve the academic quality, institutional management and fiscal stability of eligible institutions, in order to increase their self-sufficiency and strengthen their capacity to make a substantial contribution to the higher education resources of the Nation." The TCU Title III–A program is specifically designed to address the critical, unmet needs of their American Indian students and communities, in order to effectively prepare them to succeed in a global, competitive workforce. Yet, in fiscal year 2011 this critical program was cut by 11 percent. The TCUs urge the Subcommittee to appropriate $30 million in fiscal year 2012 for HEA Title III–A section 316, which is slightly less than the fiscal year 2010 appropriated funding level and the same as the President's fiscal year 2012 budget request.

Retention and support services are vital to achieving the national goal of having the highest percentage of college graduates globally, by 2020. The TRIO-Student Support Services program was created out of recognition that college access was not enough to ensure advancement and that multiple factors worked to prevent the successful completion of higher education for many low-income and first-generation students and students with disabilities. Therefore, in addition to maintaining the maximum Pell Grant award level, it is critical that Congress also sustains student assistance programs such as Student Support Services and Upward Bound so that low-income and minority students have the support necessary to allow them to persist in and complete their postsecondary courses of study.

The importance of Pell Grants to TCU students cannot be overstated. U.S. Department of Education figures show that the majority of TCU students receive Pell Grants, primarily because student income levels are so low and our students have far less access to other sources of financial aid than students at State-funded and other mainstream institutions. Within the TCU system, Pell Grants are doing exactly what they were intended to do—they are serving the needs of the lowest income students by helping them gain access to quality higher education, an essential step toward becoming active, productive members of the workforce. The TCUs urge the Subcommittee to continue to fund this critical program at the highest possible level.

*Carl D. Perkins Career and Technical Education Act*

*Tribally Controlled Postsecondary Career and Technical Institutions*.—Section 117 of the Carl D. Perkins Career and Technical Education Act provides a competitively awarded grant opportunity for tribally chartered and controlled career and technical institutions. AIHEC requests $8,200,000 to fund grants under Section 117 of the Perkins Act, the same level included in the President's fiscal year 2012 budget request.

*Native American Career and Technical Education Program*.—The Native American Career and Technical Education Program (NACTEP) under Section 116 of the Act reserves 1.25 percent of appropriated funding to support American Indian career and technical programs. The TCUs strongly urge the Subcommittee to continue to support NACTEP, which is vital to the continuation of the career and technical education programs offered at TCUs that provide job training and certifications to remote reservation communities.

*Greater Support of Indian Education Programs*

*American Indian Adult and Basic Education (Office of Vocational and Adult Education)*.—This program supports adult basic education programs for American Indians offered by State and local education agencies, Indian tribes, agencies, and TCUs. Despite a lack of funding, TCUs must find a way to continue to provide much-in-demand basic adult education classes for those American Indians that the present K–12 Indian education system has failed. Before many individuals can even begin the course work needed to learn a productive skill, they first must earn a

GED or, in some cases, even learn to read. There is an extensive need for basic adult educational programs and TCUs must have adequate and stable funding to provide these essential activities. TCUs request that the Subcommittee direct that $5 million of the funds appropriated annually for the Adult Education State Grants be made available to make competitive awards to TCUs to help meet the growing demand for adult basic education and remediation program services on their respective reservations.

*American Indian Teacher/Administrator Corps (Special Programs for Indian Children).*—American Indians are greatly underrepresented in the teaching and school administrator ranks nationally. TCUs are community based institutions of higher education making them ideal catalysts for these two initiatives because of their current work in this area and the existing articulation agreements they hold with 4-year degree granting institutions. The TCUs request that the Subcommittee maintain these two programs at the fiscal year 2010 appropriated levels to continue to produce well-qualified American Indian teachers and school administrators in and for Indian Country.

DEPARTMENT OF HEALTH AND HUMAN SERVICES/ADMINISTRATION FOR CHILDREN AND FAMILIES/HEAD START

*Tribal Colleges and Universities (TCU) Head Start Partnership Program.*—The TCU-Head Start Partnership has made a lasting investment in our Indian communities by creating and enhancing associate degree programs in Early Childhood Development and related fields. This program has afforded American Indian children Head Start programs of the highest quality. A clear barrier to the ongoing success of this partnership program is the lack of stable funds for the Partnership. The TCUs request that the Subcommittee direct the Head Start Bureau to designate $5 million, of the more than $8.1 billion included in the President's fiscal year 2012 budget request for programs under the Head Start Act, be made available for the TCU-Head Start Partnership program.

CONCLUSION

Tribal Colleges and Universities are providing access to high quality higher education opportunities to many thousands of American Indians and essential community services and programs to many more. The modest Federal investment in TCUs has already paid great dividends in terms of employment, education, and economic development and continuation of this solid investment makes sound moral and fiscal sense. TCUs need your help if they are to sustain programs and achieve their missions to serve their students and communities.

Thank you again for this opportunity to present our funding requests. We respectfully ask the Members of the Subcommittee for their continued support of the Nation's Tribal Colleges and Universities and full consideration of our fiscal year 2012 appropriations needs and recommendations.

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## PREPARED STATEMENT OF THE AMERICAN INSTITUTE FOR MEDICAL AND BIOLOGICAL ENGINEERING

Mister Chairman and Members of the Subcommittee: The American Institute for Medical and Biological Engineering (AIMBE) appreciates the opportunity to submit testimony to advocate for funding for research within the National Institutes of Health (NIH) broadly, and specifically research funding within the National Institute for Biomedical Imaging and Bioengineering (NIBIB). NIH and NIBIB provide avenues for research funding that are vital to the Nation's efforts to support medical and biological engineering (MBE) innovation. AIMBE represents 50,000 individuals and organizations throughout the United States, including major healthcare companies, academic research institutions and the top 2 percent of engineers, scientists and clinicians whose discoveries and innovations have touched the health of nearly every American. While today's testimony focuses on the impact MBE has on improving the health and well-being of Americans, it is important to note that MBE can also have a positive impact on many of the other important issues facing us today; ranging from improvements to the environment by finding green-energy solutions, to solving problems relating to hunger, disease prevention, diagnosis and treatment of disease; to economic growth spurred by the innovation of new health products.

AIMBE was founded in 1991 to establish a clear and comprehensive identity for the field of medical and biological engineering—which applies principles of engineering science and practice to imagine, create, and perfect the medical and biological discoveries that are used to improve the health and quality of life of Americans and

people across the world. AIMBE's vision is to ensure MBE innovations continue to develop for the benefit of humanity.

AIMBE applauds the past support of this committee to provide funding to NIH, and was particularly pleased at the strong investment in NIH provided by the American Recovery and Reinvestment Act. However, we were concerned over recent cuts by the continuing resolution budget for fiscal year 2011. We believe more stable, adequate, and reliable funding is necessary to ultimately ensure America remains competitive and continues to develop innovations that improve human health. An increase in funding will support important work which is highly translatable or applicable research into products that are life-saving, and life enhancing. NIBIB is the only institute at the NIH with the specific purpose of supporting and conducting biomedical engineering research, which impacts all sectors of health across many disease states. Research conducted within NIBIB is on the cutting edge of biomedical engineering and has the potential to save lives and reduce healthcare costs.

While each Institute within the NIH plays a vital role researching and identifying disease prevention and treatment; the NIBIB plays a unique role and has not benefited from large-scale NIH funding increases, such as the doubling of the budget in 2004. First appropriated with its own funding in 2004 (fiscal year 2003 and fiscal year 2004 were funded through transfers from other Institutes within NIH), the mission of NIBIB is to improve health by leading the development and accelerating the application of biomedical technologies. The NIBIB is committed to integrating the physical and engineering sciences with the life sciences to advance basic research and medical care. This is achieved through research and development of new biomedical imaging and bioengineering techniques and devices to fundamentally improve the detection, treatment, and prevention of disease; enhancing existing imaging and bioengineering modalities; supporting related research in the physical and mathematical sciences; encouraging research and development in multidisciplinary areas; supporting studies to assess the effectiveness and outcomes of new biologics, materials, processes, devices, and procedures; developing non-imaging technologies for early disease detection and assessment of health status; and developing advanced imaging and engineering techniques for conducting biomedical research at multiple scales through modeling and simulation. Finally, the NIBIB plays an important role in providing engineering research resources to the entirety of the NIH. As the only engineering research arm within the NIH, NIBIB is often relied upon to partner with other institutes at the NIH to provide engineering expertise. The Laboratory of Molecular Imaging and Nanomedicine, and Laboratory of Bioengineering and Physical Science are two examples of NIBIB's role as a partner for researchers working at other Institutes at the NIH.

We strongly recommend that early-stage, proof-of-concept projects for translational research be funded at an enhanced level, ideally 0.5 percent of all external research budgets, at all Institutes. This is critical to maintaining the U.S. lead in innovation by moving new discoveries and novel systems to the stage where third-party private funding can take them through development to the marketplace where they help patients and the health of Americans. Publicly-held companies cannot invest in this stage of work due to stockholder pressures, so the Federal Government is critical to ensuring the viability of this innovation pipeline.

*NIBIB as a Stimulus for Innovation/Cost Effectiveness*

Due in large part to the Great Recession, private industry and private investors have been less likely to invest in high-risk research, potentially slowing the pace of innovation. NIBIB fills a void by providing funding for high-risk, high-reward research that leads to the development of new technologies. Often times, private investors in biomedical innovation are unwilling to invest in this type of research, particularly in our current fiscal climate, because of the risks involved. However, NIBIB can be a mechanism to bring new technologies to market and fills the void left by a lack of private capital.

The NIBIB's Quantum Grants program, for example, challenges the research community to propose projects that have a highly focused, collaborative, and interdisciplinary approach to solve a major medical problem or to resolve a highly prevalent technology-based medical challenge. The program consists of a 3-year exploratory phase to assess feasibility and identify best approaches, followed by a second phase of 5 to 7 years. Major advances in medicine leading to quantifiable improvements in public health require the kind of funding commitment and intellectual focus found in the Quantum Grants program at NIBIB, because early stage investors are reluctant to invest in high-risk research. Additionally, the Quantum Grants offer a place for Government to invest in translational research, potentially solving huge medical problems facing Americans today.

The five currently funded Quantum Grants focus on: stem cell therapies for patients suffering from the effects of diabetes and stroke; the utilization of nanoparticles to help visualize brain tumors so that surgeons can easily see and remove a cancerous mass in a patient's brain; the development of an implantable artificial kidney offering an improved quality of life for patients currently undergoing dialysis treatment; and a microchip to capture circulating tumor cells for clinicians to diagnose cancer earlier than ever before, giving patients a greater hope for recovery thanks to earlier detection and treatment. All these projects, in their early stages of funding, have demonstrated promise for improving patient outcomes in the laboratory setting.

An increase of funding to NIBIB and the Quantum Grants program may offer opportunities to expedite research beyond laboratory study and move to clinical trial. For example, if the artificial kidney research is successful and brought to market, the cost to a person with kidney disease would radically decrease because it would eliminate the need for dialysis, which is a expensive, painful, and resource heavy procedure typically done in an out-patient hospital setting.

*The Fundamental Role of Engineering Research*

Advances in the process of engineering research, in a variety of fields, are a part of technological innovation. Medical and biological engineering draws from research specialties across disciplines (including mechanical, electrical, material, medical and biological engineering, and clinicians), bringing together teams to create unique solutions to the most pressing health problems. Engineering is the practical application of science and math to solve problems. For example, the insulin pump, which is the primary device used by patients with diabetes who requires continuous insulin infusion therapy, is the result of multi-disciplinary effort by engineers to develop a more efficient way to manage diabetes. The science to develop and perfect an insulin pump existed well before the creation of the medical device; however it took biomedical engineers to apply the basic science toward product development.

The first insulin pump to be manufactured was released in the late 70's. It was known as the "big blue brick" because of its size and appearance. It sparked interest among healthcare professionals who saw it as a device that would render syringes obsolete for people who have daily insulin injection needs. While the technology was promising, the first commercial pump lacked the controls and interface to make it a safe alternative to manual injections. Dosage was inaccurate thus making the device more of a danger than a solution.

It was only in the beginning of the 1990's that biomedical engineers began to develop more user-friendly models that could be used by diabetics. Advances in biomedical engineering research focused on reducing device size, increasing energy efficiency (and thus improving battery life), and improving reliability. Such improvements were of great benefit to insulin pump manufacturers who were able to make their models smaller, more affordable, and easier for patients to use. Insulin pumps enable many diabetic patients to live productive lives due to fewer absences from work and reduced hospitalizations.

A similar advancement in the treatment of atherolosclerosis through MBE is the use of angioplasty with an arterial stent which releases drugs directly to the coronary artery (referred to as a drug eluting stent). This advancement has replaced more then 500,000 bypass surgeries a year, at an annual cost savings of $4 billion, and an immeasurable improvement in the quality of life of patients receiving this treatment.

Engineering research in human physiology, specifically in range of motion and function, has increased the function for artificial limbs. The decreasing mortality and increasing number of disabled war veterans highlights the need for more highly functional prosthetics. Engineering research and development processes have taken the strapped wooden leg to a realistic synergic leg and foot transtibial prosthetic that employs advanced biomechanics and microelectronic controls to allow a fuller range of motion, including running. Basic engineering research in polymers and materials science has changed the look and feel of prosthetic limbs so they are no longer easily discernable, reducing the stigma, and making them more durable, lessening the cost of maintenance and replacement. Researchers in Baltimore, Cleveland, and Chicago are developing the next generation of prosthetic limbs, utilizing cutting edge biomedical engineering research to develop prostheses that are more sensitive, more responsive, and more lifelike then anything developed in the past. These new "bionic limbs" are giving patients pieces of their body back, pieces taken from them through traumatic injury or disease. Increases in funding to NIBIB, who uniquely partners with other Federal agencies such as the Department of Veterans Affairs and Department of Defense, may lead to biomedical engineering innovations

to improve the quality of life of warfighters injured on the battlefield as well as civilians.

The engineering research process has played a large part in extending and deploying innovative imaging technologies such as magnetic resonance imaging (MRI) and ultra-fast computed tomography (CT scan). These technologies facilitate early detection of disease and dysfunction, allowing for earlier treatment and slowing the progression of disease. When prescribed correctly these technologies can reduce the costs of healthcare by diagnosing diseases earlier, allowing for earlier clinical intervention and reduced hospitalizations with faster recovery times.

The Nation deserves a strong return on its investment in the basic medical research funded by NIH. Additional engineering research, including translation of basic research into new devices and more efficient medical procedures, is a critical part of ensuring that return. This combination of basic scientific studies and engineering research, will in turn, lead to many technological innovations which will improve the quality of life and well-being of Americans. The Government needs to continue to fund the vital research at NIH and NIBIB to continue to be a leader in healthcare innovation, and for the creation of jobs in the healthcare segment of our national economy.

AIMBE looks forward to the opportunity to continue this dialogue with all of you individually. Thank you again for your time and consideration on this important matter.

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## PREPARED STATEMENT OF THE AMERICAN LUNG ASSOCIATION

### SUMMARY OF PROGRAMS

*Centers for Disease Control and Prevention (CDC)*

Increased overall CDC funding—$7.7 billion
—Funding Healthy Communities—$52.8 million
—Office on Smoking and Health—$110 million
—National Asthma Control Program—$31 million
—Environment and Health Outcome Tracking—$32.1 million
—Tuberculosis programs—$231 million
—CDC influenza preparedness—$160 million
—NIOSH—$315.3 million
—Prevention and Public Health Fund—$1 billion, with $330 million for tobacco control initiatives

*National Institutes of Health (NIH)*

Increased overall NIH funding—$35 billion
National Heart, Lung and Blood Institute—$3.514 billion
National Cancer Institute—$5.725 billion
National Institute of Allergy and Infectious Diseases—$5.395 billion
National Institute of Environmental Health Sciences—$779.4 million
National Institute of Nursing Research—$163 million
National Institute on Minority Health & Health Disparities—$236.9 million
Fogarty International Center—$78.4 million

For more information about this testimony, please contact Erika Sward at esward@lungusa.org.

The American Lung Association is pleased to present our recommendations for fiscal year 2012 to the Labor, Health and Human Services, and Education Appropriations Subcommittee. The public health and research programs funded by this committee will prevent lung disease and improve and extend the lives of millions of Americans who suffer from lung disease.

The American Lung Association is the oldest voluntary health organization in the United States, with national offices and local associations around the country. Founded in 1904 to fight tuberculosis, the American Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through education, advocacy and research.

*A Sustained and Sustainable Investment*

Mr. Chairman, investments in prevention and wellness can and will pay near term and long term dividends for the health of the American people and people everywhere. That is why the American Lung Association strongly supports the Prevention and Public Health Fund established in the Affordable Care Act. This fund will provide billions of dollars to critical public health initiatives, like community programs that help people quit smoking, support groups for lung cancer patients, and classes that teach people how to avoid asthma attacks.

The United States must also maintain its commitment to medical research. A growing, sustained, predictable and reliable investment in the NIH provides hope for millions afflicted with lung disease. While our focus is on lung disease research, we strongly support increasing the investment in research across the entire National Institutes of Health.

*Lung Disease*

Each year, almost 400,000 Americans die of lung disease. It is America's number three killer, responsible for one in every six deaths. More than 37 million Americans suffer from a chronic lung disease. Each year lung disease costs the economy an estimated $173 billion. Lung diseases include: lung cancer, asthma, chronic obstructive pulmonary disease (COPD), tuberculosis, pneumonia, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease and sarcoidosis.

*Improving Public Health*

The American Lung Association strongly supports investments in the public health infrastructure. In order for the Centers for Disease Control and Prevention (CDC) to carry out its prevention mission and to assure an adequate translation of new research into effective State and local programs to improve the health of all Americans, we strongly support increasing the overall CDC funding to $7.7 billion.

We strongly encourage improved disease surveillance and health tracking to better understand diseases like asthma. We support an appropriations level of $32.1 million for the Environment and Health Outcome Tracking Network to allow Federal, State and local agencies to track potential relationships between hazards in the environment and chronic disease rates.

We strongly support investments in communities to bring together key stakeholders to identify and improve policies and environmental factors influencing health in order to reduce the burden of chronic diseases. These programs lead to a wide range of improved health outcomes including reduced tobacco use. We strongly recommend at least $52.8 million in funding for the Healthy Communities program and it remaining a separate, stand alone program.

*Tobacco Use*

Tobacco use is the leading preventable cause of death in the United States, killing more than 443,000 people every year. Smoking is responsible for one in five U.S. deaths. The direct healthcare and lost productivity costs of tobacco-caused disease and disability are also staggering, an estimated $193 billion each year.

Given the magnitude of the tobacco-caused disease burden and how much of it can be prevented; the CDC Office on Smoking and Health (OSH) should be much larger and better funded. Historically, Congress has failed to invest in tobacco control—even though public health interventions have been scientifically proven to reduce tobacco use. This neglect cannot continue if the nation wants to prevent disease and promote wellness.

The American Lung Association urges that $110 million be appropriated to OSH for fiscal year 2012 and that OSH receive an additional one-third, or $330 million, of funds from the Prevention and Public Health Fund.

*Asthma*

The American Lung Association strongly opposes the proposal in the President's budget request that would merge the National Asthma Control Program with the Healthy Homes/Lead Poisoning Prevention Program—and then slash the combined programs by more than 50 percent. The Lung Association asks this Committee to retain the National Asthma Control Program as a stand-alone program and that $31 million be appropriated to it for fiscal year 2012.

It is estimated that almost 25 million Americans currently have asthma, of whom 7.1 million are children. Asthma prevalence rates are over 37 percent higher among African Americans than whites. Studies also suggest that Puerto Ricans have higher asthma prevalence rates and age-adjusted death rates than all other racial and ethnic subgroups. Asthma is the third leading cause of hospitalization among children under the age of 15 and is a leading cause of school absences from chronic disease—accounting for over 10.5 million lost school days in 2008. Asthma costs our healthcare system over $50.1 billion annually and indirect costs from lost productivity add another $5.9 billion, for a total of $56 billion annually.

We recommend that the National Heart, Lung and Blood Institute receive $3.514 billion and the National Institute of Allergy and Infectious Diseases be appropriated $5.395 billion, and that both agencies continue their investments in asthma research in pursuit of treatments and cures.

*Lung Cancer*

An estimated 370,000 Americans are living with lung cancer. During 2010, an estimated 222,520 new cases of lung cancer were diagnosed, and 158,664 Americans died from lung cancer in 2009. Survival rates for lung cancer tend to be much lower than those of most other cancers. African Americans are the most likely to develop and die from lung cancer than persons of any other racial group.

Lung cancer receives far too little attention and focus. Given the magnitude of lung cancer and the enormity of the death toll, the American Lung Association strongly recommends that the NIH and other Federal research programs commit additional resources to lung cancer. We support a funding level of $5.725 billion for the National Cancer Institute and urge more attention and focus on lung cancer.

*Chronic Obstructive Pulmonary Disease*

Chronic obstructive pulmonary disease, or COPD, is the third leading cause of death in the United States. It has been estimated that 13.1 million patients have been diagnosed with some form of COPD and as many as 24 million adults may suffer from its consequences. In 2009, 133,737 people in the United States died of COPD. The annual cost to the Nation for COPD in 2010 was projected to be $49.9 billion. This includes $29.5 billion in direct healthcare expenditures, $8.0 billion in indirect morbidity costs and $12.4 billion in indirect mortality costs. Medicare expenses for COPD beneficiaries were nearly 2.5 times that of the expenditures for all other patients.

The American Lung Association strongly recommends that the NIH and other Federal research programs commit additional resources to COPD research programs. We strongly support funding the National Heart, Lung and Blood Institute and its lifesaving lung disease research program at $3.514 billion. The American Lung Association also asks the Committee to direct the National Heart, Lung and Blood Institute to work with the CDC and other appropriate agencies to prepare a national action plan to address COPD, which should include public awareness and surveillance activities.

*Influenza*

Influenza is a highly contagious viral infection and one of the most severe illnesses of the winter season. It is unpredictable, with seasonal death estimates ranging from 3,000 to 49,000 over the last 30 years. Further, the emerging threat of a pandemic influenza is looming as the recently emerging strain of H1N1 reminded us. Public health experts warn that 209,000 Americans could die and 865,000 would be hospitalized if a moderate flu epidemic hits the United States. To prepare for a potential pandemic, the American Lung Association supports funding the Federal CDC Influenza efforts at $160 million.

*Tuberculosis*

Tuberculosis primarily affects the lungs but can also affect other parts of the body. There are an estimated 10 million to 15 million Americans who carry latent TB infection. Each has the potential to develop active TB in the future. About 10 percent of these individuals will develop active TB disease at some point in their lives. In 2009, there were 11,545 cases of active TB reported in the United States. While declining overall TB rates are good news, the emergence and spread of multidrug resistant TB pose a significant threat to the public health of our Nation. Continued support is needed if the United States is going to continue progress toward the elimination of TB. We request that Congress increase funding for tuberculosis programs at CDC to $231 million for fiscal year 2012.

*Conclusion*

The American Lung Association also would like to indicate our strong support for CDC and NIH, particularly those programs that impact lung health. We strongly support an across the board increase for NIH with particular emphasis on the National Heart, Lung and Blood Institute, the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, the National Institute of Environmental Health Sciences, the National Institute of Nursing Research, the National Institute on Minority Health & Health Disparities and the Fogarty International Center.

Lung disease is a continuing, growing problem in the United States. It is America's number three killer, responsible for one in six deaths. Progress against lung disease is not keeping pace with other major causes of death and more must be done. The level of support this committee approves for lung disease programs should reflect the urgency illustrated by these numbers.

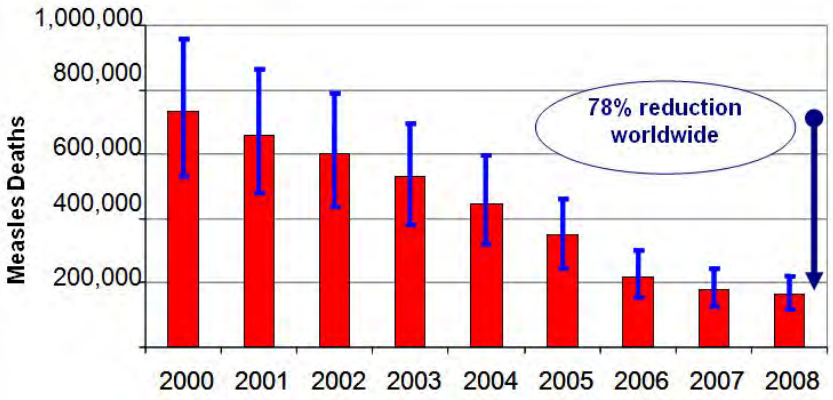
PREPARED STATEMENT OF THE AMERICAN NATIONAL RED CROSS

Chairman Tom Harkin, Ranking Member Richard Shelby, and Members of the Subcommittee, the American Red Cross and the United Nations Foundation appreciate the opportunity to submit testimony in support of measles control activities of the U.S. Centers for Disease Control and Prevention (CDC). The American Red Cross and the United Nations Foundation recognize the leadership that Congress has shown in funding CDC for these essential activities. We sincerely hope that Congress will continue to support the CDC during this critical period in measles control.

In 2001, CDC—along with the American Red Cross, the United Nations Foundation, the World Health Organization, and UNICEF—founded the Measles Initiative, a partnership committed to reducing measles deaths globally. The current U.N. goal is to reduce measles deaths by 95 percent by 2015 compared to 2000 estimates. The Measles Initiative is committed to reaching this goal by proving technical and financial support to governments and communities worldwide.

The Measles Initiative has achieved "spectacular"[1] results by supporting the vaccination of more than 700 million children. Largely due to the Measles Initiative, global measles mortality dropped 78 percent, from an estimated 733,000 deaths in 2000 to 164,000 in 2008 (the latest year for which data is available). During this same period, measles deaths in Africa fell by 92 percent, from 371,000 to 28,000.

*Figure1:* **Estimated Number of Global Measles Deaths, 2000-2008**




Working closely with host governments, the Measles Initiative has been the main international supporter of mass measles immunization campaigns since 2001. The Initiative mobilized more than $700 million and provided technical support in more than 60 developing countries on vaccination campaigns, surveillance and improving routine immunization services. From 2000 to 2008, an estimated 4.3 million measles deaths were averted as a result of these accelerated measles control activities at a donor cost of $184/death averted, making measles mortality reduction one of the most cost-effective public health interventions.

Nearly all the measles vaccination campaigns have been able to reach more than 90 percent of their target populations. Countries recognize the opportunity that measles vaccination campaigns provide in accessing mothers and young children, and "integrating" the campaigns with other life-saving health interventions has become the norm. In addition to measles vaccine, Vitamin A (crucial for preventing blindness in under nourished children), de-worming medicine (reduces malnutrition), and insecticide-treated bed nets (ITNs) for malaria prevention are distributed during vaccination campaigns. The scale of these distributions is immense. For example, more than 40 million ITNs were distributed in vaccination campaigns in the last few years. The delivery of multiple child health interventions during a single campaign is far less expensive than delivering the interventions separately, and this strategy increases the potential positive impact on children's health from a single campaign.

[1] The Lancet, Volume 8, page 13 (January 2008).

The extraordinary reduction in global measles deaths contributed nearly 25 percent of the progress to date toward Millennium Development Goal #4 (reducing under-five child mortality). However, since 2009, Africa has experienced outbreaks affecting 28 countries, resulting in a four-fold increase in reported measles cases. These outbreaks highlight the fragility of the last decade's progress. If mass immunization campaigns are not continued, measles deaths will increase rapidly with more than half a million deaths estimated for 2013 alone.

To achieve the 2015 goal and avoid a resurgence of measles the following actions are required:

—Fully implementing activities, both campaigns and strengthening routine measles coverage, in India since it is the greatest contributor to the global burden of measles.

—Sustaining the gains in reduced measles deaths, especially in Africa, by strengthening immunization programs to ensure that more than 90 percent of infants are vaccinated against measles through routine health services before their first birthday as well as conducting timely, high quality mass immunization campaigns.

—Securing sufficient funding for measles-control activities both globally and nationally. The Measles Initiative faces a funding shortfall of an estimated $212 million for 2012–2105. Implementation of timely measles campaigns is increasingly dependent upon countries funding these activities locally. The decrease in donor funds available at global level to support measles elimination activities makes increased political commitment and country ownership of the activities critical for achieving and sustaining the goal of reducing measles mortality by 90 percent.

If these challenges are not addressed, the remarkable gains made since 2000 will be lost and a major resurgence in measles deaths will occur.

By controlling measles cases in other countries, U.S. children are also being protected from the disease. Measles can cause severe complications and death. A resurgence of measles occurred in the United States between 1989 and 1991, with more than 55,000 cases reported. This resurgence was particularly severe, accounting for more than 11,000 hospitalizations and 123 deaths. Since then, measles control measures in the United States have been strengthened and endemic transmission of measles cases have been eliminated here since 2000. However, importations of measles cases into this country continue to occur each year. The costs of these cases and outbreaks are substantial, both in terms of the costs to public health departments and in terms of productivity losses among people with measles and parents of sick children. For example in 2008, 2 hospitals in Arizona spent an estimated $800,000 responding and containing 7 measles cases.[2] The United States is currently on track to have more measles cases in 2011 than any year in more than a decade.

*The Role of CDC in Global Measles Mortality Reduction*

Since fiscal year 2001, Congress has provided approximately $43.6 million annually in funding to CDC for global measles control activities. These funds were used toward the purchase of measles vaccine for use in large-scale measles vaccination campaigns in more than 60 countries in Africa and Asia, and for the provision of technical support to Ministries of Health. Specifically, this technical support includes: Planning, monitoring, and evaluating large-scale measles vaccination campaigns; conducting epidemiological investigations and laboratory surveillance of measles outbreaks; and conducting operations research to guide cost-effective and high quality measles control programs.

In addition, CDC epidemiologists and public health specialists have worked closely with WHO, UNICEF, the United Nations Foundation, and the American Red Cross to strengthen measles control programs at global and regional levels. While it is not possible to precisely quantify the impact of CDC's financial and technical support to the Measles Initiative, there is no doubt that CDC's support—made possible by the funding appropriated by Congress—was essential in helping achieve the sharp reduction in measles deaths in just 8 years.

The American Red Cross and the United Nations Foundation would like to acknowledge the leadership and work provided by CDC and recognize that CDC brings much more to the table than just financial resources. The Measles Initiative is fortunate in having a partner that provides critical personnel and technical support for vaccination campaigns and in response to disease outbreaks. CDC personnel have routinely demonstrated their ability to work well with other organizations and

[2] Chen SY, Anderson S, Kutty PK, et al. J of Infect Dis 2011; 203: 1517–1525.

provide solutions to complex problems that help critical work get done faster and more efficiently.

In fiscal year 2011, Congress appropriated approximately $49 million to fund CDC for global measles control activities, this represented at $2.6 million decrease from the previous year. The American Red Cross and the United Nations Foundation respectfully request a return to fiscal year 2010 funding levels ($52 million) for fiscal year 2012 for CDC's measles control activities to protect the investment of the last decade, and prevent a global resurgence of measles and a loss of progress toward Millennium Development Goal #4.

Your commitment has brought us unprecedented victories in reducing measles mortality around the world. In addition, your continued support for this initiative helps prevent children from suffering from this preventable disease both abroad and in the United States.

Thank you for the opportunity to submit testimony.

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PREPARED STATEMENT OF THE AMERICAN NURSES ASSOCIATION

The American Nurses Association (ANA) appreciates the opportunity to comment on fiscal year 2012 appropriations for the Title VIII Nursing Workforce Development Programs and Nurse-Managed Health Clinics. Founded in 1896, ANA is the only full-service professional association representing the interests of the Nation's 3.1 million registered nurses (RNs) through its State nurses associations, and organizational affiliates. The ANA advances the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, and projecting a positive and realistic view of nursing.

As the largest single group of clinical healthcare professionals within the health system, licensed registered nurses are educated and practice within a holistic framework that views the individual, family and community as an interconnected system that can keep us well and help us heal. Registered nurses are fundamental to the critical shift needed in health services delivery, with the goal of transforming the current "sick care" system into a true "healthcare" system. RNs are the backbone of hospitals, community clinics, school health programs, home health and long-term care programs, and serve patients in many other roles and settings. The ANA gratefully acknowledges this Subcommittee's history of support for nursing education. We also appreciate your continued recognition of the important role nurses play in the delivery of quality healthcare services, including Nurse-Managed Health Clinics (NMHCs).

*The Nursing Shortage*

A sufficient supply of nurses is critical in providing our Nation's population with quality healthcare. Registered Nurses (RNs) and Advanced Practice Registered Nurses (APRNs) play an integral role in the delivery of primary care and help to bring the focus of our healthcare system back where it belongs—on the patient and the community. The current U.S. nursing shortage is already having a detrimental impact on our healthcare system, and it is expected to grow to a 260,000 nurse shortfall by 2025. A shortage of this magnitude would be twice as large as any shortage experienced by this country since the 1960s. Cuts to Title VIII funding would be detrimental to the healthcare system and the patients we serve.

As noted above, the nursing shortage is having a detrimental impact on the entire healthcare system. Numerous studies have shown that nursing shortages contribute to medical errors, poor patient outcomes, and increased mortality rates. A study published in the March 17, 2011 issue of the New England Journal of Medicine shows that inadequate staffing is tied to higher patient mortality rate. The study supports findings of previous studies and finds that higher than typical rates of patient admissions, discharges, and transfers during a shift were associated with increased mortality—an indication of the important time and attention needed by RNs to ensure effective coordination of care for patients at critical transition periods.

*Nursing Workforce Development Programs*

The Nursing Workforce Development programs, authorized under Title VIII of the Public Health Service Act (42 U.S.C. 296 et seq.) support the supply and distribution of qualified nurses to meet our Nation's healthcare needs. Over the last 46 years, Title VIII programs have addressed each aspect of the nursing shortages—education, practice, retention, and recruitment.

—Title VIII provides the largest source of Federal funding for nursing education, offering financial support for nursing education programs, individual students, and nurses.

—These programs bolster nursing education at all levels, from entry-level preparation through graduate study.
—Title VIII programs favor institutions that educate nurses for practice in rural and medically underserved communities.
—In fiscal year 2008, these programs provided loans, scholarships, traineeships, and programmatic support to 77,395 nursing students and nurses.

The 107th Congress recognized the detrimental impact of the developing nursing shortage and passed the Nurse Reinvestment Act (Public Law 107–205). This law improved the Title VIII Nursing Workforce Development programs to meet the unique characteristics of today's shortage. These programs were also strengthened and reauthorized with the adoption of the Affordable Care Act. This achievement holds the promise of recruiting new nurses into the profession, promoting career advancement within nursing and improving patient care delivery. However, this promise cannot be met without a significant investment. ANA strongly urges Congress to increase funding for Title VIII programs to a total of $313.075 million in fiscal year 2012. This is also the amount requested in President Obama's fiscal year 2012 budget.

Current funding levels are clearly failing to meet the need. In fiscal year 2008 (most recent year statistics are available), the Health Resources and Services Administration (HRSA) was forced to turn away 92.8 percent of the eligible applicants for the Nurse Education Loan Repayment Program (NELRP), and 53 percent of the eligible applicants for the Nursing Scholarship program due to a lack of adequate funding. These programs are used to direct RNs into areas with the greatest need—including departments of public health, community health centers, and disproportionate share hospitals.

Title VIII includes the following program areas:

*Nursing Education Loan Repayment Program and Scholarships*.—This line item is comprised of the Nurse Education Loan Repayment Program (NELRP) and the Nursing Scholarship Program (NSP). In fiscal year 2010, the Nurse Education Loan Repayment Program and Scholarships received $93.8 million.

The NELRP repays up to 85 percent of a RN's student loans in return for full-time practice in a facility with a critical nursing shortage. The NELRP nurse is required to work for at least 2 years in a designated facility, during which time the NELRP repays 60 percent of the RN's student loan balance. If the nurse applies and is accepted for an optional third year an additional 25 percent of the loan is repaid.

In fiscal year 2008, HRSA received 3,039 applications for the nursing scholarship. Due to lack of funding, a mere 177 scholarships were awarded. Therefore, 2,862 nursing students (94 percent) willing to work in facilities with a critical shortage were denied access to this program.

*Nurse Faculty Loan Program*.—This program establishes a loan repayment fund within schools of nursing to increase the number of qualified nurse faculty. Nurses may use these funds to pursue a master's or doctoral degree. They must agree to teach at a school of nursing in exchange for cancellation of up to 85 percent of their educational loans, plus interest, over a 4-year period. In fiscal year 2010, this program received $25 million.

This program is vital given the critical shortage of nursing faculty. America's schools of nursing cannot increase their capacity without an influx of new teaching staff. Last year, schools of nursing were forced to turn away tens of thousands of qualified applicants due largely to the lack of faculty. In fiscal year 2008, HRSA funded 95 faculty loans.

*Nurse Education, Practice, and Retention Grants*.—This section is comprised of many programs designed to support entry-level nursing education and to enhance nursing practice. The education grants are designed to expand enrollments in baccalaureate nursing programs, develop internship and residency programs to enhance mentoring and specialty training, and provide new technologies in education including distance learning. All together, the Nurse Education, Practice, and Retention Grants supported 42,761 nurses and nursing students in fiscal year 2008. The program received $39.8 million in fiscal year 2010.

*Nursing Workforce Diversity*.—This program provides funds to enhance diversity in nursing education and practice. It supports projects to increase nursing education opportunities for individuals from disadvantaged backgrounds—including racial and ethnic minorities, as well as individuals who are economically disadvantaged. In fiscal year 2008, 85 applications were received for workforce diversity grants, 51 programs were funded. In fiscal year 2010, these programs received $16 million.

*Advanced Nursing Education*.—Advanced practice registered nurses (APRNs) are nurses who have attained advanced expertise in the clinical management of health conditions. Typically, an APRN holds a master's degree with advanced didactic and clinical preparation beyond that of the RN. Most have practice experience as RNs

prior to entering graduate school. Practice areas include, but are not limited to: anesthesiology, family medicine, gerontology, pediatrics, psychiatry, midwifery, neonatology, and women's and adult health. Title VIII grants have supported the development of virtually all initial State and regional outreach models using distance learning methodologies to provide advanced study opportunities for nurses in rural and remote areas. In fiscal year 2009, 5,649 advanced education nurses were supported through these programs. In fiscal year 2010, these programs received $64.4 million.

*Comprehensive Geriatric Education Grants*.—This authority awards grants to train and educate nurses in providing healthcare to the elderly. Funds are used to train individuals who provide direct care for the elderly, to develop and disseminate geriatric nursing curriculum, to train faculty members in geriatrics, and to provide continuing education to nurses who provide geriatric care. In fiscal year 2008, 6,514 nurses and nursing students were supported through these programs. In fiscal year 2010, these grants received $4.5 million. The growing number of elderly Americans and the impending healthcare needs of the baby boom generation make this program critically important.

*Nurse-Managed Health Clinics*

A healthcare system must value primary care and prevention to achieve improved health status of individuals, families and the community. As Congress recognized through the passage of the Affordable Care Act (ACA) money, resources and attention must be reallocated in the health system to highlight importance of, and create incentives for, primary care and prevention.

Nurses are strong supporters of community and home-based models of care. We believe that the foundation for a wellness-based healthcare system is built in these settings and reduces the amount of both money and human suffering. ANA supports the renewed focus on new and existing community-based programs such as Nurse Managed Health Centers (NMHCs).

Currently, there are more than 200 Nurse Managed Health Centers (NMHCs) in the United States which have provided care to over 2 million patients annually. ANA believes that Nurse Managed Health Centers (NMHCs) are an efficient, sensible, cost-effective way to deliver primary healthcare services. These clinics are also used as clinical sites for nursing education. The nurse-managed care model is especially effective in disease prevention and early detection, management of chronic conditions, treatment of acute illnesses, health promotion, and more. Nurse Managed Health Centers (NMHCs) can also provide a medical home for underserved individuals as well as partnering with the Federal Government to reduce health disparities.

ANA was pleased to see that the Affordable Care Act (ACA) provided grant eligibility to Nurse-Managed Health Clinics (NMHCs) to support operating costs. ACA also authorized up to $50 million a year to support operating costs. ANA strongly urges Congress to provide $20 million for the Nurse-Managed Health Clinics authorized under Title VIII of the Public Health Service Act in fiscal year 2012 as recommended in President Obama's fiscal year 2012 budget.

*Conclusion*

While ANA appreciates the continued support of this Subcommittee, we are concerned that Title VIII funding levels have not been sufficient to address the growing nursing shortage. In preparation for the implementation of healthcare reform initiatives, which ANA supports, we believe there will be an even greater need for nurses and adequate funding for these programs is even more essential. Registered Nurses (RNs) and Advanced Practice Nurses (APRNs) are key providers whose care is linked directly to the availability, cost, and quality of healthcare services. ANA asks you to meet today's shortage with a relatively modest investment of $313.075 million in fiscal year 2012 for the Health Resources and Services Administration Nursing Workforce Development programs and $20 million for Nurse-Managed Health Clinics. Thank you.

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## PREPARED STATEMENT OF THE AMERICAN PHYSICAL THERAPY ASSOCIATION

On behalf of more than 77,000 physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) thanks you for the opportunity to submit official testimony regarding recommendations for the fiscal year 2012 appropriations. APTA's mission is to improve the health and quality of life of individuals in society by advancing physical therapist practice, education, and research. Physical therapists across the country utilize a wide variety of federally funded resources to work collaboratively toward the ad-

vancement of these goals. APTA's recommendations for Federal funding, as outlined in this document, reflect a commitment toward these priorities for the good of society and the rehabilitation community.

*Department of Health and Human Services*

*National Institutes of Health (NIH)*

Rehabilitation research was funded at $458 million within NIH's approximately $31.2 billion budget in fiscal year 2010. This represents roughly 1 percent of NIH funds for an area of biomedical research that impacts a growing percentage of our Nation's seniors, persons with disabilities, young persons with chronic disease or traumatic injuries, and children with development disabilities. The Institute of Medicine (IOM) estimates that 1 in 7 individuals have an impairment or limitation that significantly limits their ability to perform activities of daily living. Investment in and recognition of rehabilitation within NIH is a necessary step toward continuing to meet the needs of these individuals in our population. Through the American Recovery and Reinvestment Act (ARRA), rehabilitation research was able to take advantage of an extra infusion of approximately $75 million in fiscal year 2009 and $93 million in fiscal year 2010. However, APTA believes that rehabilitation research at NIH has been under-funded for many years. The funds currently utilized are well-invested for the impact that rehabilitation interventions will have on the quality of lives of individuals. Continued investment and greater recognition and coordination of rehabilitation research among Institutes and across Federal departments will enhance the returns the Federal Government receives when investing in this area. Taking this into consideration, APTA recommends $31.829 billion (a $629 million increase over fiscal year 2010) for NIH in fiscal year 2012 to ensure that the momentum is maintained that was gained under the ARRA investment to improve health, spur economic growth and innovation, and advance science. APTA recognizes the extraordinary circumstances that exist during these tough budgetary times, however it still remains crucial that Federal investments in healthcare research are preserved and at least kept on pace with the rate of inflation.

Specifically, the physical therapy and rehabilitation science community recommends that Congress allocate crucial funding enhancements in the following institutes:

—$1.356 billion (a 2 percent increase over fiscal year 2010) for the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) which houses the National Center for Medical Rehabilitation Research (NCMRR), the only entity within NIH explicitly focused on the advancement of rehabilitation science. NCMRR fosters the development of scientific knowledge needed to enhance the health, productivity, independence, and quality-of-life of people with disabilities. A primary goal of the Center-supported research is to bring the health-related problems of people with disabilities to the attention of the best scientists in order to capitalize upon the myriad advances occurring in the biological, behavioral, and engineering sciences.

—$1.66 billion (a 2 percent increase over fiscal year 2010) for the National Institute of Neurological Disorders and Stroke (NINDS). This funding level is required to enhance existing initiatives and invest in new and promising research to prevent stroke and advance rehabilitation in stroke treatment. Despite being a major cause of disability and the number three cause of death in the United States, NIH invests only 1 percent of its budget in stroke research. However, APTA recognizes the advancements that NIH-funded research has achieved in the specific area of stroke rehabilitation. APTA commends this area of leadership at NIH and encourages a continued focus on rehabilitation interventions and physical therapy to maximize an individual's function and quality of life after a stroke.

—$550 million for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) for arthritis and musculoskeletal research.

*Centers for Disease Control and Prevention (CDC)*

APTA was disappointed to see the cuts that have been implemented within CDC for fiscal year 2011. The contributions of CDC to the lives of countless individuals are limited only by the resources available for carrying out its vital mission. Our Nation and the world will continue to benefit from further improvement in public health and investment in scientific advancement and prevention. APTA recommends Congress provide at least $7.7 billion for CDC's fiscal year 2012 "core programs" in the fiscal year 2012 Labor-HHS-Education Appropriations bill. This request reflects the support CDC will need to fulfill its core missions for fiscal year 2012. APTA strongly believes that the activities and programs supported by CDC are essential in protecting the health of the American people. APTA supports the Prevention and

Public Health Fund (PPHF) and its underlying purpose of providing supplemental funding as an investment to expand infrastructure for prevention initiatives. We are not supportive of efforts to use the PPHF to supplant current programmatic funding within the budgets of agencies, such as CDC.

Physical therapists play an integral role in the prevention, education, and assessment of the risk for falls. The CDC is currently only allocating $2 million per year to address the increasing prevalence of falls, a problem costing more than $19.2 billion a year. Among older adults, falls are the leading cause of injury deaths. This is why APTA respectfully requests that $21.7 million be provided in funding for the "Unintentional Injury Prevention" account to allow CDC's National Center for Injury Prevention and Control (NCIPC) to comprehensively address the large-scale growth of older adult falls. CDC has made great strides in developing and laying the groundwork for evidence-based falls prevention programs that link clinical intervention with community-based programs to make an impactful benefit for American society in addressing this expensive and burdensome healthcare problem. Without an increase in resources, CDC is unable to effectively scale-up and expand infrastructure beyond the few cities in which the programs have currently been developed to begin reaching all communities across the United States.

Traumatic Brain Injury (TBI) is a leading cause of death and disability among young Americans and continues to be the signature injury of the conflicts in Iraq and Afghanistan. CDC estimates that at least 5.3 million Americans, approximately 2 percent of the U.S. population, currently require lifelong assistance to perform activities of daily living as a result of TBI. High quality, evidence-based rehabilitation for TBI is typically a long and intensive process. From the battlefield to the football field, American adults and youth continue to sustain TBIs at an alarming rate and funding is desperately needed for better diagnostics and evaluation, treatment guidelines, improved quality of care, education and awareness, referral services, State program services, and protection and advocacy for those less able to advocate for themselves. APTA recommends at least $10 million in fiscal year 2012 for CDC's TBI Registries and Surveillance, Brain Injury Acute Care Guidelines, Prevention, and National Public Education/Awareness programs, specifically with the great work that has been produced through the "Heads Up" concussions initiative.

CDC's Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) programs screens uninsured and under-insured low-income women ages 40 to 64 for heart disease and stroke risk and those with abnormal results receive counseling, education, referral and follow up. WISEWOMAN reached over 70,000 women in only 20 States from July 2008 to June 2010. Of these women, nearly 90 percent were found to have one or more heart disease or stroke risk factors and about 30 percent had at least three. More than 60 percent of the women participated in a minimum of one behavioral modification session, and among those WISEWOMAN participants who were re-screened one year later, average blood pressure and cholesterol levels had decreased considerably. APTA recommends $37 million ($16.3 million increase over fiscal year 2010) for CDC's WISEWOMAN Program in fiscal year 2012.

*Health Resources and Services Administration (HRSA)*

With the passage of healthcare reform legislation, it becomes more important now than ever that America is able to supply an adequate and well-trained healthcare workforce to meet the demands of an expanded market of U.S. citizens that have health insurance coverage. APTA urges you to provide at least $7.65 billion for HRSA in fiscal year 2012. While we recognize the reality of the current fiscal climate, this amount reflects the minimum amount necessary for the agency to adequately meet the needs of the populations it serves. The relatively level funding HRSA has received over the past several years has undermined the ability of its successful programs to grow and be expanded to represent professions that shape the entire healthcare team, such as physical therapy. Any shortage areas of physical therapists and rehabilitation professionals may become more accentuated as the percentage of the U.S. population that has health coverage increases and demand rises. It is crucial that efforts are undertaken to strengthen the healthcare workforce and delivery across the whole spectrum of an individual's care—from onset through rehabilitation. More resources are needed for HRSA to achieve its ultimate mission of ensuring access to culturally competent, quality health services; eliminating health disparities; and rebuilding the public health and healthcare infrastructure.

In conjunction with the importance of funding TBI efforts within CDC, APTA also recommends $8 million for the HRSA Federal TBI State Grant Program and $4 million for the HRSA Federal TBI Protection & Advocacy (P&A) Systems Grant Program.

*Department of Education*

In 2008, as part of the reauthorization of the Higher Education Act (Public Law 110–315), the Loan Forgiveness for Service in Areas of National Need (LFSANN) program was created. This program would provide a modest amount of loan forgiveness for a variety of education and healthcare professional groups, including physical therapists, upon a commitment to serve in targeted populations that were identified as areas of crucial importance and national need. However, the program has not been implemented because it has not received any funding. APTA commends the recent efforts of Congress to reform the higher education loan industry. The lowering of the limit on the income-based repayment plan for consolidated Federal Direct Loans will assist the burdensome payments for all higher education loan borrowers. However, this program still fails to meet the most important impact of LFSANN—channeling providers and professionals into areas where there are demonstrated shortages and high need, such as physical therapy care for veterans and children and adolescents. APTA strongly urges Congress to take action and provide $10 million in initial funding for this vital LFSANN program that will impact the healthcare and education services of those most in need.

*National Institute for Disability and Rehabilitation Research (NIDRR)*

NIDRR has been one of the longest standing agencies to focus on federally funded medical rehabilitation research. Rehabilitation research makes a difference in the lives of individuals with impairments, functional limitations, and disability. Advancements in rehabilitation research have led to greater quality of life for individuals who have spinal cord injuries, loss of limb, stroke and other orthopedic, neurological, and cardiopulmonary disorders. Investment in NIDRR is a necessary step toward continuing to meet the needs of individuals in our population who have chronic disease, developmental disabilities or traumatic injuries. Therefore, APTA recommends at least $20 million per year for NIDRR to support research and development, capacity building, and knowledge translation in health, rehabilitation, and function.

APTA also requests $11 million for NIDRR's TBI Model Systems administered by the Department of Education. The TBI Model Systems of Care program represents an already existing vital national network of expertise and research in the field of TBI, and weakening this program would have resounding effects on both military and civilian populations. The TBI Model Systems are the only source of non-proprietary longitudinal data on what happens to people with brain injury. They are a key source of evidence-based medicine and rehabilitation care for this crucial and growing population.

*Conclusion*

As previously stated, APTA recognizes the extraordinarily tough budgetary pressures that are facing the U.S. Federal Government. However, there are certain programs and agencies that are essential and vital to the health of Americans. APTA looks forward to working with the Subcommittee and the various agencies outlined above to advance the capability of meeting the rehabilitation needs of society. If the Subcommittee has questions or needs additional resources, please contact Nate Thomas, Associate Director of Federal Government Affairs at APTA, at natethomas@apta.org or 703–706–8527. APTA's mailing address is provided on the letterhead of the first page of this document.

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## PREPARED STATEMENT OF THE AMERICAN PSYCHOLOGICAL ASSOCIATION

This statement is the testimony of the American Psychological Association (APA), the largest scientific and professional organization representing psychology in the United States and the world's largest association of psychologists. APA's membership includes more than 154,000 researchers, educators, clinicians, consultants and students. Through its divisions in 54 subfields of psychology and affiliations with 60 State, territorial and Canadian provincial associations, APA works to advance psychology as a science, as a profession and as a means of promoting health, education and human welfare. APA welcomes the opportunity to bring to your attention some priority requests and concerns for the fiscal year 2012 appropriations bill.

*Health Resources and Services Administration*

*Bureau of Health Professions*

The APA requests that the Subcommittee include $5 million for the Graduate Psychology Education Program (GPE) within the Health Resources and Services Administration. This nationally competitive grant program provides integrated healthcare

services to underserved rural and urban communities and individuals with the least access to much needed mental and behavioral health services and support (e.g., children, older adults, and chronically ill persons, victims of abuse or trauma, including veterans). To date there have been over 100 grants in 32 States to universities and hospitals throughout the Nation. All psychology graduate students who benefited from GPE funds are expected to work with underserved populations and over 80 percent will work in underserved areas immediately after completing the training.

Currently GPE is authorized under the Public Health Service Act [Public Law 105–392 Section 755(b)(1)(J)] and funded under the "Allied Health and Other Disciplines" account in the Labor-HHS Appropriations Bill. An authorization of Appropriations of $10 million was included in the Patient Protection and Affordable Care Act. It was also included in the fiscal year 2011 Omnibus bill, which did not pass, for $7 million; and it has been included in H.R. 1 for fiscal year 2011 and the Senate 2011 continuing resolutions, as well as the President's budget (for a number of years). Established in 2002, GPE grants have supported the interdisciplinary training of over 3,000 graduate students of psychology and other health professions to provide integrated healthcare services to underserved populations. The fiscal year 2012 GPE funding request will focus especially on providing services to returning military personnel and their families, unemployed persons and older adults in underserved communities. Also the GPE funding request will also be used to create training opportunities at our Nation's federally Qualified Health Centers, which play a critical role in meeting the healthcare needs of our Nation's underserved persons.

*National Institutes of Health (NIH)*

As a member of the Ad hoc Group for Medical Research Funding and the Coalition for Health Funding, APA encourages the Subcommittee to provide a minimum of $31.8 billion for the NIH. Sustained growth for NIH will build on the Nation's longstanding, bipartisan commitment to better health, which has established the United States as the world leader in medical research and innovation. NIH research means hope for patients. Potentially revolutionary new avenues of research hold promise for new early screenings and new treatments for disease. Recent funding has created dramatic new research opportunities in areas ranging from genetics to the behavioral research conducted by APA members. In addition, NIH research is boosting the economies of communities nationwide, at over 3,000 universities, medical schools, teaching hospitals and other research institutions. This committee should take justifiable pride in the progress and promise that NIH research is engendering.

There are several issues at NIH to which APA would draw the Subcommittee's attention:

—*Addictions Research Institute*.—NIH research on alcohol and substance abuse has shed important light on critical policy issues ranging from the rehabilitation of drug-addicted felons to treatment of children exposed to substances in utero. APA is closely monitoring NIH's proposal to create a new combined institute that would fund research on both alcohol and substance abuse. In our view this research is significantly underfunded when weighed against the public health and public safety impacts of alcohol, tobacco and illicit substance use, and we are concerned that research funding be maintained and increased as the new institute is created. We urge the Subcommittee to insist that NIH establish rigorous and transparent baselines of current funding levels and the allocation of those funds across the existing NIH Institutes and Centers to better assess and understand the proposed organizational change. The continued active involvement of extramural scientists at every stage of this process, as well as that of the Office of Behavioral and Social Sciences Research, will help ensure that the new institute has the right infrastructure to truly optimize the conduct of addiction research.

—*Funding for OppNet*.—For fiscal year 2012, APA supports a budget of $38.2 million for OBSSR. This sum reflects the Administration's request of $28 million for OBSSR and includes $10 million needed to support the NIH-wide commitment to carry out OppNet, an initiative strongly supported by the Subcommittee. The OppNet initiative has made significant progress since its start. Thus far, OppNet has awarded 35 competitive revisions to add basic science projects to existing research project grants. Eight competitive revisions to Small Business Innovation Research/Small Business Technology and Transfer projects have been awarded. OppNet has also provided much-needed training in basic social and behavioral sciences research.

—*National Center to Advance Translational Sciences*.—APA believes firmly that the proposed new National Center to Advance Translational Sciences should in-

clude sufficient staff expertise and resources to manage research on the translation of behavioral interventions into communities. Just as it is critical for NIH to speed the translation of research into drug or technology development, it is critical for behavioral interventions on diet, exercise, and psychotherapy to be translated and disseminated to communities in need of them.

*Centers for Disease Control and Prevention*

As a member of the Centers for Disease Control and Prevention (CDC) Coalition, APA supports an appropriation of $7.7 billion for CDC's "core programs" for fiscal year 2012. In addition to playing a key role in maintaining a strong public health infrastructure and protecting Americans from public health threats and emergencies, CDC programs play a crucial role in reducing healthcare costs and strengthening the Nation's health system. This request reflects the minimum amount CDC will need to fulfill its core missions for fiscal year 2012.

*National Center for Health Statistics*.—APA endorses the President's fiscal year 2012 request of $162 million in funding for NCHS. NCHS is the Nation's principal health statistics agency, and the health data collected by NCHS are an essential part of the Nation's statistical and public health infrastructure. The Subcommittee's support is helping NCHS rebuild after years of underinvestment and restore the collection of essential health data. With your continued support, NCHS will modernize its data collection efforts to produce higher quality, more timely data.

*Prevention Research Centers*.—APA recognizes the importance of a focus on prevention in improving health in America and the significant contributions of the Prevention Research Centers network of community, academic, and public health partners to research on evidenced based approaches in health promotion. APA urges Congress to allocate the resources necessary to support the Prevention Research Centers so that this network of academic institutions and organizations can continue to contribute as widely and effectively to prevention science. APA opposes any program consolidation that would lead to disproportionate funding cuts for the Prevention Research Centers. Insofar as consolidation of programs as proposed in the fiscal year 2012 President's budget occurs, APA requests that Congress designate specific funding for Prevention Research Centers.

*Substance Abuse and Mental Health Services Administration (SAMHSA)*

APA is highlighting three requests for the Committee's support at SAMHSA's Center for Mental Health Services:

—First, APA strongly recommends that Congress allocate the fully authorized amount ($50 million) for SAMHSA's National Child Traumatic Stress Network (NCTSN) program which works to aid the recovery of children, families, and communities impacted by a wide range of trauma, including physical and sexual abuse, natural disasters, sudden death of a loved one, the impact of war on military families, and much more. Specifically, APA recommends that SAMHSA increase the number of NCTSN grantees and maintain the collaborative model envisioned in the original authorization.

—Second, APA urges the Committee to increase its support for the Minority Fellowship Program. Racial and ethnic minorities are projected to represent 40 percent of our Nation's population in upcoming years. Therefore, APA urges Congress to increase funding for the Minority Fellowship Program by $2.6 million. This unique workforce development initiative trains ethnic minority healthcare professionals to bring mental and behavioral healthcare services to rural and underserved minority communities.

—Third, APA encourages Congress to provide at least level support for the three programs authorized under the Garrett Lee Smith Memorial Act, especially the Campus Suicide Prevention Program. These programs make suicide prevention initiatives and mental health support available to populations in need and merit continued appropriations.

*Administration on Aging*

*Mental health*.—Older adults are one of the fastest growing segments of the U.S. population and approximately 25 percent of older Americans have a mental or behavioral health problem. In particular, older white males (age 85 and over) currently have the highest rates of suicide of any group in the United States. Accordingly, APA urges an expanded effort to address the mental and behavioral health needs of older adults including implementation of the mental and behavioral health provisions in the Older Americans Act Amendments of 2006, to provide grants to States for the delivery of mental health screening, and treatment services for older individuals and programs to increase public awareness and reduce the stigma associated with mental disorders in older individuals. APA also recommends that AoA designate an officer to administer mental health services for older Americans.

*Caregivers*.—Family caregivers play an essential role in providing long-term services and supports for the chronically ill and aging. For this reason APA supports the Lifespan Respite Care Program and urges Congress to appropriate $50 million for this initiative in fiscal year 2012. In addition, the Secretary of HHS should ensure that State agencies and Aging and Disability Resource Centers (ADRCs) use the funds to serve all age groups, chronic conditions and disability categories equitably and without preference.

The agencies under this Subcommittee's jurisdiction provide critical support to APA's members, their home institutions, and their students and patients. The APA commends the Committee for accepting written testimony from public witnesses.

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PREPARED STATEMENT OF THE AMERICAN PUBLIC HEALTH ASSOCIATION

The American Public Health Association (APHA) is the oldest and most diverse organization of public health professionals and advocates in the world dedicated to promoting and protecting the health of the public and our communities. We are pleased to submit our views on Federal funding for public health activities in fiscal year 2012.

*Recommendations for Funding the Public Health Service*

APHA's budget recommendations for the Public Health Service includes funding for the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Agency for Healthcare Research and Quality (AHRQ), and the National Institutes of Health (NIH). Together all of these agencies play a critical role in keeping Americans healthy.

*CDC*

APHA believes that Congress should support CDC as an agency—not just the individual programs that it funds. In the best judgment of the CDC Coalition—given the challenges and burdens of chronic disease, a potential influenza pandemic, terrorism, disaster preparedness, new and reemerging infectious diseases and our many unmet public health needs and missed prevention opportunities—we believe the agency will require funding of at least $7.7 billion for CDC's "core programs" in fiscal year 2012. This request represents a 36 percent increase over fiscal year 2011 and a 31 percent increase over the President's fiscal year 2012 request. We are deeply disappointed with the more than $740 million in cuts to CDC's budget authority included in the proposed fiscal year 2011 continuing resolution (CR). While CDC programs will receive significant new funding from the Prevention and Public Health Fund in fiscal year 2011, we are concerned that this funding would essentially supplant cuts made to CDC's budget authority. As you know the Prevention and Public Health Fund was intended to supplement and not supplant the base funding of our public health agencies and programs.

The President's fiscal year 2012 budget proposes to consolidate a number of chronic disease programs within CDC. APHA and other advocates are currently engaged in conversations with CDC and members of Congress to better understand what this consolidation will mean for the funding that is passed on to our State and local health agencies and the various programs our members have supported in the past. We look forward to working with Congress, the Administration and CDC to ensure that any effort to consolidate the programs leads to best health outcomes for the American people. We must ensure that CDC's National Center for Chronic Disease Prevention and Health Promotion has the resources it needs to assist our States and communities in their efforts to reduce the burden of chronic disease.

By translating research findings into effective intervention efforts, CDC has been a key source of funding for many of our State and local programs that aim to improve the health of communities. Perhaps more importantly, Federal funding through CDC provides the foundation for our State and local public health departments, supporting a trained workforce, laboratory capacity and public health education communications systems.

CDC also serves as the command center for our Nation's public health defense system against emerging and reemerging infectious diseases. With the potential onset of a worldwide influenza pandemic, in addition to the many other natural and man-made threats that exist in the modern world, the CDC has become the Nation's—and the world's—expert resource and response center, coordinating communications and action and serving as the laboratory reference center. States and communities rely on CDC for accurate information and direction in a crisis or outbreak. This has been demonstrated most recently by CDC's quick response and ongoing in-

vestigation into human infections with H1N1 flu (swine flu) in the United States and internationally.

CDC's National Center for Injury Prevention and Control works to prevent unintentional and violence-related injuries to minimize the consequences of injuries when they occur by researching the problem; identifying the risk and protective factors; developing and testing interventions; and ensuring widespread adoption of proven strategies. We urge you to ensure the agency has the resources it needs to address these leading causes of death and disability.

We must address the growing disparity in the health of racial and ethnic minorities. CDC is helping States address serious disparities in infant mortality, breast and cervical cancer, cardiovascular disease, diabetes, HIV/AIDS and immunizations. APHA is committed to ending health disparities and we encourage the Subcommittee to provide adequate funds for these efforts.

We also encourage the Subcommittee to provide adequate funding for CDC's National Center for Environmental Health. We ask that the Subcommittee to continue its recent efforts to expand and enhance CDC's capacity to help the Nation prepare for and adapt to the potential health effects of climate change by providing CDC with $15 million for climate change and health activities. Expanded funding would allow CDC to provide technical assistance, training and tools to help State and local health officials and improve coordination and integration of climate change across CDC. We also urge the Committee to closely evaluate the significant cut made to CDC's Healthy Homes/Lead Poisoning Prevention and the National Asthma Control programs in the President's budget to ensure these programs have adequate funding to provide States and localities with the funding they need to protect public health.

*HRSA*

We request an overall funding level of $7.65 billion for HRSA in fiscal year 2012. This recommendation represents a 22 percent increase over fiscal year 2011 and a 12 percent increase over the President's fiscal year 2012 request. We believe this level of funding is the minimum amount necessary for HRSA to continue to meet the healthcare needs of the American public. Over the past several years, HRSA has received mostly level funding, undermining the ability of its successful programs to grow. Additionally we are deeply disappointed with the more than $1.2 billion in cuts made to the agency in the final fiscal year 2011 continuing resolution and the potential negative consequences for public health. Our fiscal year 2012 requested minimum level of funding will better allow the agency to carry out critical public health programs and services that reach millions of Americans, including training for public health and healthcare professionals, providing primary care services through community health centers, improving access to care for rural communities, supporting maternal and child healthcare programs, providing healthcare to people living with HIV/AIDS, and many more. However, much more is needed for the agency to achieve its ultimate mission of ensuring access to culturally competent, quality health services; eliminating health disparities; and rebuilding the public health and healthcare infrastructure.

HRSA operates programs in every State and thousands of communities across the country and is a national leader in providing health services for individuals and families. The agency serves as a health safety net for the medically underserved, including the 50 million Americans who were uninsured in 2009 and 50 million Americans who live in neighborhoods where primary healthcare services are scarce.

The $7.65 billion fiscal year 2012 HRSA funding request is based upon recommendations provided by public health professionals to support HRSA programs including:

—Health Professions programs support the education and training of primary care physicians, nurses, dentists, optometrists, physician assistants, nurse practitioners, public health personnel, mental and behavioral health professionals, pharmacists, and other allied health providers; improve the distribution and diversity of health professionals in medically underserved communities; and ensure a sufficient and capable health workforce able to provide care for all Americans and respond to the growing demands of our aging and increasingly diverse population. In addition, the Patient Navigator Program helps individuals in underserved communities, who suffer disproportionately from chronic diseases, navigate the health system.

—Primary Care programs support more than 7,000 community health centers in every State and territory, improving access to preventive and primary care in geographically isolated and economically distressed communities. In addition, the health centers program targets populations with special needs, including migrant and seasonal farm workers, homeless individuals and families, and those living in public housing.

—Maternal and Child Health Flexible Maternal and Child Health Block Grants, Healthy Start and other programs provide services, including prenatal and postnatal care, newborn screening tests, immunizations, school-based health services, mental health services, and well-child care for more than 34 million uninsured and underserved women and children not covered by Medicaid or the Children's Health Insurance Program, including children with special needs.
—HIV/AIDS programs provide assistance to metropolitan and other areas most severely affected by the HIV/AIDS epidemic; support comprehensive care, drug assistance and support services for people living with HIV/AIDS; provide education and training for health professionals treating people with HIV/AIDS; and address the disproportionate impact of HIV/AIDS on women and minorities.
—Family Planning Title X programs provide reproductive healthcare and other preventive services for more than 5 million low-income women at over 4,500 clinics nationwide. These programs improve maternal and child health outcomes, prevent unintended pregnancies, and reduce the rate of abortions.
—Rural Health programs improve access to care for the 60 million Americans who live in rural areas. Rural Health Outreach and Network Development Grants, Rural Health Research Centers, Rural and Community Access to Emergency Devices Program, and other programs are designed to support community-based disease prevention and health promotion projects, help rural hospitals and clinics implement new technologies and strategies, and build health system capacity in rural and frontier areas.
—Special Programs include the Organ Procurement and Transplantation Network, the National Marrow Donor Program the C.W. Bill Young Cell Transplantation Program, and National Cord Blood Inventory. Strong funding would facilitate an increase in organ, marrow and cord blood transplantation.

Greater investment is necessary to sufficiently fund HRSA services and programs that continue to face increasing demands. We urge you to consider HRSA's role in building the foundation for health service delivery and ensuring that vulnerable populations receive quality health services, while continuing to strengthen our Nation's health safety net programs. By supporting, planning for and adapting to change within our healthcare system, we can build on the successes of the past and address new gaps that may emerge in the future.

*AHRQ*

We request a funding level of at least $405 million for AHRQ for fiscal year 2012. This level of funding is needed for the agency to fully carry out its Congressional mandate to conduct, support, and disseminate research and translate research into knowledge and information that can be used to improve the health of all Americans. AHRQ focuses on improving healthcare quality, eliminating racial and ethnic disparities in health, reducing medical errors, and improving access and quality of care for children and persons with disabilities.

*SAMHSA*

APHA supports a funding level of $3.671 billion for SAMHSA for fiscal year 2012. This funding level would provide support for substance abuse prevention and treatment programs, as well as continued efforts to address emerging substance abuse problems in adolescents, the nexus of substance abuse and mental health, and other serious threats to the mental health of Americans.

*NIH*

APHA supports a funding level of $35 billion for the NIH for fiscal year 2012. The translation of fundamental research conducted at NIH provides some of the basis for community based public health programs that help to prevent and treat disease.

*Conclusion*

In closing, we emphasize that the public health system requires stronger financial investments at every stage. Successes in biomedical research must be translated into tangible prevention opportunities, screening programs, lifestyle and behavior changes, and other interventions that are effective and available for everyone. Without a robust and sustained investment in our Nation's public health agencies, we will fail to meet the mounting health challenges facing our Nation.

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## PREPARED STATEMENT OF THE AMERICAN PUBLIC POWER ASSOCIATION

The American Public Power Association (APPA) appreciates the opportunity to submit this statement supporting funding for the Low-Income Home Energy Production Assistance Program (LIHEAP) for fiscal year 2012.

APPA has consistently supported an increase in the authorization level for LIHEAP. The Administration's fiscal year 2012 budget requests $2.57 billion for LIHEAP. APPA supports extending the current level of $5.1 billion for the program.

APPA is the national service organization representing the interests of over 2,000 municipal and other State and locally owned utilities throughout the United States (all but Hawaii). Collectively, public power utilities deliver electricity to 1 of every 7 electricity consumers (approximately 46 million people), serving some of the Nation's largest cities. However, the vast majority of APPA's members serve communities with populations of 10,000 people or less.

APPA is proud of the commitment that its members have made to their low-income customers. Many public power systems have low-income energy assistance programs based on community resources and needs. Our members realize the importance of having in place a well-designed low-income customer assistance program combined with energy efficiency and weatherization programs in order to help consumers minimize their energy bills and lower their requirements for assistance. While highly successful, these local initiatives must be coupled with a strong LIHEAP program to meet the growing needs of low-income customers. In the last several years, volatile home-heating oil and natural gas prices, severe winters, high utility bills as a result of dysfunctional wholesale electricity markets and the effects of the economic downturn have all contributed to an increased reliance on LIHEAP funds. Even at $5.1 billion, LIHEAP cannot provide assistance to all who qualify for the program. Cutting this program by $2.5 billion would have very serious consequences for those who rely on the program.

Also when considering LIHEAP appropriations this year, we encourage the subcommittee to provide advanced funding for the program so that shortfalls do not occur in the winter months during the transition from one fiscal year to another. LIHEAP is one of the outstanding examples of a State-operated program with minimal requirements imposed by the Federal Government. Advanced funding for LIHEAP is critical to enabling States to optimally administer the program.

Thank you again for this opportunity to relay our support for increased LIHEAP funding for fiscal year 2012.

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## PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) is pleased to submit the following testimony on the fiscal year 2012 appropriation for the Centers for Disease Control and Prevention (CDC). The ASM is the largest single life science organization in the world with over 38,000 members. The ASM mission is to enhance the science of microbiology, to gain a better understanding of life processes and to promote the application of this knowledge for improved health and environmental well being.

The ASM supports the proposed fiscal year 2012 budget of $11.3 billion for the CDC, a 3.4 percent increase over the fiscal year 2010 funding level. The budget recognizes the importance of maintaining a strong infrastructure to address infectious disease prevention and control. The CDC's role, in partnership with State and local health departments and international partners, is to monitor for known and emerging infectious disease threats through surveillance and laboratory diagnosis, and to develop control and prevention strategies for these diseases. Examples include vaccine preventable diseases, foodborne diseases, pandemic influenza, vectorborne and zoonotic diseases, healthcare acquired infections (HAIs) and antimicrobial resistance. The proposed fiscal year 2012 budget addresses these threats and provides targeted resources for them.

The fiscal year 2012 proposed budget includes an increase in funding for HIV/AIDS, sexually transmitted diseases (STD), tuberculosis (TB), and hepatitis, and gives the States added flexibility to shift funding among these programs based on local priorities. The ASM supports this approach. The ASM also supports the $68 million increase in funding for emerging and zoonotic diseases, including $40 million in funding from the Prevention and Public Health Fund to enhance epidemiology and laboratory capacity in State health departments.

However, caution must be taken regarding any reductions in effort for "low impact, disease specific programs" as proposed in the fiscal year 2012 budget. Experience indicates that an emerging public health threat can occur with almost any pathogen, and capacity must be sustained with this possibility in mind. Examples of such complacency include the reemergence of drug resistant tuberculosis in the 1990s and West Nile virus in 1999. The proposed elimination of prion activities at CDC could have such an impact, as these diseases are related to human variant Creutzfeld Jakob Disease (vCJD) and to chronic wasting disease, which is an emerging animal health problem in several areas of the United States.

The ASM supports investments to address healthcare associated infections. CDC provided resources through the American Recovery and Reinvestment Act (ARRA) to develop programs for surveillance and prevention of HAIs, which have resulted in substantial HAI reductions in these infections with significant cost savings to the healthcare system. These investments must be sustained after ARRA funding ends, and the proposed $47 million for HAIs would accomplish this goal.

The ASM supports the $8.7 million increase in funding for food safety. The CDC recently released new estimates of foodborne diseases, concluding that 1 in 6 people in the United States get sick each year (about 48 million people). The delayed recognition of the widespread outbreaks of salmonellosis associated with eggs during 2010 demonstrates the need to sustain and enhance vigilance for foodborne outbreaks. In that outbreak, over 1,900 confirmed illnesses were reported (likely a small percentage of actual cases) and 500 million eggs were recalled. CDC's surveillance systems will also play a pivotal role in assessing the success of programs developed as a result of the recently passed Food Safety Modernization Act.

The ASM is concerned about the following proposed reductions in the fiscal year 2012 CDC budget:

—There is a substantial decline in preparedness funding, including a $72 million cut in funds for State and local preparedness grants. Such declines will have a significant impact on the ability of frontline public health workers to be able to respond to all hazard emergencies at a time of restrained budgets at the State and local level. The ASM recommends such grants be maintained at fiscal year 2010 funding levels.

—The proposed elimination of funding for the CDC genomics program should be restored. Public health genomics is an area of growing importance, including the ability to identify risk factors for enhanced susceptibility or resistance to infectious diseases. Such genetic factors have important implications for disease prevention and treatment, and must be tied to epidemiologic investigations and disease surveillance efforts.

—The ASM does not endorse the elimination of targeted funding for CDC's antimicrobial resistance (AR) activities and the transfer of these funds into the overall budget for emerging infections. While ASM appreciates the need for funding flexibility, antimicrobial resistance is a substantial public health problem that leads to significant morbidity and death and markedly increases healthcare costs. To address this threat, sustained dedicated funding is necessary.

*CDC Infectious Disease Programs Protect Public Health*

Infectious diseases cause about one-fourth of all deaths globally, more than 11 million people, over half of them children. In the United States, influenza and pneumonia account for more than 56,000 deaths each year. Of the 1.1 million people living in the United States living with HIV/AIDS, about 21 percent do not know that they are HIV positive; there are more than 56,000 new HIV infections annually. Last year, the CDC responded to multiple disease outbreaks and incidents that included surveillance of cholera in post earthquake Haiti and activation of CDC's Emergency Operations Center as part of the Federal response to the gulf oil spill.

In the United States, the economic and societal costs of infectious diseases are significant, exacerbated by previously unknown microbial pathogens, rising drug resistance among pathogens and increasing travel and commerce between geographic areas. The CDC Office of Infectious Diseases leads United States efforts to stop or minimize the onslaught of infectious diseases, with highly qualified personnel at three national centers that specialize in (1) Emerging and Zoonotic Infectious Diseases; (2) HIV/AIDS, Viral Hepatitis, STD, and TB Prevention; or (3) Immunization and Respiratory Diseases.

The ASM endorses the proposed fiscal year 2012 budget for key programs at CDC, including the following:

*Emerging Infectious Diseases/Antimicrobial Resistance*.—CDC is a world leader in detecting and preventing emerging and reemerging infectious diseases, a role which depends on strong science capabilities and readiness to confront the unexpected. CDC's infrastructure and partnerships have dealt quickly with the more than three dozen new human pathogens of medical significance identified in the past 30 years. Recent CDC advances include developing one of the first candidate vaccines against all four species of dengue virus, now in human trials, and a plan to screen U.S. blood donations for West Nile virus. fiscal year 2012 funding will support planned EID activities like the development and deployment of improved diagnostic tests for plague, dengue and chikungunya. About 75 percent of recently emerging human infectious diseases originated in animals, making zoonotic diseases another high priority at CDC, along with vectorborne diseases spread by mosquitoes, ticks, fleas and

other vectors. Two reports last year illustrate the critical nature of CDC's EID activities: In Florida, an estimated 5 percent of Key West's population showed recent exposure to the dengue fever virus; and the new antimicrobial resistance gene called New Delhi metallo β lactamase (NDM–1), first detected in 2008, is spreading to additional countries.

Increased fiscal year 2012 funding will support CDC efforts against the alarming (and rising) number of pathogens now resistant to antimicrobial drugs. As part of the U.S. Interagency Task Force on Antimicrobial Resistance, CDC distributes both intramural and extramural AR funding for surveillance, prevention, and research activities. Agency surveillance networks routinely collect data on cases of resistant pathogens. CDC provides epidemiology and laboratory support for outbreaks of AR organisms, and distributes educational materials to promote appropriate use of antimicrobials. Investments in AR programs are cost effective; one study estimated that the additional medical cost per U.S. patient infected with an AR pathogen ranges from about $19,000 to nearly $30,000. Another estimate concluded that preventing a single case of multidrug resistant (MDR) tuberculosis can save up to $700,000. In fiscal year 2010, CDC diagnosed and treated about 1,000 cases of tuberculosis (including 40 MDR) among overseas immigrant applicants and U.S. bound refugees, saving States an estimated $45 million.

*HIV/AIDS*.—Scientific advances announced last year have added new tools to CDC's numerous HIV prevention activities; using a vaginal microbicide or daily doses of an oral antiretroviral drug (PrEP) both lowered risk of infection in clinical trials. In July 2010, the Administration released its National HIV/AIDS Strategy for the United States (NHAS). Proposed fiscal year 2012 budget increases would invest substantially in the NHAS 5 year goals to reduce new infections: (1) lower the annual number of new infections by 25 percent, from 56,300 to 42,225; (2) reduce the HIV transmission rate by 30 percent, from 5 persons infected per 100 people with HIV to 3.5 persons infected; and (3) increase from 79 to 90 the percentage of people living with HIV who know their serostatus.

*Viral Hepatitis*.—Proposed fiscal year 2012 increases for viral hepatitis prevention would boost CDC surveillance in 10 high burden State and local health departments. Prevention of viral hepatitis has been successful in recent years, in large part due to vaccines against hepatitis A and B viruses. HAV incidence has decreased approximately 92 percent nationwide since 1995; rates of HBV have been reduced far below the original Healthy People 2010 goal of 4.5 cases per 100,000. In the first half of fiscal year 2010, CDC funded health departments administered over 130,000 doses of HBV vaccine to at risk adults and ensured that 87 percent of infants born to HBsAg+ women were vaccinated. Incidence of hepatitis C infections has dropped from more than 45,000 cases annually to an estimated 20,000, primarily as a result of screening the U.S. blood supply and falling case numbers among intravenous drug users. However, 2.7–3.9 million Americans have HCV, most unaware of their infection. The fiscal year 2012 budget would address last year's Institute of Medicine report, which concluded that public health programs have insufficient hepatitis related resources and that efforts to prevent and control viral hepatitis are not adequate.

*Sexually Transmitted Diseases*.—Fiscal year 2012 increases would strengthen CDC's STD infrastructure, which supports 65 State and local prevention programs, and sustain the CDC's surveillance of drug resistant STD pathogens like that causing gonorrhea. Reducing STD infections is highly cost effective; for example, CDC estimates that reductions in gonorrhea and syphilis from 1990 to 2003 saved the U.S. economy $5 billion. Cost savings with chlamydia screening in sexually active young women are an estimated $2,500–$37,000 per year. Aggressive public health efforts to prevent STDs have had positive results; for instance, from 1999 to 2009, rates of primary and secondary syphilis among females declined by 30 percent, while congenital syphilis dropped 32 percent. Yet, in general, STDs in the United States persist at unacceptable levels: CDC estimates that there are approximately 19 million new STD infections each year, which cost the U.S. healthcare system $16.4 billion annually (2009 figures).

*CDC Campaigns Prevent Disease in the United States, Worldwide*

*Healthcare Associated Infections*.—In the United States, 1 in 20 hospital patients get an infection during medical treatment. Of the nearly 2 million infections acquired in some type of healthcare setting annually, almost 100,000 are fatal. A 2009 CDC report estimates that each year U.S. hospitals spend between $28 billion and $35.7 billion to treat often preventable HAIs. Depending on the effectiveness of infection control interventions used, the CDC expects that prevention measures could save from $5.7 billion–$31.5 billion of these costs. To illustrate, intensive care units have reduced bloodstream infections in patients with central lines by 58 percent

since 2001, using CDC recommended infection control procedures and saving up to 27,000 lives and $1.8 billion. The proposed fiscal year 2012 budget would significantly increase support for the CDC's HAI activities and its National Health Care Safety Network (NHSN) that had provided monitoring capacity to more than 3,900 health facilities by the end of 2010. With the increased funding, routine NHSN participation will expand from 2,500 to 6,500 healthcare settings (5,500 hospitals; the rest include hemodialysis and long-term care facilities). In March this year, the CDC awarded $10 million for HAI research at five academic medical centers, as part of its Prevention Epicenter program.

*Immunization*.—The Administration's fiscal year 2012 CDC budget invests substantial resources into vaccine preventable diseases, continuing national immunization campaigns against diseases like seasonal and pandemic influenza. The number of lives saved and medical costs reduced can be considerable. According to the CDC, "for every birth cohort who receives seven [routine childhood] vaccines . . . society saves $9.9 billion in direct medical costs; over 33,500 lives are saved; and 14 million cases of disease are prevented." Other examples of returns on CDC investment include vaccination against Haemophilus influenzae type b (Hib), responsible for a 99 percent decline in this leading cause of bacterial meningitis in children under age 5, for an estimated medical cost savings of $950 million per year plus another $1.14 billion of retained earnings by unpaid caregivers. In the past year, CDC reported that 3 years of rotavirus vaccinations had reduced severe rotavirus disease by 85 percent, and helped develop the guidelines for deploying the new pneumococcal vaccine expected to greatly reduce pneumonia and ear infections among children. In December, CDC launched its Vaccine Tracking System to follow vaccine orders from manufacturer to distributor to health providers.

*Global Health*.—Lower respiratory tract infections, diarrheal diseases, HIV/AIDS, TB and malaria together account for nearly one-fifth of deaths globally. CDC is a lead partner in the Administration's Global Health Initiative, underscoring the importance of infectious diseases no matter where outbreaks occur. The fiscal year 2012 budget includes increase of funds for global polio eradication, an international campaign begun in 1988 that is nearing victory with only four countries still harboring endemic disease. Last year, there were about 900 cases reported, declining from more than 350,000 in 1988. fiscal year 2012 funds will purchase 254 million doses of oral polio vaccine for use in mass immunization campaigns in Southeast Asia, Africa and Europe, to achieve CDC's target of zero polio endemic countries by the end of 2012. Funding will support the CDC vaccination campaign toward a 90 percent reduction in global measles related mortality; by 2008, CDC and its partners had helped reduce measles deaths by 78 percent, from an estimated 733,000 in 2000 to about 164,000.

Quarantine and migration related activities also are part of the agency's multi level strategies in global health; CDC operates 20 U.S. quarantine stations and responds to outbreaks in refugee camps overseas. Travel and trade allow pathogens to move quickly. The 2009 "swine flu" spread to 30 countries within 6 weeks. About 1.8 million airline passengers cross international borders daily, and about half of international travelers worldwide have some kind of health problem while traveling. An estimated 50,000–70,000 refugees and 1.2 million immigrants resettle in the United States each year, while more than 2 million people travel to or through this country by air, sea, or land daily.

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### PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) wishes to submit the following written testimony on the fiscal year 2012 appropriation for the National Institutes of Health (NIH). The ASM is the largest single life science organization with over 38,000 members. Its mission is to enhance the science of microbiology, to gain a better understanding of life processes and to promote the application of this knowledge for improved health and environmental well being.

The ASM urges Congress to support strong Federal funding for biomedical research and to provide $35 billion in funding for the NIH in fiscal year 2012. Continued investments in science and public health programs are critical to the Nation's health, economic growth, national security and global leadership. Acquiring knowledge at the frontiers of science is the basis for new technologies, medical discoveries, new industries and high value jobs. Investments in biomedical research lead to more effective treatments, preventions and cures for chronic and infectious diseases, improving the quality of life for people everywhere. Reducing funding for research project grants will slow medical progress on a myriad of diseases, adversely affecting human life. Attracting and retaining scientists and maintaining the vitality of

the research enterprise will become more difficult if the Nation does not remain committed to sustained and predictable funding for research and training. We, therefore, urge Congress to make increased appropriations for biomedical research a national priority as the Federal budget is considered for the coming fiscal year.

NATIONAL INSTITUTES OF HEALTH: A CRUCIAL INVESTMENT FOR THE FUTURE

The NIH is a primary contributor to growing the Nation's economy and ensuring U.S. leadership in science. The NIH expends 97 percent of its annual budget on R&D activities through its 27 centers and institutes. NIH funding helps foster innovation among more than 300,000 research personnel at over 3,000 universities and research institutions, with about 6,000 scientists working in NIH's own laboratories.

Life saving successes in biomedical research depend on NIH support: for example, the development last year of a new 2 hour diagnostic test for tuberculosis and drug resistant TB bacteria; a potential drug against malaria parasites, evidence that an anti-HIV treatment could also prevent infection, research suggesting a role for intestinal bacteria in obesity, and the 2010 Nobel Prize winning methods to synthesize compounds that have already proven effective against HIV and herpes virus. NIH funded research improves the health of our communities, represents investment in local and national economic growth and advances U.S. science and medicine.

*Investing in Scientific Innovation, Advancing Medical Knowledge*

NIH funded research has repeatedly reshaped medicine and continues to enhance public health. NIH routinely identifies new research initiatives and pursues transformative research. NIH recently delineated five priority areas with particular promise for safeguarding our future, including:

—*High throughput technologies*.—DNA sequencing, nanotechnology and other computer supported technologies can generate massive data sets that enable comprehensive approaches to disease, like the NIH microbiome project to understand how interactions with the microbes that live on and in the human body influence health and disease.

—*Translational medicine*.—NIH programs will increasingly focus on translating basic scientific discoveries into new clinical diagnostics and treatments (bench to bedside).

—*Informing healthcare reform*.—With U.S. expenditures on healthcare approaching 20 percent of our gross domestic product, NIH research areas like personalized medicine and pharmacogenomics seek cost effective solutions through disease treatment and prevention tailored to individual patients.

—*Global health*.—In addition to NIH's ongoing efforts against AIDS, tuberculosis and malaria, more resources will go toward combating neglected tropical diseases that devastate low income countries.

—*Reinvigorating the biomedical research community*.—NIH is reevaluating the Nation's future scientific workforce needs in terms of its own training programs, as well as optimizing NIH's extramural research investments to more effectively discover innovative medical solutions.

THE IMPORTANCE OF INVESTIGATOR INITIATED RESEARCH

The majority of NIH funds are distributed across the country to extramural researchers through grants, contracts and fellowships. Investigator initiated, competitively awarded Research Project Grants (RPGs) are the single most effective mechanism for ensuring research innovation. Early in the decade, an average of 1 out of 3 grant applications were funded. In recent years, the success rate has fallen to roughly 1 in 5, with only a 15 percent success rate estimated for fiscal year 2011, despite an abundance of research opportunities.

Scientific advances require investigator inspiration and persistence often over years of research. For example, a large share of the research awarded the 2010 Nobel Prize in Chemistry occurred in a laboratory supported since 1979 by the National Institute of General Medical Sciences (NIGMS). Success developing the DNA based TB rapid diagnostic test announced last year followed more than 8 years of National Institute of Allergy and Infectious Diseases (NIAID) support. NIH funding also enables transformative research that has a higher degree of risk for failure, but potential for huge scientific rewards, like recipients of the relatively new EUREKA program (Exceptional, Unconventional Research Enabling Knowledge Acceleration) managed by NIGMS. Among this year's new NIGMS grants are projects designed to decipher the genetic code in yeast and to use bacterial components to induce patient specific stem cells that facilitate gene therapy.

At NIH, long range strategies for research success include workforce development and mentoring young researchers. NIAID, for example, met its own target of sup-

porting "new investigators" in fiscal year 2009 by funding about 20 percent of those who applied for R01 grants as first time principal investigator. NIGMS, which distributes 70 percent of its budget to research project grants, contributes an additional 10 percent to underwrite institutional training grants and fellowships that specifically fulfill its mission to train the next generation of medical scientists. In addition, NIGMS funds approximately 50 percent of Ph.D. research training positions at NIH, including the Medical Scientist Training (M.D.-Ph.D.) program. Additional NIH grant programs focus on K–12 education in science, technology, engineering and mathematics (STEM), to foster a future technical workforce.

The NIH regularly identifies research intended to ultimately produce public health benefits. In fiscal year 2009, NIAID released 33 new funding opportunity announcements that are already producing results in selected areas, including innovative approaches to vaccine development against HIV, malaria and hepatitis C, and clinical trials specifically designed to counter the threat of antimicrobial resistance among pathogens. Research concepts reviewed periodically by NIAID advisory councils may anticipate potential research initiatives for upcoming funding cycles. For example, concepts approved in September 2010 included research to prevent the spread of drug resistant pathogens; support for Functional Genomics Research Centers that will generate massive genetic data sets readily available to the broad scientific community; improved diagnostics for Lyme disease; and a "pluripotent approach" for sexual and reproductive health that might combine contraceptive methods with microbicides, vaccine or other disease preventives.

*NIH Research to Address Threats of Infectious Diseases and Antimicrobial Resistance*

Infectious diseases cause approximately 26 percent of all deaths worldwide, more than 11 million people annually. Each year infectious diseases kill approximately 6.5 million children, most in developing countries. These preventable diseases also greatly impact public health systems in the United States. For example, influenza and pneumonia account for more than 56,000 deaths annually, while each year there are more than a million new cases of sexually transmitted diseases. Despite ground breaking triumphs against infectious diseases over decades of research, both predictable and unexpected infectious agents continue to challenge medical science. In recent years of flat funding, NIAID has had to respond to additional public health threats like bioterrorism and unforeseen infectious diseases, by steadily expanding its research portfolio and its capabilities to recognize and quickly counter newly emerging and reemerging diseases in the United States and elsewhere. The scope and significance of NIAID sponsored research cannot be overstated.

The emergence of drug resistant microbial pathogens seriously complicates efforts to stop or minimize infectious diseases. The magnitude of the problem elevates the public health significance of antimicrobial resistance. Examples of clinically important microbes that are rapidly developing resistance to available drugs include bacteria that cause pneumonia, ear infections and meningitis, skin, bone, lung and bloodstream infections, urinary tract infections, foodborne infections and infections in healthcare settings. In recent years there have been dramatic examples like chloroquine resistant malaria, methicillin resistant Staphylococcus aureus (MRSA) infection and multidrug resistant and extensively drug resistant tuberculosis. Ten percent of all hospitalized patients in this country have or develop resistant infections, adding $55 billion in annual healthcare costs. The public health burden of MRSA is enormous with over 90,000 MRSA infections per year in the United States. As a result, more NIH funding must be allotted to relevant research. In 2010 NIAID announced four new contracts for large scale clinical trials (making a total of eight trials) focused on treatment alternatives for diseases for which antibiotics are prescribed most often (e.g., middle ear infections). Also in 2010, NIAID reported a newly identified MRSA toxin, the only MRSA toxin currently known to destroy specific human immune cells and a possible target of future drugs.

*HIV/AIDS*.—Since 1981, when the U.S. epidemic began, HIV/AIDS has killed more than 565,000 people in the United States. Each year there are about 2 million AIDS related deaths worldwide and an additional 2.7 million become newly infected, including about 56,000 new infections annually in the United States. An estimated 33 million are living with HIV/AIDS, over 1 million of those in this country. In large part due to NIH support, medical science now offers rising hope amidst these grim statistics, as those with HIV/AIDS live longer and better. In 2010, NIAID funded researchers reported several studies that have been called landmarks in the fight against this difficult disease:

—Preexposure prophylaxis (PrEP) with a daily dose of an approved anti-HIV drug reduces the risk of infection among men who have sex with men; studies of other at risk populations continue.

—After nearly 15 years of research, scientists discovered the first vaginal microbicide gel that gives women some protection against HIV infection.
—Various research groups have discovered at least eight antibodies that can stop HIV from infecting human cells in the laboratory, which could help scientists design effective vaccines.
—A study in Cambodia demonstrated that people coinfected with HIV and tuberculosis can benefit from starting antiretroviral therapy earlier than originally believed (antiretroviral treatment can worsen the symptoms of coinfections, so timing is critical).

*Emerging Infectious Diseases*.—Since 2003, NIAID has had principal responsibility for NIH's research and development of medical countermeasures against radiological, nuclear, chemical and biological terrorist threats. NIAID's programs on biodefense and emerging/reemerging infectious diseases are inevitably intertwined. Researchers study hemorrhagic fevers caused by Ebola and other viruses, West Nile virus, prion diseases, influenza viruses, anthrax, and dozens of other infectious diseases, seeking vaccines, therapeutics, and diagnostics to prevent or curb disease outbreaks. Last year, for instance, NIAID scientists announced a new, quick method called real time quaking induced conversion assay (RT QuIC) to detect prions, which cause fatal brain diseases like mad cow disease in cattle, Creutzfeldt Jakob disease in humans, and scrapie in sheep. Other researchers discovered a new form of murine prion disease that resembles a form of human Alzheimer's disease.

Last August, after more than a decade of work by NIAID scientists, a dengue vaccine began human clinical testing; the virus infects about 50 million to 100 million people annually. NIAID also awarded new contracts to private industry to develop delivery systems for new vaccines against anthrax and dengue fever; clinical trials of the three vaccines should begin within 3 years. Two other experimental vaccines showed promise against Marburg virus (cause of hemorrhagic fever with a fatality rate up to 80 percent) and Ebola virus (up to 90 percent fatality).

*National Security and Research*.—Beginning in the late 1990s and especially following 2001, funding for research in the Department of Defense related to global diseases that impact U.S. military on foreign soil as well as protection against biothreats on U.S. soil decreased. This research is now primarily entrusted to NIAID and other NIH institutes, FDA and CDC. Research related to defense is interdependent on advances in other areas of research, especially those related to emerging infections. Reports issues recently by the Institute of Medicine and the National Biodefense Science Board emphasize the need to properly fund these agencies for medical countermeasure development.

*Genomics*.—NIAID and NIGMS sponsor genomic research for improving human health. At NIGMS, investigators are using human genetic information to explain and identify individuals' reactions to certain drugs—research called pharmacogenetics, which is focused on the NIH goal of cost effective "predictive, personalized, and preemptive medicine." NIAID supported genomic research programs include genome sequencing centers and bioinformatics resource centers. By the end of 2010, the Institute's two Structural Genomics Centers for Infectious Diseases had determined 500 3-D protein structures from microorganisms on the NIAID Category A–C priority lists or otherwise considered major human pathogens.

*Global Health*.—Infectious diseases travel easily across international borders, and the economic stability of nations can be shaken by high rates of morbidity and mortality from such diseases. Fiscal year 2009 marked the 30th anniversary of the Institute's International Collaborations in Infectious Disease Research (ICIDR) program. That year NIAID supported 643 international projects in 97 countries, with 72 percent of the funds invested in HIV/AIDS research. In mid 2010, NIAID announced funding to establish 10 new malaria research centers around the world. NIAID supported researchers recently developed a chemical that may prove to be a new malaria drug; it has more than a decade since the last new class of antimalarials became available against a disease that kills nearly 1 million people every year. Preliminary data suggest that the new compound might be effective as a single dose, rather than the current standard treatment of multiple doses over several days. Also last year, other NIAID grantees described a previously unknown metabolic pathway used by malaria parasites to survive inside human blood cells.

## CONCLUSION

For over a century, NIH funded discoveries have saved lives, stimulated private industry and fostered the next generation of scientists and physicians. More than 130 Nobel Prize winners have received support from NIH, but more importantly, the health of millions worldwide has been improved through NIH programs. NIH investments have also yielded remarkable financial rewards, from basic research that

helped launch the biotech industry to the recent development of a highly effective meningitis vaccine that each year saves an estimated $950 million in medical costs and another $1.14 billion in patient/caregiver earnings. The ASM strongly recommends that Congress support innovation in the medical sciences and increase funding for the National Institutes of Health in fiscal year 2012.

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PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR NUTRITION

The American Society for Nutrition (ASN) appreciates the opportunity to submit testimony regarding fiscal year 2012 appropriations for the National Institutes of Health (NIH) and the National Center for Health Statistics (NCHS). ASN is the professional scientific society dedicated to bringing together the world's top researchers, clinical nutritionists and industry to advance our knowledge and application of nutrition to promote human and animal health. Our focus ranges from the most critical details of nutrition research to broad societal applications. ASN respectfully requests $35 billion for NIH, and we urge you to adopt the President's request of $162 million for NCHS in fiscal year 2012.

Basic and applied research on nutrition, nutrient composition, the relationship between nutrition and chronic disease, and nutrition monitoring are critical to the health of all Americans and the U.S. economy. Awareness of the growing epidemic of obesity and the contribution of chronic illness to burgeoning healthcare costs has highlighted the need for improved information on dietary components, dietary intake, strategies for dietary change and nutritional therapies. The health costs of obesity alone are estimated at $147 billion each year. This enormous health and economic burden is largely preventable, along with the many other chronic diseases that plague the United States. It is for this reason that we urge you to consider these recommended funding levels for two agencies under the Department of Health and Human Services that have profound effects on nutrition research, nutrition monitoring, and the health of all Americans—the National Institutes of Health and the National Center for Health Statistics.

*National Institutes of Health*

The National Institutes of Health (NIH) is responsible for conducting and supporting 90 percent (approximately $1 billion) of federally funded basic and clinical nutrition research. Nutrition research, which makes up about 4 percent of the NIH budget, is truly a trans-NIH endeavor, being conducted and funded across multiple Institutes and Centers. In order to fulfill the full potential of biomedical research, including nutrition research, ASN recommends an fiscal year 2012 funding level of $35 billion for the agency, a modest increase over the current funding level of $34 billion (including supplemental appropriations). This increase is necessary to maintain both the existing and future scientific infrastructure. Although the discovery process produces tremendous value, it often takes a lengthy and unpredictable path. Economic stagnation is disruptive to training, careers, long range projects and ultimately to progress. NIH needs sustainable and predictable budget growth to achieve the full promise of medical research to improve the health and longevity of all Americans and continue our Nation's dominance in this area.

NIH and its grantees have played a major role in the growth of knowledge that has led to an unprecedented number of scientific breakthroughs that have transformed our understanding of human health, helping Americans to live longer, healthier and more productive lives. Many of these discoveries are nutrition-related and have impacted the way clinicians prevent and treat heart disease, cancer, diabetes and other chronic diseases. By 2030 the number of Americans age 65 and older is expected to grow to 72 million, and the incidence of chronic disease will also grow. Sustained support for nutrition research is required if we are to successfully confront the healthcare challenges associated with an older population.

*CDC National Center for Health Statistics*

The National Center for Health Statistics (NCHS), housed within the Centers for Disease Control and Prevention (CDC), is the Nation's principal health statistics agency. The NCHS provides critical data on all aspects of our healthcare system, and it is responsible for monitoring the Nation's health and nutrition status through surveys such as the National Health and Nutrition Examination Survey (NHANES). Nutrition and health data are essential for tracking the nutrition, health and well being of the American public, especially for observing nutritional and health trends in our Nation's children. Through learning both what Americans eat and how their diets directly affect their health, the NCHS is able to monitor the prevalence of obesity and other chronic diseases in the United States and track the performance of preventive interventions, as well as assess consumption of "nutrients of concern"

such as Vitamin D and calcium. Data such as these are critical to guide policy development in the area of health and nutrition.

To continue support for the agency and its important mission, ASN recommends an fiscal year 2012 funding level of $162 million for the agency. Flat and decreased funding levels threaten the collection of this important information, most notably vital statistics and the NHANES. Moreover, nearly 30 percent of the funding for NHANES comes from other Federal agencies such as the NIH and the USDA Agricultural Research Service. When these agencies face flat budgets or worse, budget cuts, they withdraw much-needed support for NHANES, placing this valuable resource in peril. Sustained funding for NCHS can help to ensure uninterrupted collection of vital health and nutrition statistics.

Thank you for your support of the National Institutes of Health (NIH) and the National Center for Health Statistics (NCHS), and thank you for the opportunity to submit testimony regarding fiscal year 2012 appropriations. Please contact Sarah Ohlhorst, MS, RD, Director of Government Relations, if ASN may provide further assistance. She can be reached at address: 9650 Rockville Pike, Bethesda MD 20814; telephone number: 301.634.7281 or email address: sohlhorst@nutrition.org.

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## PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS

The American Society for Pharmacology and Experimental Therapeutics (ASPET) is pleased to submit written testimony in support of the National Institutes of Health (NIH) fiscal year 2012 budget. ASPET is a 5,100 member scientific society whose members conduct basic and clinical pharmacological research within the academic, industrial and government sectors. Our members discover and develop new medicines and therapeutic agents that fight existing and emerging diseases, as well as increase our knowledge regarding how therapeutics affects humans.

For fiscal year 2012, ASPET supports a $35 billion budget for the NIH. Research funded by the NIH improves public health, helps stimulate our economy and improves global competitiveness. Sustained growth for the NIH should be an urgent national priority. Flat funding or cuts to the NIH budget will delay cures, eliminate jobs, and jeopardize American leadership and innovation in biomedical research.

A $35 billion budget for the NIH in fiscal year 2012 will help restore some of the lost opportunities and purchasing power since 2003, when Congress finished a bipartisan effort of doubling the NIH budget. Currently, the NIH cannot begin to fund all the high quality research that needs to be done. At the moment only one-in-five research projects can be supported. The situation has now reached a critical point:

—Over the past 6 years, the number of research project grants funded by NIH has declined almost every year.

—NIH funds 2,000 fewer grants in total than in fiscal year 2004.

—NIH made 1,000 fewer competing (new and renewed) awards in 2010 than it did in 2003.

—Success rates for new applications have fallen for three straight years.

If flat funding continues, or if additional cuts are made to the NIH budget for fiscal year 2012, important research that improves the quality of life, offers life-saving new therapeutics, and ultimately reduces healthcare costs will be delayed or stopped. International competitors will continue to gain on this highly innovative U.S. enterprise, and we will lose a generation of young scientists who see no prospects for careers in biomedical research. Flat or reduced funding for NIH will mean that the agency would have to dramatically reduce new awards and many research projects in progress would not receive sufficient funding to complete the work, thus representing a waste of valuable research resources.

An fiscal year 2012 NIH budget of $35 billion would help to restore momentum to NIH funding. Scientific discovery takes time. As recent experience has shown from the post-doubling experience and more recent stimulus funding in 2009 and 2010, "boom and bust" cycles of rapid funding followed by significant periods of stagnation or retraction in the NIH budget diminish scientific progress. A $35 billion fiscal year 20121 NIH budget will help the agency manage its research portfolio effectively without too much disruption of existing grants to researchers throughout the country. The NIH, and the entire scientific enterprise, cannot rationally manage boom or bust funding cycles. Only through steady, sustainable and predictable funding increases can NIH continue to fund the highest quality biomedical research to help improve the health of all Americans and continue to make significant economic impact in many communities across the country. An fiscal year 2012 NIH budget of $35 billion will help the NIH move to more fully exploit promising areas of biomedical research and translate the resulting findings into improved healthcare.

*Investing in NIH Improves Human Health*

Diminished funding for NIH will mean a loss of scientific opportunities to discover new therapeutic targets and will create disincentives to young scientists to commit to careers in biomedical science. A $35 billion fiscal year 2012 NIH budget would provide the various institutes that make up the NIH with an opportunity to fund more high quality and innovative research in many disease areas. Earlier and significant investments in NIH research have been instrumental in improving human health:

—Parkinson's disease is estimated to afflict over 1 million Americans at an annual cost of $26 billion. The discovery of Levodopa was a breakthrough in treating the disease and allows patients to lead relatively normal, productive lives. It is estimated that treatments slowing the progress of disease by 10 percent could save the United States $327 million a year. Current treatments slow progression of disease, but more research is needed to identify the causes of the disease and develop better therapies.

—More than 38 million Americans are blind or visually impaired, and that number will grow with an aging population. Eye disease and vision loss cost the United States $68 billion annually. NIH funded research has developed new treatments that delay or prevent diabetic retinopathy, saving $1.6 billion a year. Discovery of gene variations in age related macular degeneration could result in new screening tests and preventive therapies.

—Almost 5 million Americans suffer from Alzheimer's disease at annual costs of more than $100 billion. It is estimated that by 2050 more than 14 million Americans will live with the disease. There are over 28 new drugs for Alzheimer's disease in development, but more basic research is needed to keep the pipeline for new drugs robust. Inadequate funding could delay, prevent, and improve the treatment of the disease.

—Heart disease and stroke are the number one and three killers of Americans, respectively. Cardiovascular disease costs the United States more than $350 billion annually. Since 1970, death rates from cardiovascular disease have fallen by 50 percent, but still remain the leading cause of death. Statin drugs that reduce cholesterol help to prevent heart disease and stroke, decrease recurrence of heart attacks and improve survival rates for heart transplant patients.

—Cancer is the second leading cause of death in the United States. The NIH estimates that the annual cost of the disease is over $228 billion. NIH research has shown that human papillomavirus (HPV) vaccines protect against persistent infection by the two types of HPV that cause approximately 70 percent of cervical cancers. NIH funded researchers are using nanotechnology to develop probes that could pinpoint the location of tumors and deliver drugs directly to cancer cells.

NIH-funded studies have also indicated that adopting intensive lifestyle changes delayed onset of type-2 diabetes by 58 percent, and that progesterone therapy can reduce premature births by 30 percent in at-risk women. Historically, our past investment in basic biological research has led to many innovative medicines. The National Research Council reported that of the 21 drugs with the highest therapeutic impact, only five were developed without input from the public sector. The significant past investment in the NIH has provided major gains in our knowledge of the human genome, resulting in the promise of pharmacogenomics and a reduction in adverse drug reactions that currently represent a major worldwide health concern. Already, there are several examples where complete human genome sequence analysis has pinpointed disease-causing variants that have led to improved therapy and cures. Although the costs for such analyses have been reduced dramatically by technology improvements, widespread use of this approach will require further improvements in technology that will be delayed or obstructed with inadequate NIH funding.

Unless NIH can maintain an adequate funding stream, scientific opportunities will be delayed, lost, or forfeited to other countries. This investment in NIH also will directly support jobs for U.S. citizens and residents and help to stimulate the economy.

*Investing in NIH Helps America Compete Economically*

A $35 billion budget in fiscal year 2012 will also help the NIH train the next generation of scientists. This investment will help to create jobs and promote economic growth.

Worldwide, other nations continue to invest aggressively in science. China has grown its science portfolio with annual increases to the research and development budget averaging over 23 percent annually since 2000. And while Great Britain has imposed strict austerity measures to address that Nation's debt problems, the Brit-

ish conservative party had the foresight to keep its strategic investments in science at current levels. Investment in research and development as a percentage of gross domestic product has remained static for the United States in the first decade of the 21st century, while growing by nearly 60 percent in China and 34 percent in South Korea.

NIH research funding helps to catalyze private sector growth. More than 83 percent of NIH funding is awarded to over 3,000 universities, medical schools, teaching hospitals and other research institutions in every State. NIH also helps form the key scientific foundations for the pharmaceutical and biotechnology industries.

Inadequate funding for NIH means more than a loss of scientific potential and discovery. Failing to help meet the NIH's scientific potential will mean a significant reduction in research grants, the resulting phasing-out of high quality research programs and jobs lost.

*Conclusion*

ASPET has full awareness for the many competing and important priorities facing the subcommittee. However, NIH and the biomedical research enterprise face a critical moment and the agency's contribution to the economic and physical well being of American's health should make it one of the Nation's top priorities. With enhanced and sustained funding, NIH has the potential to address many of the more promising scientific opportunities that currently challenge medicine. A $35 billion fiscal year 2012 NIH budget will allow the agency to begin moving forward again to prevent, diagnose and treat disease, restoring the NIH to its role as a national treasure that attracts and retains the best and brightest to biomedical research, and providing hope to millions of individuals afflicted with illness and disease.

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## PREPARED STATEMENT OF THE AMERICAN SOCIETY OF NEPHROLOGY

*Introduction*

The American Society of Nephrology (ASN) thank you for the opportunity to submit a statement for the record to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (LHHS Subcommittee). ASN urges the LHHS subcommittee to support robust funding for medical research in the fiscal year 2012 Federal budget.

ASN is a not-for-profit professional society of more than 11,000 scientists and physicians dedicated to cutting-edge medical research and delivering the highest quality therapies to patients. Foremost among ASN's concerns is the continued support of basic, translational, and clinical nephrology research.

The society's statement focuses on those issues and programs that most immediately fall under the committee's jurisdiction and assist our members in finding breakthrough treatments and cures for patients with kidney disease. We want to express our strong support for advancing programs supported by the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ). The ASN thanks the Subcommittee for its steadfast support of these programs and requests continued support of medical research in fiscal year 2012.

*The Face of Kidney Disease*

Chronic kidney disease now is a major public health problem in the United States, with as many as one in nine Americans or 26 million people suffering from kidney disease of some degree. This number is projected to rise, underscoring that support of medical research into the causes and treatments of kidney disease is essential to protecting public health. A growing population, a significant and growing cohort of Americans above age 65, the combined epidemics of cardiovascular disease, diabetes, and hypertension all lead to an increasing number of Americans with chronic kidney disease.

Chronic kidney disease affects people regardless of age, race, sex, socio economic background, or geographic location. It is estimated that at least 15 million people suffer from CKD, meaning that they have lost at least 50 percent of their kidney function. Most don't know it. Another 20 million more Americans are at increased risk of developing kidney disease. Again, most are unaware. Hypertension and diabetes are leading causes of kidney disease, with diabetes accounting for 44 percent of new cases of complete kidney failure. With both diabetes and hypertension on the rise, the need for additional kidney disease research takes on greater importance.

Kidney disease is also a major risk factor for cardiovascular disease, with half of patients with kidney failure dying from cardiovascular disease. Research at NIH continues to disentangle the relationship between kidney disease, cardiovascular disease, diabetes and hypertension.

Without treatment chronic kidney disease often progresses to complete kidney failure also known as end stage renal disease (ESRD), or permanent kidney failure. Patients with ESRD require dialysis or transplantation to survive for which Medicare covers the cost for almost all patients. Nearly 500,000 Americans have ESRD, and that continues to grow. Additionally, African-Americans, Native Americans, and Hispanics are at greater risk of developing ESRD than Caucasians. NIH research is helping to unlock the reasons behind these health disparities.

*Economics Costs*

Although no dollar amount can be affixed to human suffering or the loss of human life, economic data can help to identify and quantify the current and projected future financial costs associated with ESRD. The annual average cost per ESRD patient on dialysis is approximately $71,000. This major cost to Medicare highlights the need to investigate new, and better apply, recently proven strategies for preventing and slowing the progress of kidney disease.

In short, we can treat and maintain patients who are at risk for losing their kidney function but the critical need is to prevent the loss of kidney function and its complications in the first place. Meeting this vital goal can only be accomplished through more concerted research and education.

*Kidney Disease Research*

*National Institutes of Health (NIH)*

NIH research is vital to the public and economic health of the United States. As such, ASN supports the Administration's program level request of $31.987 billion for NIH in fiscal year 2012. Recognizing the economic challenges of the country's current fiscal situation, ASN nonetheless submits that maintaining level funding for NIH is imperative to the future health and well-being of the Nation. Research supported by NIH helps discover new cures and treatments for the millions of Americans with kidney disease and improves the lives of patients across the country. Medical research funded through NIH means hope for patients with kidney disease.

NIH research also serves as a vital economic engine. More than 80 percent of NIH funding flows back to States, maintaining jobs and promoting economic vitality. Support for NIH research helps ensure that the United States remains the world leader in cutting edge treatments for chronic disease. NIH grants and research fund the cures of tomorrow, and also fund researchers who form the backbone of our global competitiveness in the medical field. A drop in funding, even one that is short lived could have drastic consequences for the future research workforce.

In fiscal year 2012 an NIH budget of $31.987 billion will allow research funding to keep pace with inflation, sustain the invaluable research projects currently underway, and allow the research workforce to remain adequately supported and protect a valuable investment in human talent.

*Agency for Health Care Research and Quality (AHRQ)*

Complementing the medical research conducted at NIH, AHRQ sponsors health services research designed to improve the quality of healthcare, decrease healthcare costs, and provide access to essential healthcare services by translating research into measurable improvements in the healthcare system. AHRQ supports emerging critical issues in healthcare delivery and addresses the particular needs of at risk populations. ASN firmly believes in the value of AHRQ's research and quality agenda, which continues to provide healthcare providers, policymakers, and patients with critical information needed to improve healthcare and treatment of chronic conditions such as kidney disease. AS such ASN supports the Administration's budget request of $366 million for AHRQ in fiscal year 2012.

*Conclusion*

The progression of chronic kidney disease to kidney failure can be slowed, with further research, treatments for stopping progression or even reversing it can be envisioned. Meanwhile, millions of Americans face a gradual decline in their quality of life because of kidney disease. Treatments of kidney failure including transplantation increase the ability of patients to be productive citizens. In many cases, abnormalities associated with early stage chronic renal disease remain undetected and are not diagnosed until the late stages. Chronic kidney disease requires our serious and immediate attention.

Medical research undertaken at NIH and AHRQ is essential to the health of patients with kidney disease, both present and future. As such, ASN urges the Subcommittee to adopt level funding for these programs in fiscal year 2012.

Thank you for your continued support for medical research and kidney disease. The society appreciates the opportunity to submit written testimony in support of

NIH and AHRQ. To discuss this written testimony, ASN, medical research or kidney disease, please contact ASN Director of Policy and Public Affairs Paul Smedberg.

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PREPARED STATEMENT OF THE AMERICAN SOCIETY OF PLANT BIOLOGISTS

On behalf of the American Society of Plant Biologists (ASPB) we would like to thank the Subcommittee for its support of the National Institutes of Health (NIH).

ASPB and its members recognize the difficult fiscal environment our Nation faces, but believe investments in scientific research will be a critical step toward economic recovery. ASPB asks that the Subcommittee Members encourage increased support for plant biology research within NIH, which has contributed in innumerable ways to improving the lives of people throughout the world.

The American Society of Plant Biologists is an organization of approximately 5,000 professional plant biology researchers, educators, graduate students, and postdoctoral scientists with members in all 50 States and throughout the world. A strong voice for the global plant science community, our mission—achieved through work in the realms of research, education, and public policy—is to promote the growth and development of plant biology, to encourage and communicate research in plant biology, and to promote the interests and growth of plant scientists in general.

*Plant Biology Research and America's Future*

Plants are vital to our very existence. They harvest sunlight, converting it to chemical energy for food and feed; they take up carbon dioxide and produce oxygen; and they are the primary producers on which all life depends. Indeed, plant biology research is making many fundamental contributions in the areas of domestic fuel security and environmental stewardship; the continued and sustainable development of better foods, fabrics, pharmaceuticals, and building materials; and in the understanding of basic biological principles that underpin improvements in the health and nutrition of all Americans. In fact, the 2009 National Research Council (NRC) report A New Biology for the 21st Century placed plant biology at the center of urgent priorities in energy, food, health, and the environment.

For example, because plants are the ultimate source of both human nutrition and nutrition for domestic animals, plant biology has the potential to contribute greatly to reducing healthcare costs as well as playing an integral role in discovery of new drugs and therapies. Although the National Institutes of Health does offer some funding support to plant biology research, additional support would enable plant biologists to offer much more to advance the missions of the National Institutes of Health.

The importance of disciplinary and agency integration is a central theme of several recent NRC reports including A New Biology for the 21st Century, Research at the Intersection of the Physical and Life Sciences, and Inspired by Biology: From Molecules to Materials to Machines. ASPB encourages NIH to continue and expand its partnerships with other Federal science agencies—including the National Science Foundation, Department of Agriculture and Department of Energy—in advancing understanding about living systems that has application to a range of areas including human health.

*Plant Biology and the National Institutes of Health*

The mission of the NIH is to pursue "fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability." Plant biology research is highly relevant to this mission.

Plants are often the ideal model systems to advance our "fundamental knowledge about the nature and behavior of living systems," as they provide the context of multi-cellularity while affording ease of genetic manipulation, a lesser regulatory burden, and inexpensive maintenance requirements than the use of animal systems. Many basic biological components and mechanisms are shared by both plants and animals. For example, a molecule named cryptochrome that senses light was identified first in plants and subsequently found to also function in humans, where it plays a central role in regulating our biological clock. Several human genetic disorders are linked to the malfunctioning of this clock—not to mention the effect of jet lag. As another example, some fungal pathogens can infect both humans and plants, and the molecular mechanisms employed by both the pathogen and its targeted host can be very similar.

More recently, a property known as RNA interface was first noted in plants; plant biologists trying to increase the color intensity of petunias by introducing a gene inducing pigment production instead observed a loss of color. RNA interface, which

has potential application in the treatment of human disease, was further elucidated in other plants and animals and earned two American scientists—Andrew Fire and Craig Mello—the 2006 Nobel Prize in Physiology or Medicine.

*Health and Nutrition*

Plant biology research is also central to the application of basic knowledge to "extend healthy life and reduce the burdens of illness and disability." This connection is most obvious in the inter-related areas of nutrition and clinical medicine. Without good nutrition, there cannot be good health. Indeed, one World Health Organization study on childhood nutrition in developing countries concluded that over 50 percent of the deaths of children less than 5 years of age could be attributed to malnutrition's effects in exacerbating common illnesses such as respiratory infections and diarrhea. Strikingly, most of these deaths were not linked to severe malnutrition but only to mild or moderate nutritional deficiencies. Plant biology researchers are working today to improve the nutritional content of crop plants by, for example, increasing the availability of nutrients and vitamins such as iron, vitamin E, and vitamin A. (Up to 500,000 children in the developing world go blind every year as a result of vitamin A deficiency).

By contrast, obesity, cardiac disease, and cancer take a striking toll in the developed world. Among many plant biology initiatives relevant to these concerns are research to improve the lipid composition of plant fats and efforts to optimize concentrations of plant compounds that are known to have anti-carcinogenic properties, such as the glucosinolates found in broccoli and cabbage, and the lycopenes found in tomato. Beta-glucans from certain cereals reduce serum cholesterol and insulin demand in diabetics. And scientists are able to use the fundamental knowledge of protein structures to reduce non-nutritious compounds, increasing the density and quality of proteins in some grains. Ongoing development of crop varieties with tailored nutraceutical content is an important contribution that plant biologists are making toward realizing the goal of personalized medicine, especially personalized preventative medicine.

*Drug Discovery*

Plants are also fundamentally important as sources of both extant drugs and drug discovery leads. In fact, over 10 percent of the drugs considered by the World Health Organization to be "basic and essential" are still exclusively obtained from flowering plants. Some historical examples are quinine, which is derived from the bark of the cinchona tree and was the first highly effective anti-malarial drug; and the plant alkaloid morphine, which revolutionized the treatment of pain. These pharmaceuticals are still in use today.

A more recent example of the importance of plant-based pharmaceuticals is the anti-cancer drug taxol. The discovery of taxol came about through collaborative work involving scientists at the National Cancer Institute within NIH and plant biologists at the U.S. Department of Agriculture. The plant biologists collected a wide diversity of plant materials, which were then evaluated for anti-carcinogenic properties. It was found that the bark of the Pacific yew tree yielded one such compound, which was isolated and named taxol after the tree's Latin name, Taxus brevifolia. Originally, taxol could only be obtained from the tree bark itself, but additional research led to the elucidation of its molecular structure and eventually to its chemical synthesis in the laboratory.

On the basis of a growing understanding of metabolic networks, plants will continue to be sources for the development of new medicines to help treat cancer and other ailments. Taxol is just one example of a plant secondary compound. Since plants produce an estimated 200,000 such compounds, they will continue to provide a fruitful source of new drug leads, particularly if collaborations such as the one described above can be fostered and funded. With additional research support, plant biologists can lead the way to developing new medicines and biomedical applications to enhance the treatment of devastating diseases.

*Conclusion*

Despite the fact that plant biology research underlies so many vital practical considerations for our country, the amount invested in understanding the basic function and mechanisms of plants is small when compared with broader impacts.

The NIH does recognize that plants are a vital component of its mission. However, because the boundaries of plant biology research are permeable and because information about plants integrates with many different disciplines that are highly relevant to NIH, ASPB hopes that the Subcommittee will provide direction to NIH to support additional plant biology research in order to help pioneer new discoveries and new methods in biomedical research.

Thank you for your consideration of our testimony on behalf of the American Society of Plant Biologists. Please do not hesitate to contact ASPB if we can be of any assistance in the future; ASPB Public Affairs Director Dr. Adam P. Fagen can be reached at 301–296–0898 (phone), 301–296–0899 (fax), or afagen@aspb.org.

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## PREPARED STATEMENT OF THE AMERICAN SOCIETY OF TROPICAL MEDICINE AND HYGIENE

The American Society of Tropical Medicine and Hygiene—the principal professional membership organization representing, educating, and supporting scientists, physicians, clinicians, researchers, epidemiologists, and other health professionals dedicated to the prevention and control of tropical diseases—appreciates the opportunity to submit testimony to the Senate Labor, Health and Human Services, and Education Appropriations Subcommittee.

We understand the fiscal constraints we as a country are in and are sensitive to the job Congress must do. The benefits of U.S. investment in tropical diseases are not only humanitarian, they are diplomatic as well. With this in mind, we respectfully request that the Subcommittee fund the following agencies in the fiscal year 2012 LHHS Appropriations bill to allow them to maintain their current programs and research priorities while ensuring a continued U.S. Government investment in global health and tropical medicine research and development:

National Institutes of Health, specifically:

—Malaria and neglected tropical disease treatment, control, and research and development efforts within the National Institute of Allergy and Infectious Diseases;

—An expanded focus on the treatment, control, and research and development for new tools for diarrheal disease within the NIH; specifically the inclusion of enteric infections on the Research, Condition, and Disease Categorization (RCDC) process on the Research Portfolio Online Reporting Tools (RePORT) website; and,

—Research capacity development in countries where populations are at heightened risk for malaria, NTDs, and diarrheal diseases through the Fogarty International Center.

The Centers for Disease Control and Prevention, including:

—CDC global health programs such as the CDC malaria program and providing direct funding to the CDC for NTD and diarrheal disease work; and

—Preserving and funding the activities of the CDC Vector Borne Disease Program as they merge with the Emerging and Infectious Disease Program to protect the United States from new and emerging infections.

### RETURN ON INVESTMENT OF U.S.-FUNDED RESEARCH

CDC and NIH play essential roles in research and development for tropical medicine and global health. Both agencies are at the forefront of the new science that leads to tools to combat malaria and NTDs. This research provides jobs for American researchers and an opportunity for the United States to be a leader in the fight against global disease, in addition to lifesaving new drugs and diagnostics to some of the poorest, most at-risk people in the world.

For example, in Illinois, where ASTMH is based, 57,000 people are employed in bioscience research, which includes global health research. Illinois receives over $700 million in funding from NIH and over $200 million from CDC.[1] New Jersey also has a high level of investment in health-related research and development, with over 211,000 jobs supported by global health, and an economic impact of more than $60 billion on the State in 2009.[2] Small investments in global health and tropical medicine research and development can yield big returns for State economies and research institutions.

### TROPICAL DISEASE

Most tropical diseases are prevalent in either sub-Saharan Africa, parts of Asia (including the Indian subcontinent), or Central and South America. Many of the world's developing nations are located in these areas; thus, tropical medicine tends to focus on diseases that impact the world's most impoverished individuals.

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[1] Research America, "Global Health R&D, A Smart Investment for Illinois," http://www.researchamerica.org/uploads/ILGHeconomicsheet.pdf.

[2] Research America, "Global Health R&D, A Smart Investment for New Jersey," http://www.researchamerica.org/uploads/NewJerseyFactSheet.pdf.

*Malaria*.—Malaria remains a global emergency affecting mostly poor women and children; it is an acute, sometimes fatal disease. Despite being treatable and preventable, malaria is one of the leading causes of death and disease worldwide. Approximately every 30 seconds, a child dies of malaria—a total of about 800,000 under the age of 5 every year. The World Health Organization estimates that one half of the world's people are at risk for malaria and that there are 108 malaria-endemic countries. Additionally, WHO has estimated that malaria reduces sub-Saharan Africa's economic growth by up to 1.3 percent per year.

*Neglected Tropical Diseases, also known as Diseases of Poverty*.—NTDs are a group of chronic parasitic diseases, such as hookworm, elephantiasis, schistosomiasis, and river blindness, which represent the most common infections of the world's poorest people. These infections have been revealed as the stealth reason why the "bottom billion"—the 1.4 billion poorest people living below the poverty line—cannot escape poverty, because of the effects of these diseases on reducing child growth, cognition and intellect, and worker productivity.

*Diarrheal disease*.—The child death toll due to diarrheal illnesses exceeds that of AIDS, tuberculosis, and malaria combined. In poor countries, diarrheal disease is second only to pneumonia as the cause of death among children under 5 years old. Every week, 31,000 children in low-income countries die from diarrheal diseases.

The United States has a long history of leading the fight against tropical diseases that cause human suffering and pose financial burden that can negatively impact a country's economic and political stability. Tropical diseases, many of them neglected for decades, impact U.S. citizens working or traveling overseas, as well as our military personnel. Furthermore, some of the agents responsible for these diseases can be introduced and become established in the United States (like West Nile virus), or might even be weaponized.

NATIONAL INSTITUTES OF HEALTH

*National Institute of Allergy and Infectious Diseases*.—A long-term investment is critical to achieve the drugs, diagnostics, and research capacity needed to control malaria and NTDs. NIAID, the lead institute for malaria research, plays an important role in developing the drugs and vaccines needed to fight malaria. The NIH, through NIAID, also conducts research to better understand NTDs, through its own basic and clinical studies as well as extramural research.

ASTMH encourages the subcommittee to:

—Increase funding for NIH to expand the agency's investment in malaria, NTD, diarrheal disease research and to coordinate that work with other government agencies to maximize resources and ensure development of basic discoveries into usable solutions;

—Specifically invest in NIAID to support its role at the forefront of these efforts to developing the next generation of drugs, vaccines, and other interventions; and,

—Urge NIH to include enteric infections and neglected diseases in its RCDC process on the RePORT website to outline the work that is being done in these important research areas.

*Fogarty International Center (FIC)*.—Biomedical research has provided major advances in the treatment and prevention of malaria, NTDs, and other infectious diseases. These benefits, however, are often slow to reach the people who need them most. FIC plays a critical role in strengthening science and public health research institutions in low-income countries. FIC works to strengthen research capacity in countries where populations are particularly vulnerable to threats posed by malaria, NTDs, and other infectious disease. This maximizes the impact of U.S. investments and is critical to fighting malaria and other tropical diseases.

ASTMH encourages the subcommittee to:

—Allocate sufficient resources to FIC in fiscal year 2012 to increase these efforts, particularly as they address the control and treatment of malaria, NTDs and diarrheal disease.

THE CENTERS FOR DISEASE CONTROL AND PREVENTION

*Malaria Efforts*.—Malaria has been eliminated as an endemic threat in the United States for over fifty years and CDC remains on the cutting edge of global efforts to reduce the toll of this deadly disease. CDC efforts on malaria fall into three broad categories: prevention, treatment, and monitoring/evaluation of efforts. The agency performs a wide range of basic research within these categories, such as:

—Conducting research on antimalarial drug resistance to inform new strategies and prevention approaches;

—Assessing new monitoring, evaluation, and surveillance strategies;
—Conducting additional research on malaria vaccines, including field evaluations; and
—Developing innovative public health strategies for improving access to antimalarial treatment and delaying the appearance of antimalarial drug resistance.

ASTMH encourages the subcommittee to:
—Fund a comprehensive approach to effective and efficient malaria control, including adequately funding the important contributions of CDC.

*NTD Programs*.—CDC currently receives zero dollars directly for NTD work; however this should be changed to allow for more comprehensive work to be done on NTDs at the CDC. CDC has a long history of working on NTDs and has provided much of the science that underlies the global policies and programs in existence today. This work is important to any global health initiative, as individuals are often infected with multiple NTDs simultaneously.

ASTMH encourages the subcommittee to:
—Provide direct funding to CDC to continue its work on NTDs; and
—Urge CDC to continue its monitoring, evaluation, and technical assistance in these areas as an underpinning of efforts to control and eliminate these diseases.

*Vector-borne Disease Program (VBDP)*.—The President's fiscal year 2012 budget folds the CDC Vector Borne Disease Program into the newly configured Emerging and Zoonotic Infectious Diseases program at CDC. Through the VBDP, researchers are able to practice essential surveillance and monitoring activities that protect the United States from deadly infections before they reach our borders. The world is becoming increasingly smaller as international travel increases and new pathogens are introduced quickly into new environments. We have seen this with SARS, avian influenza, and now, dengue fever, in the United States. Arboviruses like dengue, and others, such as chikungunya, are a constant threat to travelers, and to Americans generally.

Dengue fever, a disease with increased risk for Americans as the weather warms and dengue cases increase, is an example of why it is imperative that CDC be able to continue its disease monitoring and surveillance activities to protect the country from new and emerging threats like dengue and other arboviruses. Dengue fever, a viral disease transmitted by the Aedes mosquito, recently reemerged as a threat to Americans, with documented cases in the Florida Keys. Dengue usually results in fever, headache, and chills, but hemorrhagic dengue fever can cause severe internal bleeding, loss of blood, and even death. Because the Aedes mosquito is urban dwelling and often breeds in areas of poor sanitation, dengue is a serious concern for poor residents of costal, urban areas in Texas, Louisiana, Mississippi, Alabama, and Florida.

ASTMH encourages the subcommittee to:
—Ensure that CDC maintain these important activities by continuing CDC funding for VBDP activities and require the program receive at least their fiscal year 2010 level of funding.

### CONCLUSION

Thank you for your attention to these important U.S. and global health matters. We know Congress and the American people face many challenges in choosing funding priorities, and we hope you will provide the requested fiscal year 2012 resources to those programs identified above that meet critical needs for Americans and people around the world. ASTMH appreciates the opportunity to share its expertise, and we thank you for your consideration of these requests that will help improve the lives of Americans and the global poor.

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## PREPARED STATEMENT OF THE AMERICAN THORACIC SOCIETY

### SUMMARY: FUNDING RECOMMENDATIONS

[In millions of dollars]

| | Amount |
|---|---|
| National Institutes of Health | 35,000 |
| National Heart, Lung and Blood Institute | 3,514 |
| National Institute of Allergy and Infectious Disease | 5,395 |
| National Institute of Environmental Health Sciences | 779.4 |

SUMMARY: FUNDING RECOMMENDATIONS—Continued

[In millions of dollars]

| | Amount |
|---|---|
| Fogarty International Center | 78.4 |
| National Institute of Nursing Research | 163 |
| Centers for Disease Control and Prevention | 7,700 |
| National Institute for Occupational Safety & Health | 332.4 |
| Asthma Programs | 31 |
| Div. of Tuberculosis Elimination | 231 |
| Office on Smoking and Health | 330 |
| National Sleep Awareness Roundtable (NSART) | 1 |

The American Thoracic Society (ATS) is pleased to submit our recommendations for programs in the Labor Health and Human Services and Education Appropriations Subcommittee purview. Founded in 1905, the ATS is an international education and scientific society of 15,000 specialists focused on respiratory, critical care and sleep medicine.

*Lung Disease in America*

Diseases of breathing constitute the third leading cause of death in the United States, responsible for one of every seven deaths. Diseases affecting the respiratory (breathing) system include chronic obstructive pulmonary disease (COPD), lung cancer, tuberculosis, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease, sarcoidosis, asthma, and critical illness. COPD is now the third leading cause of disease death. The number of people with asthma in the United States has surged over 150 percent since 1980 and the root causes of the disease are still not fully known.

Despite the rising lung disease burden, lung disease research is underfunded. In fiscal year 2010, lung disease research represented just 22.6 percent of the National Heart Lung and Blood Institute's (NHLBI) budget. Although COPD is the third leading cause of death in the United States, research funding for the disease is a small fraction of the money invested for the other three leading causes of death. In order to stem the devastating effects of lung disease, research funding must continue to grow.

*National Institutes of Health*

The NIH is the world's leader in groundbreaking biomedical health research into the prevention, treatment and cure of diseases such as lung cancer, COPD and tuberculosis. Eighty-five percent of the NIH budget is invested in U.S. communities through universities, medical schools, hospitals and innovative small businesses, creating jobs and economic productivity. The American Reinvestment Recovery Act (ARRA) has generated remarkable scientific innovation that is paving the way for medical advances to improve patient outcomes. Without a funding increase in fiscal year 2012 to sustain the research pipeline, the NIH will be forced to reduce the number of research grants funded, which will result in the halting of vital research into diseases affecting millions around the world. We ask the subcommittee to provide $35 billion in funding for the NIH in fiscal year 2012.

*Centers for Disease Control and Prevention*

In order to ensure that health promotion and chronic disease prevention are given top priority in Federal funding, the ATS supports a funding level for the Centers for Disease Control and Prevention (CDC) that enables it to carry out its prevention mission, and ensure a translation of new research into effective State and local public health programs. We ask that the CDC budget be adjusted to reflect increased needs in chronic disease prevention, infectious disease control, including TB control to prevent the spread of drug-resistant TB, and occupational safety and health research and training. The ATS recommends a funding level of $7.7 billion for the CDC in fiscal year 2012.

*COPD*

COPD is the third leading cause of death in the United States and the third leading cause of death worldwide, yet the disease remains relatively unknown to most Americans. COPD is the term used to describe the limitation in breathing due mainly to emphysema and chronic bronchitis. CDC estimates that 12 million patients have COPD; an additional 12 million Americans are unaware that they have this life threatening disease. In 2010, the estimated economic cost of lung disease in the

United States was $186 billion, including $117 billion in direct health expenditures and $69 billion in indirect morbidity and mortality costs.

Despite the growing burden of COPD, the United States does not currently have a comprehensive public health action plan on the disease. The ATS urges Congress to direct the NHLBI to develop a national action plan on COPD, in coordination with the Centers for Disease Control and Prevention (CDC) to expand COPD surveillance, development of public health interventions and research on the disease and increase public awareness of the disease. The NHLBI has shown successful leadership in educating the public about COPD through the COPD Education and Prevention Program.

CDC has an additional role to play in this work. We urge CDC to include COPD-based questions to future CDC health surveys, including the National Health and Nutrition Evaluation Survey (NHANES), the National Health Information Survey (NHIS) and the Behavioral Risk Factor Surveillance Survey (BRFSS).

*Tobacco Control*

Cigarette smoking is the leading preventable cause of death in the United States, responsible for one in five deaths annually. The ATS is pleased that the Department of Health and Human Services has made tobacco use prevention a key priority. The CDC's Office of Smoking and Health coordinates public health efforts to reduce tobacco use. In order to significantly reduce tobacco use within 5 years, as recommended by the subcommittee in fiscal year 2010, the ATS recommends a total funding level of $330 million for the Office of Smoking and Health in fiscal year 2012, which includes an allocation of $220 million from the Prevention and Public Health Fund.

*Pediatric Lung Disease*

The ATS is pleased to report that infant death rates for various lung diseases have declined for the past 10 years. In 2007, of the 10 leading causes of infant mortality, 4 were lung diseases or had a lung disease component. Many of the precursors of adult respiratory disease start in childhood. It is estimated that close to 22 million people suffer from asthma, including an estimated 7.1 million children. The ATS encourages the NHLBI to continue with its research efforts to study lung development and pediatric lung diseases.

*Asthma*

Asthma is a significant public health problem in the United States. Approximately 23 million Americans currently have asthma, including 7.1 million children. In 2009, 3,445 Americans in 2009 died as a result of asthma exacerbations. Asthma is the third leading cause of hospitalization among children under the age of 15 and is a leading cause of school absences from chronic disease. The disease costs our healthcare system over $50.1 billion per year. African Americans have the highest asthma prevalence of any racial/ethnic group.

The President's fiscal year 2012 budget request proposes to merge the CDC's National Asthma Control Program with the Healthy Homes/Lead Poisoning Prevention Program and recommends funding cuts to the combined programs of over 50 percent. The ATS is deeply concerned that this proposal would drastically reduce States' capacity to implement a proven public health response to this disease. Asthma public health interventions are cost-effective. A study published in the American Journal of Respiratory Critical Care recently found that for every dollar invested in asthma interventions, there was a $36 benefit. We urge the subcommittee to ensure that CDC's National Asthma Control Program remains a stand-alone program and receives an appropriation of $31 million for fiscal year 2012.

*Sleep*

Several research studies demonstrate that sleep-disordered breathing and sleep-related illnesses affect an estimated 50–70 million Americans. The public health impact of sleep illnesses and sleep disordered breathing is still being determined, but is known to include increased mortality, traffic accidents, lost work and school productivity, cardiovascular disease, obesity, mental health disorders, and other sleep-related comorbidities. Despite the increased need for study in this area, research on sleep and sleep-related disorders has been underfunded. The ATS recommends a funding level of $1 million in fiscal year 2012 to support activities related to sleep and sleep disorders at the CDC, including for the National Sleep Awareness Roundtable (NSART), surveillance activities, and public educational activities. The ATS also recommends an increase of funding for research on sleep disorders at the Nation Center for Sleep Disordered Research (NCSDR) at the NHLBI.

*Tuberculosis*

Tuberculosis (TB) is the second leading global infectious disease killer, claiming 1.7 million lives each year. It is estimated that 9–12 million Americans have latent tuberculosis. Drug-resistant TB poses a particular challenge to domestic TB control due to the high costs of treatment and intensive healthcare resources required. The global TB pandemic and spread of drug resistant TB presents a persistent public health threat to the United States.

Despite declining rates, persistent challenges to TB control in the United States remain. Specifically: (1) racial and ethnic minorities continue to suffer from TB more than majority populations; (2) foreign-born persons are adversely impacted; (3) sporadic outbreaks occur, outstripping local capacity; (4) continued emergence of drug resistance; and (5) there are critical needs for new diagnostics, treatment and prevention tools.

The Comprehensive Tuberculosis Elimination Act (CTEA, Public Law 110–392), enacted in 2008, reauthorized programs at CDC with the goal of putting the United States back on the path to eliminating TB. The ATS, recommends a funding level of $231 million in fiscal year 2012 for CDC's Division of TB Elimination, as authorized under the CTEA, and encourages the NIH to expand efforts, as requested under the CTEA, to develop new tools to reduce the rising global TB burden.

*Critical Illness*

The burden associated with the provision of care to critically ill patients is anticipated to increase significantly as the population ages. Approximately 200,000 people in the United States require hospitalization in an intensive care unit because they develop a form of pulmonary disease called Acute Lung Injury. Despite the best available treatments, 75,000 of these individuals die each year from this disease. Investigation into diagnosis, treatment and outcomes in critically ill patients should be a high priority, and the NIH should be encouraged and funded to coordinate investigation related to critical illness in order to meet this growing national imperative.

*Fogarty International Center*

The Fogarty International Center (FIC) at NIH provides training grants to U.S. universities to teach AIDS treatment and research techniques to international physicians and researchers. Because of the link between AIDS and TB infection, FIC has created supplemental TB training grants for these institutions to train international health professionals in TB treatment and research. The ATS recommends Congress provide $78.4 million for FIC in fiscal year 2012, to allow expansion of the TB training grant program from a supplemental grant to an open competition grant.

*Researching and Preventing Occupational Lung Disease*

The National Institute of Occupational Safety and Health (NIOSH) is the sole Federal agency responsible for conducting research and making recommendations for the prevention of work-related diseases and injury. The ATS recommends that Congress provide $364.3 million in fiscal year 2012 for NIOSH to expand or establish the following activities: the National Occupational Research Agenda (NORA); tracking systems for identifying and responding to hazardous exposures and risks in the workplace; emergency preparedness and response activities; and training medical professionals in the diagnosis and treatment of occupational illness and injury.

*Conclusion*

Lung disease is a growing problem in the United States. The level of support this subcommittee approves for lung disease programs should reflect the urgency illustrated by these numbers. The ATS appreciates the opportunity to submit this statement to the subcommittee.

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## PREPARED STATEMENT OF THE AMERICANS FOR NURSING SHORTAGE RELIEF

The undersigned organizations of the ANSR Alliance greatly appreciate the opportunity to submit written testimony regarding fiscal year 2012 appropriations for the Title VIII Nursing Workforce Development Programs at the Health Resources and Services Administration (HRSA) and the Nurse Managed Health Clinics as authorized under Title III of the Public Health Service Act. We represent a diverse cross-section of healthcare and other related organizations, healthcare providers, and supporters of nursing issues that have united to address the national nursing shortage. ANSR stands ready to work with Congress to advance programs and policy that will ensure our Nation has a sufficient and adequately prepared nursing workforce to

provide quality care to all well into the 21st century. The Alliance, therefore, urges Congress to:

—Appropriate $313 million in funding for Nursing Workforce Development Programs under Title VIII of the Public Health Service Act at the Health Resources and Services Administration (HRSA) in fiscal year 2012.

—Appropriate $20 million in fiscal year 2012 for the Nurse Managed Health Clinics as authorized under Title III of the Public Health Service Act.

*The Nursing Shortage*

Nursing is the largest healthcare profession in the United States. According to the National Council of State Boards of Nursing, there were nearly 3.780 million licensed RNs in 2009. Nurses and advanced practice nurses (nurse practitioners, nurse midwives, clinical nurse specialists, and certified registered nurse anesthetists) work in a variety of settings, including primary care, public health, long-term care, surgical care facilities, and hospitals. The March 2008 study, The Future of the Nursing Workforce in the United States: Data, Trends, and Implications, calculates a projected demand of 500,000 full-time equivalent registered nurses by 2025. According to the U.S. Bureau of Labor Statistics, employment of registered nurses is expected to grow by 22 percent from 2008 to 2018, much faster than the average for all occupations and, because the occupation is very large, 581,500 new jobs will result. Based on these scenarios, the shortage presents an extremely serious challenge in the delivery of high quality, cost-effective services, as the Nation looks to reform the current healthcare system. Even considering only the smaller projection of vacancies, this shortage still results in a critical gap in nursing service, essentially three times the 2001 nursing shortage.

*The Desperate Need for Nurse Faculty*

Nursing vacancies exist throughout the entire healthcare system, including long-term care, home care and public health. Even the Department of Veterans Affairs, the largest sole employer of RNs in the United States, has a nursing vacancy rate of 10 percent. In 2006, the American Hospital Association reported that hospitals needed 116,000 more RNs to fill immediate vacancies, and that this 8.1 percent vacancy rate affects hospitals' ability to provide patient care. Government estimates indicate that this situation only promises to worsen due to an insufficient supply of individuals matriculating in nursing schools, an aging existing workforce, and the inadequate availability of nursing faculty to educate and train the next generation of nurses. At the exact same time that the nursing shortage is expected to worsen, the baby boom generation is aging and the number of individuals with serious, life-threatening, and chronic conditions requiring nursing care will increase. Consequently, more must be done today by the government to help ensure an adequate nursing workforce for the patients/clients of today and tomorrow.

A particular focus on securing and retaining adequate numbers of faculty is essential to ensure that all individuals interested in—and qualified for—nursing school can matriculate in the year that they are accepted. The National League for Nursing found that in the 2009–2010 academic year,

—42 percent of qualified applications to prelicensure RN programs were turned away.

—One in four (25.1 percent) of prelicensure RN programs turned away qualified applicants.

—Four out of five (60 percent) of prelicensure RN programs were considered "highly selective" by national college admissions standards, accepting less than 50 percent of applications for admission.

Aside from having a limited number of faculty, nursing programs struggle to provide space for clinical laboratories and to secure a sufficient number of clinical training sites at healthcare facilities.

ANSR supports the need for sustained attention on the efficacy and performance of existing and proposed programs to improve nursing practices and strengthen the nursing workforce. The support of research and evaluation studies that test models of nursing practice and workforce development is integral to advancing healthcare for all in America. Investments in research and evaluation studies have a direct effect on the caliber of nursing care. Our collective goal of improving the quality of patient care, reducing costs, and efficiently delivering appropriate healthcare to those in need is served best by aggressive nursing research and performance and impact evaluation at the program level.

*The Nursing Supply Impacts the Nation's Health and Economic Safety*

Nurses make a difference in the lives of patients from disease prevention and management to education to responding to emergencies. Chronic diseases, such as heart disease, stroke, cancer, and diabetes, are the most preventable of all health

problems as well as the most costly. Nearly half of Americans suffer from one or more chronic conditions and chronic disease accounts for 70 percent of all deaths. In addition, increased rates of obesity and chronic disease are the primary cause of disability and diminished quality of life.

Even though America spends more than $2 trillion annually on healthcare—more than any other nation in the world—tens of millions of Americans suffer every day from preventable diseases like type 2 diabetes, heart disease, and some forms of cancer that rob them of their health and quality of life. In addition, major vulnerabilities remain in our emergency preparedness to respond to natural, technological and manmade hazards. An October 2008 report issued by Trust for America's Health, entitled "Blueprint for a Healthier America," found that the health and safety of Americans depend on the next generation of professionals in public health. Further, existing efforts to recruit and retain the public health workforce are insufficient. New policies and incentives must be created to make public service careers in public health an attractive professional path, especially for the emerging workforce and those changing careers.

The Institute of Medicine report, Hospital-Based Emergency Care: At the Breaking Point, notes that nursing shortages in U.S. hospitals continue to disrupt hospitals operations and are detrimental to patient care and safety. Hospitals and other healthcare facilities across the country are vulnerable to mass casualty incidents themselves and/or in emergency and disaster preparedness situations. As in the public health sector, a mass casualty incident occurs as a result of an event where sudden and high patient volume exceeds the facilities resources. Such events may include the more commonly realized multi-car pile-ups, train crashes, hazardous material exposure in a building or within a community, high occupancy catastrophic fires, or the extraordinary events such as pandemics, weather-related disasters, and intentional catastrophic acts of violence.

Since 80 percent of disaster victims present at the emergency department, nurses as first receivers are an important aspect of the public health system as well as the healthcare system in general. The nursing shortage has a significant adverse impact on the ability of communities to respond to health emergencies, including natural, technological and manmade hazards.

*Summary*

The link between healthcare and our Nation's economic security and global competitiveness is undeniable. Having a sufficient nursing workforce to meet the demands of a highly diverse and aging population is an essential component to reforming the healthcare system as well as improving the health status of the Nation and reducing healthcare costs. To mitigate the immediate effect of the nursing shortage and to address all of these policy areas, ANSR requests $313 million in funding for Nursing Workforce Development Programs under Title VIII of the Public Health Service Act at HRSA and $20 million for the Nurse Managed Health Clinics under Title III of the Public Health Service Act in fiscal year 2012.

LIST OF ANSR MEMBER ORGANIZATIONS

Academy of Medical-Surgical Nurses
American Academy of Ambulatory Care Nursing
American Association of Critical-Care Nurses
American Association of Nurse Assessment Coordinators
American Organization of Nurse Executives
American Society for Pain Management Nursing
American Society of PeriAnesthesia Nurses
Association for Radiologic & Imaging Nursing
Association of Community Health Nursing Educators
Association of Pediatric Hematology/ Oncology Nurses
Emergency Nurses Association
Infusion Nurses Society
International Nurses Society on Addictions
National Association of Clinical Nurse Specialists
National Association of Hispanic Nurses
National Association of Nurse Practitioners in Women's Health
National Council of State Boards of Nursing
National Council of Women's Organizations
National League for Nursing
National Nursing Centers Consortium
National Student Nurses' Association, Inc.
Nurses Organization of Veterans Affairs
Society of Trauma Nurses

PREPARED STATEMENT OF THE ARTHRITIS FOUNDATION

The Arthritis Foundation greatly appreciates the opportunity to submit testimony in support of increased investment for arthritis research, prevention and programs at the Centers for Disease Control and Prevention (CDC); National Institutes of Health (NIH); Agency for Healthcare Research and Quality (AHRQ); and for the Health Resources and Services Administration (HRSA).

Arthritis is a complex family of musculoskeletal disorders with many causes, not yet fully understood, and so far there are no cures. It consists of more than 100 different diseases or conditions that destroy joints, bones, muscles, cartilage and other connective tissue which hampers or halts physical movement. Arthritis is one of the most prevalent chronic health problems and the most common cause of disability in the United States. 50 million people (1 in 5 adults) and almost 300,000 children live with the pain of arthritis every day. Arthritis limits the daily activities of 21 million Americans and accounts for $128 billion annually in economic costs, including $81 billion in direct costs for physician visits and surgical interventions and $47 billion in indirect costs for missed work days. Counter to public perception, two-thirds of the people with doctor-diagnosed arthritis are under the age of 65. The pain, cost and disability associated with arthritis is simply unacceptable.

By the year 2030, an estimated 67 million or 25 percent of the projected adult population will have arthritis. Furthermore, arthritis limits the ability of people to effectively manage other chronic diseases. More than 57 percent of adults with heart disease and more than 52 percent of adults with diabetes also have arthritis. The Arthritis Foundation strongly believes that in order to prevent or delay arthritis from disabling people and diminishing their quality of life that a significant investment in proven prevention and intervention strategies is essential.

The following items summarize the Arthritis Foundation fiscal year 2012 funding recommendations for health agencies under the Subcommittee's jurisdiction.

*Centers for Disease Control and Prevention*

The Arthritis Foundation recommends a level of $7.7 billion for CDC's core programs in fiscal year 2012. This amount is representative of what CDC needs to fulfill its core public health mission in fiscal year 2012; activities and programs that are essential to protect the health of the American people. CDC continues to be faced with unprecedented challenges and responsibilities, ranging from chronic disease prevention, eliminating health disparities, bioterrorism preparedness, to combating the obesity epidemic. More than 70 percent of CDC's budget actually flows out to States and local health organizations and academic institutions, many of which are currently struggling to meet growing needs with fewer resources.

The President's fiscal year 2012 budget request proposed to collapse existing programs for the top five leading chronic disease causes of death and disability—arthritis, cancer, diabetes, and heart disease and stroke—into a single State Block Grant program along with State funding for public health activities related to nutrition, physical activity, obesity and school health. These Administration proposals also rely on funding from the Prevention and Public Health Fund to support these activities.

In light of the fiscal challenges facing the Nation and the need to reduce inefficiencies from Federal program overlap and lack of coordination, the Arthritis Foundation recognizes that the CDC must combat chronic disease through careful coordination and collaboration across strategic programs. However, at the same time, agency leadership must ensure that the vital public health infrastructure that has been developed over the past two decades for combating arthritis should not be dismantled.

The clear need to ensure that the burgeoning number of Americans with arthritis are served by effective efforts, lead the Arthritis Foundation to conclude that, as proposed, the Administration's consolidated chronic disease prevention program is not in the best interest of those with arthritis. To sustain and build on the achievements and progress made to date in combating arthritis, it is critical that arthritis-specific activities are preserved and strengthened in any approach to combating chronic disease.

As the fiscal year 2012 funding process continues, the Arthritis Foundation appreciates the opportunity to evaluate any consolidated chronic disease program proposal to ensure that the following priorities are addressed:

—Programs should be designed around similar target populations, including people with or at risk of arthritis, the Nation's most common cause of disability and a major barrier to physical activity.

—Any consolidation must be limited to programs with clear programmatic and operational overlap.

—CDC and states must retain staff expertise in disease areas and the infrastructure to support them;
—Programs must be supported by State-based advisory groups made up of stakeholders from the impacted disease areas;
—A national advisory committee at CDC should be created to foster stakeholder involvement from arthritis and other chronic disease communities.

The CDC's arthritis program received $13.1 million in fiscal year 2011 funding and about half of that amount will be distributed via competitive grant to 12 States. Research shows that the pain and disability of arthritis can be decreased through early diagnosis and appropriate management, including evidence-based self-management activities that enable weight control and physical activity. The Arthritis Foundation's Self-Help Program, a group education program, has been proven to reduce arthritis pain by 20 percent and physician visits by 40 percent. These evidence-based interventions are recognized by the CDC to reduce the pain of arthritis and importantly reduce healthcare expenditures through a reduction in physician visits. For arthritis prevention to grow to include another 12–15 States an investment of an additional $10 million is required.

*National Institutes of Health/National Institute of Arthritis and Musculoskeletal and Skin Diseases*

The Arthritis Foundation supports $35 billion in fiscal year 2012 for NIH to invest in improving the health and quality of life for all Americans. NIH-funded research drives scientific innovation and develops new and better diagnostics, improved prevention strategies, and more effective treatments. Approximately 83 percent of appropriated funds for NIH research are sent to every State in the Nation in the form of merit based peer review grants. These investigator initiated grants enable the highest quality of research to be conducted at research facilities and hospitals all across the Nation employing hundreds of thousand of individuals and representing an integral part of hundreds of local communities. Congress should recognize the unique role NIH plays as the economic engine in the biomedical industry.

NIH-funded research has led to new treatments, which have greatly improved the quality of life for people living with arthritis; however, the ultimate goal is to find a cure. The Arthritis Foundation firmly believes research holds the key to tomorrow's advances and provides hope for a future free from arthritis pain. As one of the largest non-profit contributors to arthritis research, the Arthritis Foundation fills a vital role in the big picture of arthritis research. Our research program complements government and industry-based arthritis research by focusing on training new investigators and pursuing innovative strategies for preventing, controlling and curing arthritis.

The mission of the NIH/National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases and the training of basic and clinical scientists to carry out this research. Research opportunities at NIAMS are being curtailed due to the stagnating and in some cases declining numbers of new grants being awarded. The training of new investigators has unnecessarily slowed down and contributed to a crisis in the research community where new investigators have begun to leave biomedical research careers. The Arthritis Foundation urges Congress to prioritize NIAMS funding to address the Nations most chronic, disabling and costly diseases.

Last year, scientists supported by the National Institutes of Health developed a technique that lead to the successful re-growth of damaged leg joints in animals. The accomplishment shows that it's possible to lure the body's own cells to injured regions and generate new tissues, such as cartilage and bone. The finding could point the way toward joint renewal in humans, which could be a dramatic and less costly alternative to the 1 million joint replacement surgeries each year.

Juvenile arthritis afflicts 300,000 children in the United States and when left untreated, it can cause permanent damage to joints and tissues throughout the body. Juvenile arthritis has serious consequences that can limit a young person's ability to grow properly, learn, and become a productive citizen in the workforce. With a dire critical shortage of pediatric rheumatologists to treat these children, it is vital that the NIH and NIAMS continue supporting a national network of cooperating clinical centers for the care and study of children with arthritis through the Childhood Arthritis and Rheumatology Research Alliance (CARRA). This NIH funded project is in the beginning stages of collecting data from the largest group of children with juvenile rheumatic diseases nationwide. The data will be available to pediatric rheumatologists throughout the United States. The collection and distribution of such disease data are crucial to the understanding of the progression of juvenile arthritis and specific outcomes related to treatment. NIH must continue to fund

this invaluable resource to improve the outcomes and lives of children with juvenile arthritis as is currently done for children with cancer. The Arthritis Foundation has also invested our research dollars in this CARRA initiative.

Public investment in biomedical research holds the real promise of improving the lives of millions of Americans with arthritis. An investment in NIH funded research is an investment in our Nation's future.

*Health Resources and Services Administration*

The Arthritis Foundation strongly recommends funding a loan repayment program for pediatric specialist at the $30 million level within HRSA for fiscal year 2012. A pediatric loan repayment program was authorized by Congress in 2010 (in the Affordable Care Act) and requires funding to commence. HRSA is essential to developing the healthcare workforce that is so critical in primary care as well as shortages in specialty care, like pediatric rheumatology.

Juvenile arthritis is the leading cause of acquired disability in children and is the sixth most common childhood disease. Sustaining the field of pediatric rheumatology is essential to the care of the almost 300,000 children under the age of 18 living with a form of juvenile arthritis. Children who are diagnosed with juvenile arthritis will live with this chronic and potentially disabling disease for their entire life. Therefore, it is imperative that children are diagnosed quickly and start treatment before significant irreversible joint damage is done. However, it is a challenge to first find a pediatric rheumatologist, as nine States do not have a single one, and then to have a timely appointment as many States have only one or two to see thousands of patients. Pediatric rheumatology is one of the smallest pediatric subspecialties with less than 200 pediatric rheumatologists actively practicing in the United States. A report to Congress in 2007 stated there was a 75 percent shortage of pediatric rheumatologists and recommended loan repayment program to help address this critical workforce shortage issue. The Affordable Care Act included authorizing HRSA $30 million to establish a loan repayment program for pediatric specialists including pediatric rheumatologists. The Arthritis Foundation strongly recommends the Subcommittee provide an initial appropriation to begin this critical program.

*Agency for Healthcare Research and Quality (AHRQ)*

The Arthritis Foundation recommends an overall funding level of $405 million for AHRQ in fiscal year 2012. AHRQ funds research and programs at local universities, hospitals, and health departments that improve healthcare quality, enhance consumer choice, advance patient safety, improve efficiency, reduce medical errors, and broaden access to essential services. Specifically, the science funded by AHRQ provides consumers and their healthcare professionals with valuable evidence to make the right healthcare decisions for themselves and their families.

The Arthritis Foundation appreciates the opportunity to submit our recommendations for fiscal year 2012 to Congress on behalf of the 50 million adults and 300,000 children with arthritis and looks forward to working with the Subcommittee in the coming months.

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## PREPARED STATEMENT OF ASME INTERNATIONAL

The NIH Task Force ("Task Force") of the ASME Bioengineering Division is pleased to provide comments on the bioengineering-related programs contained within the National Institutes of Health (NIH) fiscal year 2012 budget request. The Task Force is focused on the application of mechanical engineering knowledge, skills, and principles for the conception, design, development, analysis and operation of biomechanical systems.

*The Importance of Bioengineering*

Bioengineering is an interdisciplinary field that applies physical, chemical, and mathematical sciences, and engineering principles to the study of biology, medicine, behavior, and health. It advances knowledge from the molecular to the organ levels, and develops new and novel biologics, materials processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health. Bioengineers have employed mechanical engineering principles in the development of many life-saving and life-improving technologies, such as the artificial heart, prosthetic joints, diagnostics, and numerous rehabilitation technologies.

*Background*

The NIH is the world's largest organization dedicated to improving health through medical science. During the last 50 years, NIH has played a leading role in the major breakthroughs that have increased average life expectancy by 15 to 20 years.

The NIH is comprised of different Institutes and Centers that support a wide spectrum of research activities including basic research, disease and treatment-related studies, and epidemiological analyses. The mission of individual Institutes and Centers varies from either study of a particular organ (e.g. heart, kidney, eye), a given disease (e.g. cancer, infectious diseases, mental illness), a stage of life (e.g. childhood, old age), or finally it may encompass crosscutting needs (e.g., sequencing of the human genome). The National Institute of Biomedical Imaging and Bioengineering (NIBIB) focuses on the development, application, and acceleration of biomedical technologies to improve outcomes for a broad range of healthcare challenges.

*Fiscal Year 2012 NIH Budget Request*

The total fiscal year 2012 NIH budget request is $31.98 billion, or 2.4 percent above the $31.08 billion fiscal year 2010 appropriated amount and 4.1 percent above the $30.7 billion provided for fiscal year 2011. The Task Force recognizes that this proposed increase is significant given the Administration's commitment to reducing the Federal deficit. However, the Task Force notes that the Administration's 2.4 percent increase to the overall NIH budget from fiscal year 2010 to fiscal year 2012 is less than the up to 3 percent projected increase in medical research costs due to inflation for fiscal year 2012 alone—as predicted by the Biomedical Research and Development Price Index (BRDPI). This inflationary pressure is compounded with the $30.7 billion appropriation for fiscal year 2011, a $260 million or 0.8 percent reduction in funding from the previous fiscal year, and a BRDPI of 2.9 percent for fiscal year 2011, resulting in a significant decrease in funding for the NIH over fiscal year 2010 to fiscal year 2012.

NIH is enacting policies to guide investments while limiting the impact of these inflationary cost increases, including a 1 percent increase in the average cost of competing and non-competing Research Project Grants (RPGs); a 1 percent increase in Research Centers and Other Research; and a 1 percent increase for Intramural Research and Research Management and Support; and constraints on staffing levels. However, these policies alone are not sufficient to offset the need for additional support for critical areas of health research, especially given reduction in funding and high inflation rate for fiscal year 2011. We therefore fully support the President's proposed fiscal year 2012 budget level for the NIH given current budget constraints, but further recommend out-year budget increases well beyond BRDPI inflation rates.

The Task Force further notes that NIH received $10.4 billion as part of the American Recovery and Reinvestment Act (ARRA) of 2009 (Public Law 111–5), an important influx for several key divisions of NIH over the fiscal year 2009 and fiscal year 2010 funding cycles, particularly the NIBIB, which received $78 million—less than 1 percent of the $10.4 billion ARRA budget assigned to the NIH for the fiscal year 2009 and fiscal year 2010 funding cycles. NIBIB has already exhausted this budget, leaving no additional ARRA funding to leverage through the fiscal year 2011 budget cycle and underscoring the need for more robust investment in bioengineering at NIBIB. While this one-time influx of funding for health research and infrastructure was justified, the Task Force notes that the unstable nature of such funding inhibits the potential impact on the economy and should not be viewed as a viable substitute for steady and consistent support from Congress for these critical national research priorities.

The Administration estimates 9,158 Research Project Grants (RPG) will be supported under the fiscal year 2012 budget for NIH-wide RPGs. From fiscal year 2010 to fiscal year 2011, inflationary pressures and budget factors combined to result in a decrease of 652 in the number of competing RPGs. The Task Force commends the Administration for again focusing on funding RPGs in fiscal year 2012, resulting in an increase of 424 supported grants over the fiscal year 2011 level of competing RPGs. We reiterate again however, that the number of RPGs supported from fiscal year 2010 to fiscal year 2012 will still decline by 228 under this austere fiscal year 2012 budget scenario.

*NIBIB Research Funding*

The Administration's fiscal year 2012 budget request supports $322 million for the NIBIB, an increase of $5.6 million or 1.8 percent from the fiscal year 2010 appropriated amount. The mission of the NIBIB is to seek to improve human health by leading the development and application of emerging and breakthrough tech-

nologies based on a merging of the biological, physical, and engineering sciences. As noted above, this increase is well under the 3 percent projected increase in research costs due to inflation (predicted by the BRDPI index) and, as a consequence, actually results in an effective decrease in funding for NIBIB compared to fiscal year 2010.

The budget for NIBIB Research Grants would remain flat at $262.7 million. Funding for intramural research would increase 7.3 percent to $11.8 million from $11 million in fiscal year 2010. NIBIB's Research Management and Support request is $17.3 million, a 3 percent increase over fiscal year 2010.

NIBIB funds the Applied Science and Technology (AST) program, which supports the development and application of innovative technologies, methods, products, and devices for research and clinical application that transform the practice of medicine. The fiscal year 2012 request for AST is $170.6 million, a $2.2 million increase or 1.3 percent increase from fiscal year 2010.

Additionally, NIBIB funds the Discover Science and Technology (DST) program, which is focused on the discovery of innovative biomedical engineering and imaging principles for the benefit of public health. The fiscal year 2011 request for DST is $95.3 million, a $1.2 million or 1.3 percent increase from fiscal year 2010.

The Technological Competitiveness-Bridging the Sciences program, which funds interdisciplinary approaches to research, would receive $25.9 million in fiscal year 2012, a $0.9 million increase or 3.6 percent over the fiscal year 2010 enacted level.

*Task Force Recommendations*

The Task Force is concerned that the United States faces rapidly growing challenges from our counterparts in the European Union and Asia with regards to bioengineering advancements. While total health-related U.S. research and development investments have expanded significantly over the last decade, investment in bioengineering at NIBIB have remained relatively flat over the last several years. In fact, the fiscal year 2012 budget actually represents a small reduction in funding when the fiscal year 2003 NIBIB appropriation of $280 million is adjusted for inflation—$329 million in 2010 dollars—leaving NIBIB with an effective reduction in funding of $7 million since 2003.

The Task Force wishes to emphasize that, in many instances, bioengineering-based solutions to healthcare problems can result in improved health outcomes and reductions in healthcare costs. For example, coronary stent implantation procedures cost approximately $20,000, compared to bypass graft surgery at double the cost. Stenting involves materials science (metals and polymers), mechanical design, computational mechanical modeling, imaging technologies, etc. that bioengineers work to develop. Not only is the procedure less costly, but the patient can return to normal function within a few days rather than months to recover from bypass surgery, greatly reducing other costs to the economy. Therefore, we strongly urge Congress to consider increased funding for bioengineering within the NIBIB and across NIH, and work to strengthen these investments in the long run to reduce U.S. healthcare costs and support continued U.S. leadership in bioengineering.

Even during these challenging fiscal times, the NIBIB must obtain sustained funding increases, both to accelerate medical advancements as our Nation's population ages, and to mirror the growth taking place in the bioengineering field. The Task Force believes that the Administration's budget request for fiscal year 2012 is not aligned with the long-term challenges posed by this objective; a 1.8 percent budget increase will not keep up with current inflationary increases for biomedical research, eroding the United States' ability to lay the groundwork for the medical advancements of tomorrow.

While the Task Force supports Federal proposals that seek to double Federal research and development in the physical sciences over the next decade, we believe that strong Federal support for bioengineering and the life sciences is essential to the health and competitiveness of the United States. The supplemental funding that NIH received as part of ARRA and the budget request by the Administration does not erase the past several years of disappointing budgets. Congress and the Administration should work to develop a specific plan, beyond President Obama's call for "innovations in healthcare technology" to focus on specific and attainable medical and biomedical research priorities which will reduce the costs of healthcare and improve healthcare outcomes. Further, Congress and the Administration should include in this strategy new mechanisms for partnerships between NSF and the NIH to promote bioengineering research and education. The Task Force feels these initiatives are necessary to build capacity in the U.S. bioengineering workforce and improve the competitiveness of the U.S. bioengineering research community.

PREPARED STATEMENT OF THE ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY (APIC) AND THE SOCIETY FOR HEALTHCARE EPIDEMIOLOGY OF AMERICA (SHEA)

The Association for Professionals in Infection Control and Epidemiology (APIC) and The Society for Healthcare Epidemiology of America (SHEA) thank you for this opportunity to submit testimony on Federal efforts to eliminate healthcare-associated infections (HAIs).

APIC's mission is to improve health and patient safety by reducing the risk of HAIs and related adverse outcomes. The organization's more than 14,000 members, known as infection preventionists, direct infection prevention and control programs that save lives and improve the bottom line for hospitals and other healthcare facilities throughout the United States and around the globe. Our association strives to promote a culture within healthcare institutions where all members of the healthcare team fully embrace the elimination of HAIs. We advance these efforts through education, research, collaboration, practice guidance, public policy, and support for credentialing.

SHEA was founded in 1980 to advance the application of the science of healthcare epidemiology. The Society works to achieve the highest quality of patient care and healthcare personnel safety in all healthcare settings by applying epidemiologic principles and prevention strategies to a wide range of quality-of-care issues. SHEA is a growing organization, strengthened by its membership in all branches of medicine, public health, and healthcare epidemiology. SHEA and its members are committed to implementing evidence-based strategies to prevent HAIs. SHEA members have scientific expertise in evaluating potential strategies for eliminating preventable HAIs.

APIC and SHEA collaborate with a wide range of infection prevention and infectious diseases societies, specialty medical societies in other fields, quality improvement organizations, and patient safety organizations in order to identify and disseminate evidence-based practices. The Centers for Disease Control and Prevention (CDC), its Division of Healthcare Quality Promotion (DHQP) and the Federal Healthcare Infection Control Practices Advisory Committee (HICPAC), and the Council of State and Territorial Epidemiologists (CSTE) have been invaluable Federal partners in the development of guidelines for the prevention and control of HAIs and in their support of translational research designed to bring evidence-based practices to patient care. Further, collaboration between experts in the field (epidemiologists and infection preventionists), the CDC and the Agency for Healthcare Research and Quality (AHRQ) plays a critical role in defining and prioritizing the research agenda. In 2008, APIC and SHEA aligned with The Joint Commission and the American Hospital Association to produce and promote the implementation of evidence-based recommendations in the Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals (http://www.shea-online.org/about/compendium.cfm). APIC and SHEA also contribute expert scientific advice to quality improvement organizations such as the Institute for Healthcare Improvement (IHI), the National Quality Forum (NQF), and State-based task forces focused on infection prevention and public reporting issues.

HAIs are among the leading causes of preventable death in the United States, accounting for an estimated 1.7 million infections and 99,000 associated deaths in 2002. In addition to the substantial human suffering caused by HAIs, these infections contribute $28 billion to $33 billion in excess healthcare costs each year.

The good news is that some of these infections are on the decline. In particular, bloodstream infections associated with indwelling central venous catheters, or "central lines," are largely preventable when healthcare providers use the CDC infection prevention recommendations in the context of a performance improvement collaborative. Healthcare professionals have reduced these infections in hospital intensive care unit (ICU) patients by 58 percent since 2001, which represents up to 27,000 lives saved. In spite of this notable progress, there is a great deal of work to be done to achieve the goal of HAI elimination. These additional opportunities to save lives and improve patient safety involve settings outside ICUs and those patients who need hemodialysis.

To build and then sustain these winnable battles against HAIs, we urge you, in fiscal year 2012, to support the CDC Coalition's request for $7.7 billion for the CDC's "core programs." Within that broader area, the CDC is currently involved in a number of projects that have allowed for significant progress to be made in reducing HAIs. In light of this important work, we ask that you provide the CDC with its requested amount of $47.4 million for HAI prevention activities.

Included among these activities is support for State-based programs to expand facility enrollment in the CDC's National Healthcare Safety Network (NHSN), an im-

portant reporting and monitoring tool that enables officials to track where HAIs are occurring and identify where improvements need to be made. NHSN's data analysis function helps our members analyze facility-specific data and compare rates to national metrics. Importantly, the patients we serve throughout the United States have established expectations that reported reductions in the frequency of HAIs are accurate. APIC and SHEA have, through their respective networks of members, identified limitations in other measures of performance. These studies have consistently identified that data from the CDC's NHSN provides a more precise picture of performance relative to reduction of HAIs. Many States consider NHSN to be the best option for implementing standardized reporting of HAI data. The CDC has also been supporting research networks to address important scientific gaps in HAI prevention, improvement in HAI tracking and monitoring methodologies, as well as responding to requests for assistance from health departments and healthcare facilities. It is vital to ensure that the NHSN meets these expectations from patients and that our successes are real and tangible improvements in the care provided.

In addition, we request that the Subcommittee provide $50 million for antimicrobial resistance activities. As the CDC states in its request, "repeated and improper uses of antibiotics are important factors in the increase in drug-resistant bacteria, viruses, and parasites," and "preventing infections and decreasing inappropriate antibiotic use are the best strategies to control resistance." Ensuring the effectiveness of antibiotics well into the future is vital for the nation's public health. It is essential, therefore, that the CDC maintains the ability to monitor organism resistance in healthcare and promote appropriate antibiotic use. This has become even more critical due to two recent developments. First, pharmaceutical manufacturers have largely abandoned development of newer antibiotics because there are several market-based disincentives to investing in this research and development. Second, there is an epidemic of infections caused by Clostridium difficile, a bacterium that is triggered by use of antibiotics. These infections are widespread, disproportionately affect older adults, and can be fatal. There are several examples in the scientific literature that demonstrate the rate of C. difficile infections drops in facilities with active, effective antimicrobial stewardship programs.

We also support the Administration's $5 million request for HAI activities. This funding will allow HHS, under the HHS Action Plan to Prevent Healthcare-Associated Infections (HAI Action Plan), to prioritize recommended clinical practices, strengthen data systems, and develop and launch a nationwide HAI prevention campaign. APIC and SHEA members have been engaged in this partnership for HAI prevention under the leadership of HHS Assistant Secretary for Health, Dr. Howard Koh and Deputy Assistant Secretary for Healthcare Quality, Dr. Don Wright.

We believe the development of the HAI Action Plan and the funding to support these activities has been critical to the effort to build support for a coordinated Federal plan and message on preventing infections. Additionally, we strongly believe that the CDC has the necessary expertise to define appropriate metrics through which the HAI Action Plan can best measure its efforts.

APIC and SHEA also request that the Subcommittee approve $10.7 million for the Centers for Medicare and Medicaid Services (CMS) surveys of ambulatory surgical centers (ASCs) as part of the budget request addressing direct survey costs. CMS's survey process, jointly developed with the CDC in this case, consists of targeting infection control deficiencies in ASCs with a frequency of every 4 years. Due to the increasing number of surgeries performed in outpatient settings, and the need to ensure that basic infection prevention practices are followed, APIC believes continuation of this survey tool is essential. This support will also protect patients' lives as there have been several outbreaks in ASCs involving transmission of bloodborne pathogens, such as hepatitis C, due to unsafe practices.

Also within the direct survey costs portion of CMS's request, the agency indicates plans to launch an HAI pilot program as part of the HHS HAI strategic plan. This promises to produce a significant amount of feedback on HAI prevention as CMS intends to survey critical access hospitals and smaller hospitals across 10 to 25 States. This will allow officials to gather information from facilities whose practices and data have not traditionally been monitored or widely shared.

APIC and SHEA are pleased with the Administration's continued support of biomedical research by providing an increase of almost $32 billion for the National Institutes of Health (NIH) in fiscal year 2012, a 2.4 percent increase over fiscal year 2010 levels. The NIH is the single largest funding source for infectious diseases research in the United States and the life-source for many academic research centers. The NIH-funded work conducted at these centers lays the ground work for advancements in treatments, cures, and medical technologies. It is critical that we maintain this momentum for medical research capacity.

Unfortunately, support for basic, translational, and epidemiological HAI research has not been a priority of the NIH. Despite the fact that HAIs are among the top ten annual causes of death in the United States, scientists studying these infections have received relatively less funding than colleagues in many other disciplines. In 2008, NIH estimated that it spent more than $2.9 billion on funding for HIV/AIDS research, approximately $2 billion on cardiovascular disease research, and about $664 million on obesity research. By comparison, the National Institute of Allergy and Infectious Diseases (NIAID) provided $18 million for MRSA research. APIC and SHEA believe that as the magnitude of the HAI problem becomes an increasing part of our public health dialogue, it is imperative that the Congress and funding organizations put significant resources behind this momentum.

The limited availability of Federal funding to study HAIs has the effect of steering young investigators interested in pursuing research on HAIs toward other, better-funded fields. While industry funding is available, the potential conflicts of interest, particularly in the area of infection prevention technologies, make this option seriously problematic. These challenges are limiting professional interest in the field and hampering the clinical research enterprise at a time when it should be expanding.

Our field is faced with the need to bundle, implement and adhere to interventions we believe to be successful while simultaneously conducting basic, epidemiological, pathogenetic and translational studies that are needed to move our discipline to the next level of evidence-based patient safety. The current convergence of scientific, public and legislative interest in reducing rates of HAIs can provide the necessary momentum to address and answer important questions in HAI research. APIC and SHEA strongly urge you to enhance NIH funding for fiscal year 2012 to ensure adequate support for the research foundation that holds the key to addressing the multifaceted challenges presented by HAIs.

Finally, we support the $34 million in the Administration's fiscal year 2012 budget that would continue, and allow expansion of, funding for AHRQ grants related to HAI prevention in multiple healthcare settings, including surgical and dialysis centers. Infections are one of the leading causes of hospitalization and death for patients on hemodialysis. According to the CDC, approximately 37,000 bloodstream infections occurred in hemodialysis outpatients with central lines (2008). AHRQ's plans to broaden research support in ambulatory and long-term care settings to align with the HHS HAI Action Plan represent another positive step in addressing HAIs in a comprehensive fashion.

We thank you for the opportunity to submit testimony and greatly appreciate this Subcommittee's assistance in providing the necessary funding for the Federal Government to have a leadership role in the effort to eliminate HAIs.

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## PREPARED STATEMENT OF THE ASSOCIATION FOR RESEARCH IN VISION AND OPHTHALMOLOGY

*Congressional and Presidential support for biomedical research*

In 2009, Congress spoke volumes in passing S. Res. 209 and H. Res. 366, which designated the years 2010 to 2020 as The Decade of Vision, in which the majority of 78 million Baby Boomers will face the greatest risk for aging eye disease. This decade is not the time for a less-than-inflationary increase for a community that lost 20.1 percent purchasing power over the course of the last 10 years.[1]

As President Obama has stated repeatedly, most recently during the 2011 State of the Union Address, biomedical research reduces healthcare costs, increases productivity, and it ensures global competitiveness of the United States.

ARVO has two major requests for Senate:

—For Senate to budget NIH in fiscal year 2012 at $35 billion.

This amount: Is a $3 billion increase over the President's proposed budget; maintains NIH net funding levels from fiscal year 2009 and fiscal year 2010; and ensures that NIH can maintain funding for existing grants and award the same number of new grants.

—For Senate to make vision health a priority and fund NEI in fiscal year 2012 above the 1.8 percent increase over last year that was proposed by the President.

—We request this even if Congress does not fund NIH at $35 billion.

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[1] Calculations were based solely upon annual biomedical research and development price index (BRDPI) and annual appropriated amounts. Fiscal year 2011 funding levels and fiscal year 2011 BRDPI were not part of the calculation.

—Why? Investing in research is a short term investment, with a 2.2-fold economic return from innovation. It has a long term pay-off that can reduce healthcare spending on eye diseases that are increasing in aging populations and growing minority populations that have vision health disparities (e.g. glaucoma and diabetic retinopathy). The majority of research grant budgets pay for good paying positions. Very little of the budget goes towards supplies and equipment. It addresses one of American's greatest fears: fear of losing eye sight.

*Grant review eliminates budget excess*

ARVO stands behind member John Ash, Ph.D., who stated the following during January 2011 ARVO Advocacy Day visits to Capitol Hill: "We understand the need for budget cuts, but we should be cutting budgets similar to how U.S. citizens trim their household budgets, not across the board, but rather where there is waste and inefficiency. We challenge you to find another government agency that uses money more efficiently than the National Institutes of Health."

The strategic plan for NIH grant programs (for example, the NEI strategic plan) represents the collective vision of hundreds of scientists throughout the United States. Funding decisions for individual grant applications are awarded based on scientific merit and past progress. Specifically, experts review grant applications and assign scores based on the quality and impact of the proposed research. Scientific merit and funding decisions are based on applicant competitiveness among peers. An additional level of scrutiny and guidance is provided by an NEI program panel of experts, the National Advisory Eye Council. Progress on funded projects is monitored annually by NIH, and excess budgets are trimmed taking into consideration ongoing development of other projects. Thus, the process is highly competitive from conception of a project through completion.

*Cost of vision impairment*

Vision disorders are the fourth most prevalent disability in the United States and the most frequent cause of disability in children. NEI estimates that vision impairment and eye disease cost the United States $68 billion annually. However, this number does not factor in the impact of indirect healthcare costs, lost productivity, reduced independence, diminished quality of life, increased depression, and accelerated mortality.

NEI's fiscal year 2010 baseline funding of $707 million reflects just a little more than 1 percent of the annual costs of eye disease. The continuum of vision loss presents a major public health problem, as well as a significant financial challenge to the public and private sectors.

*Prevention saves money long term*

Seventy-seven percent of Americans agree that research is part of the solution to rising healthcare costs, and 84 percent understand that prevention and wellness reduce healthcare costs (Your Candidates-Your Health Poll, August 2010). Less-than-inflationary budget increases represent short term cost-cutting that will cost taxpayers more money in the long term. Prevention can save Medicare/Medicaid payments for vision care in the aging population and in minority populations with disproportionate incidence of eye disease (e.g. glaucoma and diabetic retinopathy). NEI funding is a vital investment in overall health and vision health of our Nation that prevents health expenditures. Maintaining vision allows people to remain independent and employed, reduces family burdens, and ultimately, improves the safety of individuals and the entire community (driving safety being a prime example).

*Research is an economic investment*

Merely 2 percent of Americans think research is not important to the U.S. economy (National Poll, May 2010). The largest portion of NIH grant budgets is for salaries distributed across the country, and many of the positions funded are for good paying jobs. The lower paying jobs are an investment in training the future biomedical research work force. To learn about the economic impact of research by state, visit http://www.researchamerica.org/economic__impact.

*Vision research improves eye care*

Below are three of the top vision success stories since 2003, as reported by nearly 400 U.S.-based ARVO members, who work at NEI-funded institutions. Examples come from responses to an ARVO survey about the NEI strategic plan. There were too many vision achievements to list them all.

*Drug therapies for macular degeneration (AMD).*—Vision researchers developed a therapy to treat the most aggressive form of AMD ("wet" AMD) that works much better than even hoped for. Not only is vision loss stopped, in many cases sight is

partially regained. The therapy is so successful that it is now being used for other eye complications (e.g., eye infections, injuries and diabetes). Furthermore, a National Eye Institute-funded clinical trial (Comparison of AMD Treatments Trial), comparing safety and effectiveness of two drugs to treat advanced AMD, shows that a $50 drug (Avastin) is as effective as a $2,000 drug (Lucentis). Since 250,000 patients are treated each year for AMD, this will reduce Medicare and other government health spending. http://1.usa.gov/jZpZyv

*Gene therapies for eye disease*.—Vision researchers developed gene therapies for three retinal diseases: Leber congenital amaurosis, color blindness and retinitis pigmentosa. They also identified important genetic risk factors for age-related eye diseases, including age-related macular degeneration and glaucoma. Critically, these discoveries are the first "pay-off" of any kind from the Human Genome Project for patients and taxpayers.

*Cellular and molecular therapies*.—Using regenerative medical approaches, vision researchers made important progress in repairing damaged eye tissues (e.g., cornea and retina). By repairing damaged tissues vision function is rescued.

*Continued vision research needs*

ARVO members expressed continued need for research support for the following areas (and many additional areas not covered here).

—*Aging eye disease*.—Accelerate our efforts in basic and translational research to discover the causes of and new treatments for macular degeneration, diabetic retinopathy and other vision-robbing diseases whose risks of occurrence and severity increase with age.

—*Children's vision*.—Find noninvasive ways to detect vision problems in children early enough to start treatment before vision is lost or their education is affected.

—*Brain and eye injury*.—Develop ways to rapidly seal wounds and trauma encountered by civilians and the military, so ocular and brain function can be maintained.

—*Eye pain*.—Understand the basis of eye pain and develop therapies to treat it.

—*Eye infections*.—Identify better ways to identify and treat drug-resistant eye-infections with antibiotics and anti-viral medications. Certain infections can destroy eye tissues in just 24 hours.

—*Invest in shared therapeutic targets*.—Identify common, shared causes for common eye diseases and common systemic diseases. Establish meaningful collaborations between researchers, so shared therapeutic strategies may be developed that can treat multiple diseases.

—*Identify at-risk groups and raise awareness*.—Support development of educational tools to raise awareness and treatment compliance in people in age groups or ethnic groups, who are more susceptible to certain eye diseases.

Understand environmental factors that make it more likely to develop eye disease and educate people on how to prevent eye disease.

—*Eye surgery*.—Identify circumstances when the risk of performing eye surgery is greater than the benefit. Develop ways to treat sight problems without surgery, including facilitating natural wound healing.

*Resources*

Facts about State vision health: http://apps.nccd.cdc.gov/DDT__VHI/VHIHome.aspx.

Fact sheet about vision and blindness: http://www.researchamerica.org/uploads/factsheet16vision.pdf.

The Silver Book: Vision Loss. http://www.eyeresearch.org/pdf/VisionLossSilverbook.pdf.

*About ARVO*

ARVO is the world's largest international association of vision scientists (scientists who study diseases and disorders of the eye). About 80 percent of members from the United States (>7,000 total) are supported by NIH grant funding. Vision science is a multi-disciplinary field, but the National Eye Institute is the only free-standing NIH institute with a mission statement that specifically addresses vision research. ARVO supports increased fiscal year 2011 and fiscal year 2012 NIH funding.

ARVO is also a member of the National Alliance for Eye and Vision Research, and supports their testimony. www.eyeresearch.org

PREPARED STATEMENT OF THE ASSOCIATION OF AMERICAN CANCER INSTITUTES

The Association of American Cancer Institutes (AACI), representing 94 of the Nation's premier academic and free-standing cancer centers, appreciates the opportunity to submit this statement for consideration by the United States Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations.

AACI thanks the administration, Congress and the Subcommittee for their longstanding commitment to ensuring quality care for cancer patients, as well as for providing researchers with the tools that they need to develop better cancer treatments and, ultimately, to cure this disease.

President Obama's fiscal year 2012 budget calls for $31.829 billion for NIH. This is an increase of $1.045 billion (3.4 percent) over the fiscal year 2010 comparable level of $30.784 billion. The President's proposed budget for the National Cancer Institute would be increased by $95 million, to $5.2 billion.

Sustaining progress against cancer requires a Federal commitment to funding research through the NIH and NCI at a level that at least keeps pace with medical inflation. With that in mind, AACI is joining with its colleagues in the biomedical research community in supporting the proposed increases for NIH and NCI and in calling on Congress to further strengthen the impact of the President's request by increasing funding to $35 billion for NIH and to $5.9 billion for NCI. The requested increases account for lost funding due to discontinuation of the American Recovery and Reinvestment Act of 2009, and the ongoing shortfall in NIH and NCI funding in relation to annual changes in the Biomedical Research and Development Price Index (BRDPI), which indicates how much the NIH budget must change to maintain purchasing power.

Taking a closer look at the President's proposed fiscal year 2012 budget, as with so many complicated and vitally important matters, the devil is in the details. While the President's budget includes a proposed increase of $95.31 million over fiscal year 2010 for NCI, the line item funding for Cooperative Clinical Research remains the same as fiscal year 2010—$254.487 million. Other NCI line items show funding decreases, including Comprehensive/Specialized Cancer Centers ($46.001 million decrease) and Research and Development Contracts ($39.409 million decrease).

AACI and its members are acutely aware of the difficult fiscal environment that the country is facing. The vast majority of our cancer centers exist within universities that are undergoing drastic budget reductions and as a consequence, directors at our member cancer centers are already facing extreme budgetary challenges. Furthermore, many of our senior and most promising young investigators are now without NCI funding and are requiring significant bridge funding from private sources. In recent years, however, it has become more challenging to raise philanthropic and other external funds. As a result, we continue to be highly dependent on Federal cancer center grants.

Recent developments at one member center, the Nevada Cancer Institute (NVCI), illustrate that need. Serving 15,000 patients since it opened in 2005, NVCI has recently lain off half of its 300 employees. In a local news report, NVCI officials cited a number of reasons for the layoffs, including a miserable economy that has hurt fundraising, a worsening reimbursement environment that provides less money from government and private insurance entities for services rendered, and fewer Federal grant dollars in the recession. ("Debt puts Nevada Cancer Institute on heels", Las Vegas Review-Journal, April 8, 2011.)

Cancer centers are already challenged to provide the infrastructure necessary to support funded researchers, and cuts in Federal grants will limit our ability to provide well functioning shared resources to investigators who depend on them to complete their research. For most matrix cancer centers, the majority of NCI grant funds are used to sustain the shared resources so essential to basic, translational, clinical and population cancer research, or to provide matching dollars which allow departments to recruit new cancer researchers to a university and support them until they receive their first grants.

As highlighted by NCI Director Harold Varmus in a January "town hall" meeting with NCI staff, independent investigator research is a particularly valuable resource, particularly in the area of genomics and molecular epidemiology. Such research is highly dependent on state-of-the-art shared resources like tissue processing and banking, DNA sequencing, microRNA platforms, proteomics, biostatistics and biomedical informatics. This infrastructure is expensive, and it is not clear where cancer centers would turn for alternative funding if NCI grant contributions to these efforts were reduced.

An investigator and medicinal chemist at a large AACI member center spent 7 years developing two new targeted drugs that are now in clinical trial testing. One

agent shows promise in cancers of the blood; the other against breast, colon, lung and prostate tumors. Research on these agents required advanced technologies provided by the center's shared resources, including analytical cell-sorting, microarray assays, and toxicopathological evaluations of mouse models, which are an essential part of drug discovery. If budget cuts had forced the closure of one or more of these shared resources, these new targeted therapies might never have made it to the patients who are now benefiting from them. The researcher has 8 to 10 more compounds in the pipeline, the fate of which hinges largely on the 2012 budget. Unfortunately, hundreds of other promising cancer researchers across the U.S. share this troubling uncertainty.

*Cancer Research: Benefiting Americans' Health and Economic Well-being*

Cancer's financial and personal impact on America is substantial and growing—one in two men and one in three women will face cancer in their lifetimes, and cancer cost our Nation more than $228 billion in 2008 (Centers for Disease Control and Preventions, Addressing The Cancer Burden: At A Glance 2010).

The U.S. Centers for Disease Control & Prevention's latest report on cancer survivorship, "Cancer Survivors-United States, 2007", shows that the number of cancer survivors in the United States increased from 3 million in 1971 to 9.8 million in 2001 and 11.7 million in 2007—an increase from 1.5 percent to 4 percent of the U.S. population. Cancer survivors largely consist of people who are 65 years of age or older and women. More than a million people were alive in 2007 after being diagnosed with cancer 25 years or more earlier. Of the 11.7 million people living with cancer in 2007, 7 million were 65 years of age or older, 6.3 million were women, and 4.7 million were diagnosed 10 years earlier or more

Investing in cancer research is a prudent step—both for the health of our Nation and for its economic well-being. Cancer research, conducted in academic laboratories across the country, saves money by reducing healthcare costs associated with the disease, enhances the United States' global competitiveness, and has a positive economic impact on localities that house a major research center.

In May 2011, AACI engaged Tripp Umbach, a research firm specializing in economic impact studies, to conduct an analysis of potential effects on statewide and national economic activity and employment resulting from NCI funding cuts to AACI cancer centers. Two reduced funding levels were considered: (1) a "conservative" 0.8 percent reduction, as implemented in the 2011 continuing resolution for the Federal budget, passed by Congress in March, and, (2) an "aggressive" 5.3 percent cut, reflecting an overall fiscal year 2012 budget reduction proposed by some members of Congress. This reduction would rollback NCI funding to 2008 levels. The impact of the 0.8 percent cut is already being felt: NCI announced on May 5 that it would need to cut funding for the NCI cancer centers program by 5 percent.

The report estimates that the total economic decline resulting from a 0.8 percent cut in NCI funding would result in a loss of at least $84.5 million to the U.S. economy, with a 5.3 percent funding drop causing a $564.7 million economic loss nationwide. The economic impact is even greater when overall NIH funding is considered. A 0.8 percent reduction in NIH funding would mean a $530.8 million loss to the U.S. economy, with a 5.3 percent reduction leading to a $3.5 billion loss.

Employment declines from the 0.8 percent NCI funding reduction would total at least 629 jobs while 4,200 jobs would be lost with a 5.3 percent funding cut. Applying the same calculations to total NIH appropriations would eliminate nearly 4,000 jobs based on the conservative reduction, increasing to 26,300 jobs lost with a 5.3 percent cut. It is important to note that research and health sciences jobs are generally high-paying and the loss of even a handful of such jobs can have a measurable effect on local economic activity.

While the economic aspects of cancer research are important, what cannot be overstated is the impact cancer research has had on individuals' lives—lives that have been lengthened and even saved by virtue of discoveries made in cancer research laboratories at cancer centers across the United States.

Biomedical research has provided Americans with better cancer treatments, as well as enhanced cancer screening and prevention efforts. Some of the most exciting breakthroughs in current cancer research are those in the field of personalized medicine. In personalized medicine for cancer, not only is the disease itself considered when determining treatments, but so is the individual's unique genetic code. This combination allows physicians to better identify those at risk for cancer, detect the disease, and treat the cancer in a targeted fashion that minimizes side effects and refines treatment in a way to provide the maximum benefit to the patient.

In the laboratory setting, multi-disciplinary teams of scientists are working together to understand the significance of the human genome in cancer. For instance, the Cancer Genetic Markers of Susceptibility initiative is comparing the DNA of

men and women with breast or prostate cancer with that of men and women without the diseases to better understand the diseases. The Cancer Genome Atlas is in development as a comprehensive catalog of genetic changes that occur in cancer.

Illustrating the successes realized by cancer research, NCI's most recent Annual Report to the Nation on the Status of Cancer reported that rates of death in the United States from all cancers for men and women continued to decline between 2003 and 2007, the most recent reporting period available. The report also finds that the overall rate of new cancer diagnoses for men and women combined decreased an average of slightly less than 1 percent per year for the same period.

Despite those improvements, "cancer disparities" abound, with different groups of cancer sufferers and cancer types showing little improvement or higher rates of incidence. For example, childhood cancer incidence rates (rates of new diagnoses) continued to increase while death rates in this age group decreased. Childhood cancer is classified as cancers occurring in those 19 years of age or younger. And there are several other forms of cancer (e.g. pancreatic, lung) and patient populations (racial and ethnic minorities, the poor, those with psychosocial issues) with high rates of cancer mortality and morbidity. Furthermore, with the increased incidence and survival comes higher morbidity because two-thirds of this surviving patient population experience late effects that are classified as serious to life-threatening.

*The Nation's Cancer Centers*

The nexus of cancer research in the United States is the Nation's network of cancer centers represented by AACI. These cancer centers conduct the highest-quality cancer research anywhere in the world and provide exceptional patient care. The Nation's research institutions, which house AACI's member cancer centers, receive an estimated $3.71 billion from the National Cancer Institute (NCI) to conduct cancer research in fiscal year 2010; more than two-thirds of NCI's total budget (U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute 2010 Fact Book). In fact, approximately 84 percent of NCI's budget supports research at nearly 650 universities, hospitals, cancer centers, and other institutions in all 50 States. Because these centers are networked nationally, opportunities for collaborations are many—assuring wise and non-duplicative investment of scarce Federal dollars.

In addition to conducting basic, clinical, and population research, the cancer centers are largely responsible for training the cancer workforce that will practice in the United States in the years to come. Much of this training depends on Federal dollars, via training grants and other funding from NCI. Sustained Federal support will significantly enhance the centers' ability to continue to train the next generation of cancer specialists—both researchers and providers of cancer care.

By providing access to a wide array of expertise and programs specializing in prevention, diagnosis, and treatment of cancer, cancer centers play an important role in reducing the burden of cancer in their communities. The majority of the clinical trials of new interventions for cancer are carried out at the nation's network of cancer centers.

*Conclusion*

These are exciting times in science and, particularly, in cancer research. The AACI cancer center network is unrivaled in its pursuit of excellence, and places the highest priority on affording all Americans access to superior cancer care, including novel treatments and clinical trials. It is through the power of collaborative innovation that we will accelerate progress toward a future without cancer, and research funding through the NIH and NCI is essential to achieving our goals.

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PREPARED STATEMENT OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 134 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians. The association appreciates the opportunity to address four programs that play critical roles in assisting medical schools and teaching hospitals to fulfill their missions of education, research, and patient care: the National Institutes of Health (NIH); the Agency for Healthcare Research and Quality (AHRQ); health professions education funding through the Health Resources and Services Administration (HRSA)'s Bureau of Health Professions; and the National Health Service Corps. The AAMC appreciates the Subcommittee's longstanding, bipartisan efforts to strengthen these programs.

*National Institutes of Health*.—The NIH is one of the Nation's greatest achievements. The Federal Government's unwavering support for medical research through the NIH has created a scientific enterprise that is the envy of the world and has contributed greatly to improving the health and well-being of all Americans—indeed of all humankind.

The AAMC is grateful to the Subcommittee for its efforts to prioritize NIH funding in fiscal year 2011 and supports the budget request of $31.748 billion for NIH in fiscal year 2012. More than 83 percent of NIH research funding is awarded to more than 3,000 research institutions in every State; at least half of this funding supports life-saving research at America's medical schools and teaching hospitals. This successful partnership not only lays the foundation for improved health and quality of life, but also strengthens the Nation's long-term economy.

The foundation of scientific knowledge built through NIH-funded research drives medical innovation that improves health and quality of life through new and better diagnostics, improved prevention strategies, and more effective treatments. NIH research has contributed to dramatically increased and improved life expectancy over the past century. A baby born today can look forward to an average life span of nearly 78 years—almost three decades longer than a baby born in 1900, and life expectancy continues to increase. People are staying active longer, too: the proportion of older people with chronic disabilities dropped by nearly a third between 1982 and 2005. Thanks to insights from NIH-funded studies, the death rate for coronary heart disease is more than 60 percent lower—and the death rate for stroke, 70 percent lower—than in the World War II era.

For example, a new ability to comprehend the genetic mechanisms responsible for disease is already providing insights into diagnostics and identifying a new array of drug targets. We are entering an era of personalized medicine, where prevention, diagnosis, and treatment of disease can be individualized, instead of using the standardized approach that all too often wastes healthcare resources and potentially subjects patients to unnecessary and ineffective medical treatments and diagnostic procedures.

Peer-reviewed, investigator-initiated basic research is the heart of NIH research. These inquiries into the fundamental cellular, molecular, and genetic events of life are essential if we are to make real progress toward understanding and conquering disease. Additional funding is needed to sustain and enhance basic research activities, including increasing support for current researchers and promoting opportunities for new investigators and in those areas of biomedical science that historically have been underfunded.

The application of the results of basic research to the detection, diagnosis, treatment, and prevention of disease is the ultimate goal of medical research. Clinical research not only is the pathway for applying basic research findings, but it often provides important insights and leads to further basic research opportunities. The AAMC supports additional funding for the continued expansion of clinical research and clinical research training opportunities, including rigorous, targeted post-doctoral training; developmental support for new and junior investigators; and career support for established clinical investigators, especially to enable them to mentor new investigators.

Anecdotal evidence suggests that changes in healthcare delivery systems and other financial factors pose a serious threat to the research infrastructure of America's medical schools and teaching hospitals, particularly for clinical research. The AAMC supports efforts to enhance the research infrastructure, including resources for clinical and translational research; instrumentation and emerging technologies; and animal and other research models.

Among the areas NIH has identified as ripe for investment and integral to the health of the American people is enhancing the evidence base for healthcare decisions. NIH's long-standing investment in Comparative Effectiveness Research (CER) has informed the clinical guidelines that assist physicians and their patients in making better decisions about the most effective care. Knowledge from NIH-supported CER has changed the way diabetes, atrial fibrillation, hypertension, HIV/AIDS, schizophrenia, and many other conditions are treated. In addition to diagnostic and treatment trials, knowing more about the performance of disease prevention initiatives and medical care delivery will improve health.

The AAMC supports efforts to reinvigorate research training, including developing expanded medical research opportunities for minority and disadvantaged students. For example, the volume of data being generated by genomics research, as well as the increasing power and sophistication of computing assets on the researcher's lab bench, have created an urgent need, both in academic and industrial settings, for talented individuals well-trained in biology, computational technologies,

bioinformatics, and mathematics to realize the promise offered by modern interdisciplinary research.

The AAMC is heartened by the Administration's proposals to provide a four percent stipend increase for predoctoral and postdoctoral research trainees supported by NIH's Ruth L. Kirschstein National Research Service Awards program. These stipend increases are necessary if medical research is to remain an attractive career option for the brightest U.S. students. Attracting the most talented students and postdoctoral fellows is essential if the United States is to retain its position of world leadership in biomedical and behavioral research.

As Raymond Orbach, former Under Secretary for Science at the Department of Energy for President George W. Bush, noted in a recent editorial in Science, "Other countries, such as China and India, are increasing their funding of scientific research because they understand its critical role in spurring technological advances and other innovations. If the United States is to compete in the global economy, it too must continue to invest in research programs."

*Agency for Healthcare Research and Quality*.—Complementing the medical research supported by NIH, AHRQ sponsors health services research designed to improve the quality of healthcare, decrease healthcare costs, and provide access to essential healthcare services by translating research into measurable improvements in the healthcare system. The AAMC firmly believes in the value of health services research as the Nation continues to strive to provide high-quality, efficient, and cost-effective healthcare to all of its citizens. The AAMC joins the Friends of AHRQ in recommending $405 million for the agency in fiscal year 2012.

As the lead Federal agency to improve healthcare quality, AHRQ's overall mission is to support research and disseminate information that improves the delivery of healthcare by identifying evidence-based medical practices and procedures. The Friends of AHRQ funding recommendation will allow AHRQ to continue to support patient-centered health research and other valuable research initiatives including strategies for translating the knowledge gained from patient-centered research into clinical practice, healthcare delivery, and provider and patient behaviors. These research findings will better guide and enhance consumer and clinical decisionmaking, provide improved healthcare services, and promote efficiency in the organization of public and private systems of healthcare delivery.

*Health Professions Funding*.—The Title VII and VIII health professions and nursing education programs are the only Federal programs designed to improve the supply, distribution, and diversity of the Nation's healthcare workforce. For almost 50 years, Title VII and Title VIII have provided education and training opportunities to a wide variety of aspiring healthcare professionals, both preparing them for careers in the health professions and helping bring healthcare services to our rural and underserved communities. Through loans, loan guarantees, and scholarships to students, and grants and contracts to academic institutions and non-profit organizations, the Title VII and Title VIII programs fill the gaps in the supply of health professionals not met by traditional market forces. The AAMC supports the fiscal year 2012 request of $762.5 million for these important workforce programs in the upcoming fiscal year.

Since 1963, the Title VII and Title VIII education and training programs have helped the workforce adapt to the evolving healthcare needs of the ever-changing American population. In an effort to renew and update Titles VII and VIII to meet current workforce challenges, the programs were reauthorized in 2010—the first reauthorization in the past decade. Reauthorization not only improved the efficiency of the Title VII and Title VIII programs, but also laid the groundwork for innovative programs with an increased focus on recruiting and retaining professionals in underserved communities.

The AAMC appreciates the Subcommittee's longstanding support of the Title VII and Title VIII programs, as well as bipartisan recognition that a strong healthcare workforce is essential to the continued health and prosperity of the American people, particularly in the face of unprecedented existing and looming provider shortages. However, recognition alone will not solve the significant disparities between the needs of the American people and the number of providers willing and able to care for them. To ensure that the Nation's already fragile healthcare system is able to care for the expanding elderly population; meet the unique needs of the country's sick and ailing children and minority populations; and provide essential primary care services to the neediest amongst us, it is essential that Congress prioritize the healthcare workforce with a strong commitment to the Title VII and Title VIII health professions programs in fiscal year 2012.

In addition to funding for Title VII and Title VIII, HRSA's Bureau of Health Professions also supports the Children's Hospitals Graduate Medical Education program. This program provides critical Federal graduate medical education support

for children's hospitals to prepare the future primary care workforce for our Nation's children and for pediatric specialty care—the greatest workforce shortage in children's healthcare. The AAMC has serious concerns about the President's plan to eliminate support for this essential program in fiscal year 2012, as well as the $48.5 million (15 percent) cut imposed on the program in fiscal year 2011. At a time when the Nation faces a critical doctor shortage and more Americans are about to enter the health insurance system, any cuts to funding that supports physician training will have serious repercussions for Americans' health. We strongly urge restoration to $317.5 million in fiscal year 2012.

*National Health Service Corps*.—The AAMC lauds the commitment of the Affordable Care Act to address health professional workforce shortages by authorizing up to $535.1 million for the NHSC in fiscal year 2012. The NHSC is widely recognized—both in Washington and in the underserved areas it helps—as a success on many fronts. It improves access to healthcare for the growing numbers of underserved Americans, provides incentives for practitioners to enter primary care, reduces the financial burden that the cost of health professions education places on new practitioners, and helps ensure access to health professions education for students from all backgrounds. Over its 39-year history, the NHSC has offered recruitment incentives, in the form of scholarship and loan repayment support, to more than 37,000 health professionals committed to serving the underserved.

In spite of the NHSC's success, demand for health professionals across the country remains high. At a field strength of 7,530 in fiscal year 2010, the NHSC fell over 24,000 practitioners short of fulfilling the need for primary care, dental, and mental health practitioners in Health Professions Shortage Areas (HPSAs), as estimate by HRSA. While the "American Recovery and Reinvestment Act of 2009" (Public Law 111–5) provided a temporary boost in annual awards, this increase must be sustained to help address the health professionals workforce shortage and growing maldistribution.

The AAMC supports the president's fiscal year 2012 budget request of $124 million, which returns the NHSC to fiscal year 2008 discretionary levels. The president's budget also assumes that the NHSC has access to $295 million in additional dedicated funding through the HHS Secretary's CHC Fund. This additional funding is necessary to sustain the increased NHSC field strength and help address current health professional workforce shortages. The AAMC further recommends that the Subcommittee include report language directing the Secretary to provide this enhanced funding for the NHSC over the fiscal year 2008 level, as directed under healthcare reform.

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## Prepared Statement of the Association of American Veterinary Medical Colleges

The Association of American Veterinary Medical Colleges (AAVMC) is pleased to submit this statement for the record in support of the fiscal year 2012 budget request of $449.5 million for the health professions education programs authorized under Title VII of the Public Health Service Act and administered through the Health Resources and Services Administration (HRSA). AAVMC is also pleased to provide comments on the pending transfer of authorities of the National Center for Research Resources (NCRR) within the National Institutes of Health (NIH).

AAVMC provides leadership for and promotes excellence in academic veterinary medicine to prepare the veterinary workforce with the scientific knowledge and skills required to meet societal needs through the protection of animal health, the relief of animal suffering, the conservation of animal resources, the promotion of public health, and the advancement of medical knowledge. AAVMC provides leadership for the academic veterinary medical community, including in the United States all 28 colleges of veterinary medicine, nine departments of veterinary science, eight departments of comparative medicine, two other veterinary medical educational institutions; and internationally, all five veterinary medical colleges in Canada, eleven international colleges of veterinary medicine, and three international affiliate colleges of veterinary medicine.

The Title VII and VIII health professions and nursing programs provide education and training opportunities to a wide variety of aspiring healthcare professionals, including veterinarians. An essential component of the healthcare safety net, the Title VII and Title VIII programs are the only Federal programs designed to train healthcare providers in interdisciplinary settings to meet the needs of the country's special and underserved populations, as well as to increase minority representation in the healthcare workforce.

While we are keenly aware that the Subcommittee continues to face difficult decisions as it seeks to improve the Nation's fiscal health, a continued Congressional commitment to programs supporting healthcare workforce development is essential to the physical health and prosperity of the American people.

The two areas within HRSA of greatest importance to AAVMC members are the Public Health Workforce Development programs and Student Financial Assistance.

The Public Health Workforce Development programs are designed to increase the number of individuals trained in public health, to identify the causes of health problems, and to respond to such issues as managed care, new disease strains, food supply, and bioterrorism. The Public Health Traineeships and Public Health Training Centers seek to alleviate the critical shortage of public health professionals by providing up-to-date training for current and future public health workers, particularly in underserved areas. The Title VII reauthorization reorganized this cluster to include a focus on loan repayment as an incentive for public health professionals to practice in disciplines and settings experiencing shortages. The Public Health Workforce Loan Repayment Program provides loan repayment for public health professionals accepting employment with Federal, State, local, and tribal public health agencies.

AAVMC is also working to amend these authorizations so that veterinarians engaged in public health are explicitly included and prioritized for funding as their counterparts in human medicine and dentistry are. On March 8, 2011 the United States House of Representatives passed H.R. 525, the Veterinary Public Health Amendments Act. AAVMC is eager to see this legislation pass the Senate and become law so that the urgent workforce needs of veterinarians engaged in public health are fully recognized and supported, as the needs of their counterparts in human medicine are.

The loan programs under Student Financial Assistance support financially needy and disadvantaged medical and nursing school students in covering the costs of their education The Health Professional Student Loan (HPSL) program provides loans covering the cost of attendance for financially needy health professions students based on institutional determination. The HPSL program is funded out of each institution's revolving fund and does not receive Federal appropriations. The Loans for Disadvantaged Students program provides grants to health professions institutions to make loans to health professions students from disadvantaged backgrounds.

AAVMC would also like to express concern over the pending reorganization and possible elimination of NCRR programs over the coming fiscal year. We recognize the importance of the NIH's initiative to create the National Center for Advancing Translational Sciences (NCATS) and welcome the potential benefits to our Nation's health of an invigorated focus on translational medicine and therapeutics. AAVMC's faculty members are proud of their significant contributions toward improving human health through transdisciplinary involvement and collaboration in translational research and comparative medicine. The support offered by NCRR programs and resources to our institutions and faculty have made possible their important contributions to our Nation's health.

To successfully fulfill its mission of accelerating the development and delivery of new, more effective therapeutics, NCATS will rely on a diverse team of appropriately trained laboratory scientists and clinical researchers capitalizing on the development of tools and technologies and making discoveries at molecular and cellular levels that can be tested and proven in animal-based studies. Although a logical and rational argument can be made for including NCRR's Clinical and Translational Science Award (CTSA) program, which is designed to develop teams of investigators from various fields of research who can transform scientific discoveries made in the laboratory into treatments and strategies for patients in the clinic, into the new NCATS, the same cannot be said for excluding and dismembering other components of NCRR, such as animal resources, training programs, and high-end instrumentation and technologies which are so critical to NCATS mission.

Further, as indicated in the NCRR Task Force Straw Model, proposing to subdivide these other NCRR components disrupts the extant scientific synergies that have been demonstrated meritorious to date, and forfeits the strategic relationships that have been built between programs over the last 20 years. For example, splitting the animal resources into different administrative structures erects a bureaucratic obstacle that needlessly hinders the flow of basic scientific discoveries made in induced genetic mutations in mice to clinically applicable mechanisms-of-action studied and tested in non-human primates.

Although it is expected that following this restructuring NCRR will no longer exist as a center, a rational consideration would be to maintain a large component of NCRR programs together after reassignment of the CTSA program within the

new NCATS. Those charged with making these decisions should be mindful that NCRR's unique, cross-cutting programs are and have been successful through careful planning, thoughtful leadership, and effective management by its administrative and scientific staff, program officers, and officials who understand these programs and are most qualified to ensure continued success of their respective programs and initiatives.

We urge members of this committee to examine the issues raised above and seek answers from the Administration as you conduct the constitutionally mandated responsibility of overseeing Federal agencies and their actions, such as the proposed reorganization within NIH.

Thank you for the opportunity to provide comments on the fiscal year 2012 budget for the Department of Health and Human Services. AAVMC is please to serve as a resource to Congress as you debate these important issues. Please feel free to contact me directly at 202–371–9195 x. 117 or by writing to bsmith@aavmc.org.

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PREPARED STATEMENT OF THE ASSOCIATION OF INDEPENDENT RESEARCH INSTITUTES

The Association of Independent Research Institutes (AIRI) respectfully submits this written testimony for the record to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies. AIRI appreciates the commitment that the members of this Subcommittee have made to biomedical research through your strong support for the National Institutes of Health (NIH), and recommends that you maintain this support for NIH in fiscal year 2012 by providing $31.987 billion for NIH in fiscal year 2012, which represents a 3.4 percent increase above the fiscal year 2011 level.

AIRI is a national organization of more than 80 independent, non-profit research institutes that perform basic and clinical research in the biological and behavioral sciences. AIRI institutes vary in size, with budgets ranging from a few million to hundreds of millions of dollars. In addition, each AIRI member institution is governed by its own independent board of directors, which allows our members to focus on discovery-based research while remaining structurally nimble and capable of adjusting their research programs to emerging areas of inquiry. Researchers at independent research institutes consistently exceed the success rates of the overall NIH grantee pool, and receive about 10 percent of NIH's peer-reviewed, competitively awarded extramural grants.

In recent years, Congress has taken important steps to jump start the Nation's economy through investments in science. Simultaneously, the NIH community is advancing and accelerating the biomedical research agenda in this country by focusing on scientific opportunities to address public health challenges. However, flat NIH budgets since 2003 have affected the agency's ability to pursue new, cutting-edge opportunities. This funding uncertainty is disruptive to training, careers, long-range projects, and ultimately, to research progress. The research engine needs a predictable, sustained investment in science to maximize the Nation's return.

Not only is NIH research essential to advancing health, it also plays a key economic role in communities nationwide. More than 83 percent of NIH funding is spent in communities across the Nation, creating jobs at more than 3,000 independent research institutions, universities, teaching hospitals, and other institutions in every State. NIH research also supports long-term competitiveness for American workers. NIH funding forms one of the key foundations for sustained U.S. global competitiveness in industries like biotechnology, medical device and pharmaceutical development, and more.

Highlighted below are examples of how independent research institutes uniquely contribute to the NIH mission and activities.

*Translating Research into Treatments and Therapeutics*.—To further its primary goal of improving health, NIH is engaged in a significant reorganization process focused on advancing translational science. AIRI looks forward to collaborating with NIH in this area as independent research institutes are particularly adept at translating basic discoveries into therapeutics, often partnering with industry. As a network of efficient, nimble independent research institutes that have been conducting translational research for years, AIRI is well-positioned to be a strong partner in bringing research from the bench to the bedside.

Currently, over 15 AIRI member institutions are affiliated and collaborate with the Clinical and Translational Science Awards (CTSA) program. Many AIRI institutes also support research on human embryonic stem cells (hESC) with the hope of discovering new and innovative disease interventions. However, uncertainty surrounding NIH funding and hESC research will hinder the agency's efforts to ad-

vance the introduction of new, life-saving cures and treatments into the marketplace.

*Fostering the Next Generation Scientific Workforce*.—The biomedical research community is dependent upon a knowledgeable, skilled, and diverse workforce to address current and future critical health research questions. While the primary function of AIRI member institutions is research, most are highly involved in training the next generation of biomedical researchers and ensuring that a pipeline of promising scientists are prepared to make significant and potentially transformative discoveries in a variety of areas.

AIRI supports policies that promote the United States' ability to maintain a competitive edge in biomedical science. Initiatives focusing on career development and recruitment of a diverse scientific workforce are important to innovation in biomedical research and the public health of the Nation. The cultivation and preservation of this workforce is dependent upon several factors:

—The ability to recruit scientists and students globally is essential to maintaining a strong workforce.

—Training programs both in basic and clinical biomedical research, initiatives focusing on career development, and recruiting a diverse scientific workforce are important to innovation in biomedical research for the benefit of public health.

—The continued national emphasis on promoting education in the fields of science, technology, engineering, and mathematics (STEM) is key to bolstering the pipeline.

*Pursuing New Knowledge*.—The NIH model for conducting biomedical research, which involves supporting scientists at universities, medical centers, and independent research institutes, provides an effective approach to making fundamental discoveries in the laboratory that can be translated into medical advances that save lives. Moreover, efforts to expand the knowledge base in medical and associated sciences bolster the Nation's economic well-being and ensure a continued high return on the public investment in research.

AIRI member institutions are private, stand-alone research centers that set their sights on the vast frontiers of medical science, specifically focused on pursuing knowledge about the biology and behavior of living systems and the application of that knowledge to improve human life and reduce the burdens of illness and disability. Additionally, AIRI member institutes have embraced technologies and research centers to collaborate on biological research for all diseases. Using advanced technology platforms or "cores," AIRI researchers use genomics, imaging, and other broad-based technologies to advance therapeutics development and drug discovery.

*Providing Efficiency and Flexibility*.—AIRI member institutes' small size and flexibility provide an environment that is particularly conducive to creativity and innovation. Independent research institutes possess a unique versatility and culture that encourages them to share expertise, information, and equipment across all research institutions and elsewhere. These collaborative activities help minimize bureaucracy and increase efficiency, allowing for fruitful partnerships with entities in a variety of disciplines and industries. Also, unlike institutes of higher education, independent research institutes are able to focus solely on scientific inquiry and discoveries, allowing them to respond quickly to the research needs of the country.

*Supporting Local Economies*.—AIRI is unique from other biomedical research organizations in that our membership consists of institutions located in regions not traditionally associated with cutting-edge research. AIRI members are located in 25 States, including many smaller or less-populated States that do not have major academic research institutions. In many of these regions, independent research institutes are major employers and economic engines, and exemplify the positive impact of investing in research and science.

AIRI thanks the Subcommittee for its important work dedicated to ensuring the health of the Nation, and we appreciate this opportunity to urge the Subcommittee to provide $31.987 billion for NIH in the fiscal year 2012 appropriations bill. AIRI looks forward to working with Congress to support research that improves the health and quality of life for all Americans.

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## PREPARED STATEMENT OF THE ASSOCIATION OF MATERNAL & CHILD HEALTH PROGRAMS

Chairman Harkin and distinguished subcommittee members: On behalf of the Association of Maternal & Child Health Programs (AMCHP), I am pleased to submit testimony describing AMCHP's request for $700 million in funding for fiscal year 2012 for the Title V Maternal and Child Health Services block grant, a 5 percent increase over fiscal year 2010. The Maternal and Child Health (MCH) Services

Block Grant supports a wide range of programs that meet State and locally determined needs. In 2008, over 40 million individuals were served by maternal and child health programs supported through the MCH Services Block Grant.

AMCHP did not develop this request lightly and our members are very cognizant of the many important and urgent discussions about reducing the Federal deficit and Government spending. However, we strongly contend that with the recent economic downturn and increased need to provide services to vulnerable populations a $700 million request is worthy of serious consideration by the Committee.

The MCH Services Block Grant provides support and services to millions of American women, infants and children, including children with special healthcare needs. It has been proven a cost effective, value-based, and flexible funding source used to address the most pressing and unique needs of each State. States and jurisdictions use the MCH Services Block Grant to design and implement a wide range of maternal and child health programs that meet national and State needs. Although specific initiatives may vary among the 59 States and jurisdictions, all of them work to accomplish the following:

—Reduce infant mortality and incidence of disabling conditions among children;
—Increase the number of children appropriately immunized against disease;
—Increase the number of children in low-income households who receive assessments and follow-up diagnostic and treatment services;
—Provide and ensure access to comprehensive perinatal care for women; preventative and child care services; comprehensive care, including long-term care services, for children with special healthcare needs; and rehabilitation services for blind and disabled children; and
—Facilitate the development of comprehensive, family centered, community-based, culturally competent, coordinated systems of care for children with special healthcare needs.

The MCH Services Block Grant improves the health of America's women and children by:

—Supporting programs that work. The MCH Services Block Grant earned the highest program rating by the Office of Management and Budget's (OMB) Program Assessment Rating Tool (PART). OMB found that MCH Services Block Grant funded programs helped to decrease the infant mortality rate, prevent disabling conditions, increase the number of children immunized, increase access to care for uninsured children, and improve the overall health of mothers and children. Reduced MCH Services Block Grant funding threatens the ability of these programs to carry on this work. Our results are available to the public through a national website known as the Title V Information System. Such a transparent system is remarkably rare for a Federal program and we are proud of the progress we have made in demonstrating results.
—Addressing the growing health needs of women, children and families. As States face economic hardships and face limits on their Medicaid and CHIP programs, more women and children seek care and preventive services through MCH Services Block Grant funded programs. Resources are needed to reduce infant mortality, provide a range of preventive health and early intervention services to those in need, improve oral healthcare, reach more children and youth with special healthcare needs, and reduce racial disparities in healthcare.
—Supporting and integrating other federally funded programs such as Community Health Centers, Healthy Start, WIC, CHIP and Medicaid. The MCH Services Block Grant helps identify areas of need in a State and works with all State and Federal programs to complement healthcare services and promote disease prevention for women, children, and families.

To help illustrate the importance of MCH Services Block Grant funding I would like to share Michelle's story. Michelle is a young girl from Iowa who was helped by Iowa's MCH Services Block Grant supported programs.

Katrina is the mother of Michelle, an energetic, 10 year old girl from Spencer, Iowa who loves listening to music, riding and playing with horses. While enrolling her daughter into school, Katrina got a "mother's feeling" that something just wasn't quite right with her daughter and despite the family pediatrician telling her that there was nothing wrong, she reached out to the Child Health Specialty Clinic (CHSC) in Sioux City for help. It was at that Title V funded clinic that it was discovered by a professional geneticist that her child was suffering from Phelan-McDermid Syndrome (PMS). PMS is caused by damage to, or deletion of, specific genes and impacts normal childhood development. Frequently, individuals with PMS have intellectual disabilities along with little or no expressive language and often there can be a large variety of moderate and even some severe physical disabilities.

Because of the proper diagnosis from the geneticist at the specialty clinic, Katrina is able to get her daughter proper physical rehabilitation treatments twice a week from her local hospital back home in Spencer. A diagnosis of this kind could not have been found without the aid of CHSC staff and the clinic in Sioux City, which along with all Iowan CHSC clinics, are funded by the Title V Maternal & Child Health Block Grant. Title V is so valuable because CHSC clinics provide direct clinical services to children when services are not readily available in the community. CHSC clinics also provide care coordination, family support and infrastructure building, all in an effort to continue to improve healthcare for children and families across the entire state.

Thanks to Child Health Specialty Clinics, Iowan families are able to receive testing and diagnosis that they can find nowhere else. Not only are the people at these clinics determined to help children medically, they also make a point to get to know the children on a personal level. Katrina describes the people at the clinic by stating: "They know each and every child when they arrive, and they truly love the kids they see." If you were to ask Katrina how she felt about Iowa's Title V funded specialty clinics she wouldn't shy away from telling you that, "They help so much. The people there really do care."

The MCH Services Block Grant supports a similar network in every State and none of this could happen without the MCH Services Block Grant. We hope that all our Nation's citizens are as proud as Katrina because of the work of MCH Services Block Grant supported programs and professionals.

America has made huge strides in advancing the health of women and children but our country faces huge challenges in improving maternal and child health outcomes and addressing the needs of vulnerable children. On the sentinel measures of how well our society is doing to protect women and children we compare badly to other industrialized countries. Today, the United States ranks 30th in infant mortality rates and 41st in maternal mortality. Sadly, every 18 minutes a baby in America dies before his or her first birthday and each day in America we lose 12 babies due to a Sudden Unexpected Infant Death. There are places in this country where the African-American infant mortality rate is double, and in some places even triple, the rate for whites. Preventable injuries remain the leading cause of death for all children. Nationwide we still fail to adequately screen all young children for developmental concerns, and childhood obesity has reached epidemic proportions threatening to reverse a century of progress in extending life expectancy to our Nation's very future.

Without adequate funding MCH Services Block Grant programs will be overwhelmed by the mismatch between State needs and available resources. AMCHP members ask for your leadership in making the important decision to fund the MCH Services Block Grant at $700 million for fiscal year 2012. State maternal and child health programs have a long track record of demonstrating our positive impact on MCH outcomes and are fully accountable for the funds that we receive. Maintaining vital funding for the MCH Services Block Grant is an effective and efficient way to support our Nation's women, children, and families.

In closing Mr. Chairman and distinguished members, I ask you to imagine with me an America in which every child has the opportunity to live until his or her first birthday; a Nation where our Federal and State partnership has effectively moved the needle on our most pressing maternal and child health issues such as infant mortality. Imagine all American parents being as proud as Katrina. Imagine a day when we are celebrating significant reductions or even the total elimination of health disparities by creatively solving our most urgent maternal and child health challenges.

The MCH Services Block Grant aims to do just that using resources effectively to improve the health of all of America's women and children. Supporting the MCH Services Block Grant is a cost-effective investment in our Nation's future. We appreciate you support and leadership in funding it at $700 million for Federal fiscal year 2012.

Thank you.

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## PREPARED STATEMENT OF THE ASSOCIATION OF MINORITY HEALTH PROFESSIONS SCHOOLS

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. Wayne J. Riley, Chairman of the Board of Directors of the Association of Minority Health Professions Schools (AMHPS) and the President and Chief Executive Officer of Meharry Medical College. AMHPS, established in 1976, is a consortium of our Nation's 12 historically

black medical, dental, pharmacy, and veterinary schools. The members are two dental schools at Howard University and Meharry Medical College; four schools of medicine at The Charles Drew University, Howard University, Meharry Medical College, and Morehouse School of Medicine; five schools of pharmacy at Florida A&M University, Hampton University, Howard University, Texas Southern University, and Xavier University; and one school of veterinary medicine at Tuskegee University. In all of these roles, I have seen firsthand the importance of minority health professions institutions and the Title VII Health Professions Training programs.

Mr. Chairman, I want to welcome you to this new role of leading the L–HHS Subcommittee. I speak for our institutions, when I say that the minority health professions institutions and the Title VII Health Professionals Training programs address a critical national need. Persistent and severe staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Furthermore, even after the landmark passage of health reform, it is important to note that our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example while blacks represent approximately 15 percent of the U.S. population, only 2–3 percent of the Nation's health professions workforce is black. Mr. Chairman, I would like to share with you how your committee can help AMHPS continue our efforts to help provide quality health professionals and close our Nation's health disparity gap.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health profession institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need—even in austere financial times.

An October 2006 study by the Health Resources and Services Administration (HRSA), entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

In fiscal year 2012, funding for the Title VII Health Professions Training programs must at the very least be maintained, especially the funding for the Minority Centers of Excellence (COEs) and Health Careers Opportunity Program (HCOPs). In addition, the funding for the National Institutes of Health (NIH)'s National Institute on Minority Health and Health Disparities (NIMHD), as well as the Department of Health and Human Services (HHS)'s Office of Minority Health (OMH), should be preserved.

*Minority Centers of Excellence*.—COEs focus on improving student recruitment and performance, improving curricula in cultural competence, facilitating research on minority health issues and training students to provide health services to minority individuals. COEs were first established in recognition of the contribution made by four historically black health professions institutions to the training of minorities in the health professions. Congress later went on to authorize the establishment of "Hispanic", "Native American" and "Other" Historically black COEs. For fiscal year 2012, I recommend a funding level of $24.602 million for COEs.

*Health Careers Opportunity Program (HCOP)*.—HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary schools in order to identify and nurture

promising students who demonstrate that they have the talent and potential to become a health professional. For fiscal year 2012, I recommend a funding level of $22.133 million for HCOPs.

*National Insitutes of Health*

*Research Centers at Minority Institutions*.—The Research Centers at Minority Institutions program (RCMI), currently administered by the National Center for Research Resources, has a long and distinguished record of helping our institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2012.

*National Institute on Minority Health and Health Disparities*.—The National Institute on Minority Health and Health Disparities (NIMHD) is charged with addressing the longstanding health status gap between minority and nonminority populations. The NIMHD helps health professions institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, and other learning resources. The NIMHD also supports biomedical research focused on eliminating health disparities and develops a comprehensive plan for research on minority health at the NIH. Furthermore, the NIMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities through the Centers of Excellence program. For fiscal year 2012, I recommend funded increases proportional with the funding of the over NIH.

*Department of Health and Human Services*

*Office of Minority Health*.—Specific programs at OMH include: assisting medically underserved communities with the greatest need in solving health disparities and attracting and retaining health professionals; assisting minority institutions in acquiring real property to expand their campuses and increase their capacity to train minorities for medical careers; supporting conferences for high school and undergraduate students to interest them in healthcareers, and supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions.

The OMH has the potential to play a critical role in addressing health disparities. For fiscal year 2012, I recommend a funding level of $65 million for the OMH.

*Department of Education*

*Strengthening Historically Black Graduate Institutions*.—The Department of Education's Strengthening Historically Black Graduate Institutions (HBGI) program (Title III, Part B, Section 326) is extremely important to AMHPS. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2012, an appropriation of $65 million is suggested to continue the vital support that this program provides to historically black graduate institutions.

Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, AMHPS' member institutions and the Title VII Health Professions Training programs and the historically black health professions schools can help this country to overcome health disparities. Congress must be careful not to eliminate, paralyze or stifle the institutions and programs that have been proven to work. The Association seeks to close the ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work towards the goal of eliminating that disparity everyday.

Thank you, Mr. Chairman, and I welcome every opportunity to answer questions for your records.

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## PREPARED STATEMENT OF THE ASSOCIATION OF PUBLIC TELEVISION STATIONS

On behalf of America's 361 public television stations, we appreciate the opportunity to submit testimony for the record on the importance of Federal funding for local public television stations.

*Corporation for Public Broadcasting—Fiscal Year 2014 Request: $495 million, 2-year advance funded*

More than 40 years after the inception of public television, local stations continue to serve as the treasured cultural institutions envisioned by their founders, reaching America's local communities with unsurpassed programming and services.

Public broadcasting serves the public good—in education, public affairs, public safety, cultural affairs and many other areas—and richly deserves public support. The overwhelming majority of Americans agree. In a recent bi-partisan poll conducted by Hart Research Associates/American Viewpoint, nearly 70 percent of American voters, including majorities of self-identifying Democrats, Independents, and Republicans, support continued Federal funding for public broadcasting. In addition, the same poll shows that Americans consider PBS to be the second most appropriate expenditure of public funds, behind only national defense. Federal support for CPB and local public television stations has resulted in a nationwide system of locally owned and controlled, trusted, community-driven and community responsive media entities.

Furthermore, the power of digital technology has enabled stations to greatly expand their delivery platforms to reach Americans where they are increasingly consuming media—online and on-demand—in addition to on-air. At the same time that stations are expanding their services and the impact they have in their communities, stations are also facing unprecedented funding challenges—presenting them with the greatest financial hurdles in their 40 year history. Every revenue source upon which our operations depend is under tremendous pressure. State funding support is in a wholesale free-fall. Despite serving as a long-time example of the incredible work that can be accomplished by a public-private partnership, this model is in peril as the current economic climate has put immense pressure on private funding sources. Continued Federal support for public broadcasting is more important now than ever before.

More than 70 percent of funding appropriated to CPB reaches local stations in the form of Community Service Grants (CSGs). On average, Federal spending makes up approximately 15 percent of local television station's budgets. However, for many smaller and rural stations, Federal funding represents more than 30–50 percent (and in a handful of instances, an even larger percentage) of their total budget. For all stations, this Federal funding is the "lifeblood" of public broadcasting, providing critical seed money to local stations which leverage each $1 of the Federal investment to raise over $6 from state legislatures, private foundations and their viewers.

Funding through CPB is absolutely essential to public television stations. Stations rely on the Federal investment to develop local programming, operate their facilities, pay their employees and provide community resources on-air, on-line and on-the-ground. This funding is particularly important to rural stations who struggle to raise local funds from individual donors due to the smaller and often economically strained population base. At the same time it is often more costly to serve rural areas due to the topography and distances between communities.

A 2007 GAO report concluded that Federal funding, such as CSGs, is an irreplaceable source of revenue, and that "substantial growth of nonFederal funding appears unlikely." It also found that "cuts in Federal funding could lead to a reduction in staff, local programming or services."

At an annual cost of about $1.39 per year for each American, public broadcasting is a smart investment. This successful public-private partnership creates important economic activity while providing an essential educational and cultural service. Public broadcasting directly supports over 21,000 jobs, and of the vast majority of them are in local public television and radio stations in hundreds of communities across America.

In addition, the advent of digital technology has created enormous potential for stations, allowing them to bring content to Americans in new, innovative ways while retaining our public service mission. Public television stations are now utilizing a wide array of digital tools to expand their current roles as educators, local conveners and vital sources of trusted information at a time when their communities need them most.

For example, in an effort to confront the dropout crisis in America's high schools, CPB has just announced a significant investment and partnership with local stations and their communities to address this daunting problem that could have disastrous effects on America's future if it is not soon addressed. Together with schools and organizations that are already addressing the dropout crisis, the stations will provide their resources and services to raise awareness, coordinate action with community partners, and work directly with students, parents, teachers, mentors, volunteers and leaders to lower the drop-out rate in their respective communities.

In order for our stations to continue playing this vital role in their communities, APTS and PBS respectfully request $495 million for CPB, two-year advance funded for fiscal year 2014.

Advance funding is essential to the mission of public broadcasting. This long-standing practice, which was enacted by President Ford in 1976, allows stations the ability to maximize fundraising efforts to leverage the promise of Federal dollars for local impact—ensuring the continuation of this strong public-private partnership. The 2-year advance funding mechanism also gives stations critical lead time needed to plan and produce high-quality programs. Additionally, the 2-year advance funding mechanism insulates programming decisions from political influence, as President Ford and the Congress intended in their initial proposal for advance funding.

*Ready To Learn—Fiscal Year 2012 Request: $27.3 million (Department of Education)*

The Ready to Learn Television program's success in improving children's literacy and preparing them for school is proven and unquestioned.

Ready To Learn combines the power of public media's on-air and online educational content with on-the-ground local station community engagement to build the reading skills of children between the ages of two and eight, especially those from low-income families or those most lacking reading skills.

Over the last 5 years, 60 independent studies have proven the effectiveness of the Ready To Learn approach. For example, in one study pre-schoolers who were exposed to a curriculum composed of programming and interactive games from top Ready To Learn programs, including SUPER WHY!, Between the Lions and Sesame Street, outscored children who received a comparison (science) curriculum in all five measures of early literacy.

In addition to being research-based and teacher tested, the Ready To Learn Television program also provides excellent value for our Federal dollars. In the last five-year grant round, public broadcasting leveraged an additional $50 million in funding to augment the $73 million investment by the Department of Education for content production. Without the investment of the Federal Government, this supplemental investment would likely end.

The President's budget proposes consolidating public broadcasting's signature early education initiative, the Ready To Learn Television program, into a larger grant program. APTS and PBS are concerned that the consolidation of this program could lead to, at worst, the elimination of this critical program that has been the driving force behind the creation of public television's unparalleled children's educational programming. At best, the proposed budget would remove the mechanisms that have provided for the tremendously efficient and effective nature in which the Ready To Learn Television program has successfully operated.

Consolidation or elimination of the Ready To Learn Television program would severely affect the ability of local stations to respond to their communities' educational needs, removing the needed resources provided by this program for children, parents and teachers.

Ready To Learn is public television. This program is a shining example of a public-private partnership as Federal funds are leveraged to create the most popular and impactful children's educational content that is supplemented by on-line and on-the-ground resources. Without the Ready To Learn Television program, millions of families would lose access to this incredible high-quality education content, especially low-income and underserved households for whom this program is targeted.

We urge the Committee to maintain the Ready To Learn Television program as a stable line-item in the fiscal year 2012 budget and resist the calls for consolidation. APTS and PBS respectfully request level funding of $27.3 million for the Ready To Learn Television program in fiscal year 2012.

*CPB Digital Funding—Fiscal Year 2012 Request: $36 million*

Public television stations have been at the forefront of the digital transition, embracing the technology early and recognizing its benefits to their viewers. Fortunately, Congress wisely recognized that the federally mandated transition to digital broadcast would place a hardship on public television's limited resources. Since 2001, Congress has provided public television stations with funds to ensure that they have the ability to continue to meet their public service mission and deliver the highest quality educational, cultural and public affairs programming post-transition.

Although the federally mandated portion of the transition is complete, what remains to be finished is the ability of stations to fully replicate their analog services in digital. As stations have completed the transition of their main transmitters, they will continue to convert their master controls, digital storage equipment and other studio equipment—necessary to produce and distribute local educational program-

ming. The CPB Digital program is also critical to providing funds that can be invested in interactive public media that maximizes investments in digital infrastructure—including such content investments as the American Archive.

Public television has used this new public digital spectrum to maximize programming choices by offering an array of new channel options, including the national offerings of Vme (the first 24-hour, Spanish-language, educational channel), World, and Create.

More importantly, stations have also used these multicast capabilities to expand their local offerings with digital channels dedicated to community or State-focused programming. Some stations have even utilized this technology to provide gavel-to-gavel coverage of their State legislatures. In addition, digital broadcasting has enabled stations to double the amount of noncommercial, children's educational programming offered to the American public.

APTS and PBS respectfully request $36 million in CPB Digital funding for fiscal year 2012 to enable stations to fully leverage this groundbreaking technology.

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PREPARED STATEMENT OF THE ASSOCIATION OF REHABILITATION NURSES

*Introduction*

On behalf of the Association of Rehabilitation Nurses (ARN), I appreciate having the opportunity to submit written testimony to the Senate L-HHS Appropriations Subcommittee regarding funding for nursing and rehabilitation related programs in fiscal year 2012. ARN represents more than 5,700 Registered Nurses (RNs) who work to enhance the quality of life for those affected by physical disability and/or chronic illness. ARN understands that Congress has many concerns and limited resources, but believes that chronic illnesses and physical disabilities are heavy burdens on our society that must be addressed.

*Rehabilitation Nurses and Rehabilitation Nursing*

Rehabilitation nurses help individuals affected by chronic illness and/or physical disability adapt to their condition, achieve their greatest potential, and work toward productive, independent lives. They take a holistic approach to meeting patients' nursing and medical, vocational, educational, environmental, and spiritual needs. Rehabilitation nurses begin to work with individuals and their families soon after the onset of a disabling injury or chronic illness. They continue to provide support and care, including patient and family education, which empowers these individuals when they return home, or to work, or school. The rehabilitation nurse often teaches patients and their caregivers how to access systems and resources.

Rehabilitation nursing is a philosophy of care, not a work setting or a phase of treatment. These nurses base their practice on rehabilitative and restorative principles by: (1) managing complex medical issues; (2) collaborating with other specialists; (3) providing ongoing patient/caregiver education; (4) setting goals for maximum independence; and (5) establishing plans of care to maintain optimal wellness. Rehabilitation nurses practice in all settings, including freestanding rehabilitation facilities, hospitals, long-term subacute care facilities/skilled nursing facilities, long-term acute care facilities, comprehensive outpatient rehabilitation facilities, home health, and private practices, just to name a few.

With the Affordable Care Act's focus on creating a system that will increase access to quality care, emphasize prevention, and decrease cost, it is critical that a substantial investment be made in the nursing workforce programs and in the scientific research that provides the basis for nursing practice. To ensure that patients receive the best quality care possible, ARN supports Federal programs and research institutions that address the national nursing shortage and conduct research focused on nursing and medical rehabilitation, e.g., traumatic brain injury. Therefore, ARN respectfully requests that the Subcommittee provide increased funding for the following programs:

*Nursing Workforce and Development Programs at the Health Resources and Services Administration (HRSA)*

ARN supports efforts to resolve the national nursing shortage, including appropriate funding to address the shortage of qualified nursing faculty. Rehabilitation nursing requires a high-level of education and technical expertise, and ARN is committed to assuring and protecting access to professional nursing care delivered by highly-educated, well-trained, and experienced Registered Nurses (RNs) for individuals affected by chronic illness and/or physical disability.

According to the Health Resources and Services Administration (HRSA), in 2010, our healthcare workforce experienced a shortage of more than 400,000 nurses.[1] The demand for nurses will continue to grow as the baby-boomer population ages, nurses retire, and the need for healthcare intensifies. Implementation of the new health reform law will also increase the need for a well-trained and highly skilled nursing workforce. The Institute of Medicine has released recommendations on how to help the nursing workforce to meet these new demands, but we are destined to fall short of these lofty goals if there are not enough nurses to facilitate change.

According to the U.S. Bureau of Labor Statistics, nursing is the Nation's top profession in terms of projected job growth, with more than 581,500 new nursing positions being created through 2018.[2] These positions are in addition to the existing jobs that healthcare employers have not been able to fill. Educating new nurses to fill these gaping vacancies is a great way to put Americans back to work and simultaneously enhance an ailing healthcare system.

ARN strongly supports the national nursing community's request of $313.075 million in fiscal year 2012 funding for Federal Nursing Workforce Development programs at HRSA.

*National Institute on Disability and Rehabilitation Research (NIDRR)*

The National Institute on Disability and Rehabilitation Research (NIDRR) provides leadership and support for a comprehensive program of research related to the rehabilitation of individuals with disabilities. As one of the components of the Office of Special Education and Rehabilitative Services at the U.S. Department of Education, NIDRR operates along with the Rehabilitation Services Administration and the Office of Special Education Programs.

The mission of NIDRR is to generate new knowledge and promote its effective use to improve the abilities of people with disabilities to perform activities of their choice in the community, and also to expand society's capacity to provide full opportunities and accommodations for its citizens with disabilities. NIDRR conducts comprehensive and coordinated programs of research and related activities to maximize the full inclusion, social integration, employment and independent living of individuals of all ages with disabilities. NIDRR's focus includes research in areas such as: employment, health and function, technology for access and function, independent living and community integration, and other associated disability research areas.

ARN strongly supports the work of NIDRR and encourages Congress to provide the maximum possible fiscal year 2012 funding level.

*National Institute of Nursing Research (NINR)*

ARN understands that research is essential for the advancement of nursing science, and believes new concepts must be developed and tested to sustain the continued growth and maturation of the rehabilitation nursing specialty. The National Institute of Nursing Research (NINR) works to create cost-effective and high-quality healthcare by testing new nursing science concepts and investigating how to best integrate them into daily practice. Through grants, research training, and interdisciplinary collaborations, NINR addresses care management of patients during illness and recovery, reduction of risks for disease and disability, promotion of healthy lifestyles, enhancement of quality of life for those with chronic illness, and care for individuals at the end of life. NINR's broad mandate includes seeking to prevent and delay disease and to ease the symptoms associated with both chronic and acute illnesses. NINR's recent areas of research focus include the following: End of life and palliative care in rural areas; research in multi-cultural societies; bio-behavioral methods to improve outcomes research; and increasing health promotion through comprehensive studies.

ARN respectfully requests $163 million in fiscal year 2012 funding for NINR to continue its efforts to address issues related to chronic and acute illnesses.

*Traumatic Brian Injury (TBI)*

According to the Brain Injury Association of America, 1.7 million people sustain a traumatic brain injury (TBI) each year.[3] This figure does not include the 150,000 cases of TBI suffered by soldiers returning from wars in Afghanistan and conflicts around the world.

The annual national cost of providing treatment and services for these patients is estimated to be nearly $60 million in direct care and lost workplace productivity. Continued fiscal support of the Traumatic Brain Injury Act will provide critical

[1] http://bhpr.hrsa.gov/healthworkforce/reports/nursing/rnbehindprojections/4.htm.
[2] http://www.bls.gov/oco/ocos083.htm#outlook.
[3] http://www.biausa.org/living-with-brain-injury.htm.

funding needed to further develop research and improve the lives of individuals who suffer from traumatic brain injury.

Continued funding of the TBI Act will promote sound public health policy in brain injury prevention, research, education, treatment, and community-based services, while informing the public of needed support for individuals living with TBI and their families.

ARN strongly supports the current work being done by the Centers for Disease Control and Prevention (CDC) and HRSA on TBI programs. These programs contribute to the overall body of knowledge in rehabilitation medicine.

ARN urges Congress to support the following fiscal year 2012 funding requests for programs within the TBI Act: $10 million for CDC's TBI registries and surveillance, prevention and national public education and awareness efforts; $8 million for the HRSA Federal TBI State Grant Program; and $4 million for the HRSA Federal TBI Protection and Advocacy Systems Grant Program.

*Conclusion*

ARN appreciates the opportunity to share our priorities for fiscal year 2012 funding levels for nursing and rehabilitation programs. ARN maintains a strong commitment to working with Members of Congress, other nursing and rehabilitation organizations, and other stakeholders to ensure that the rehabilitation nurses of today continue to practice tomorrow. By providing the fiscal year 2012 funding levels detailed above, we believe the Subcommittee will be taking the steps necessary to ensure that our Nation has a sufficient nursing workforce to care for patients requiring rehabilitation from chronic illness and/or physical disability.

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## PREPARED STATEMENT OF THE BRAIN INJURY ASSOCIATION OF AMERICA

Thank you for the opportunity to submit this written testimony with regard to the fiscal year 2012 Labor-HHS-Education appropriations bill. My testimony is on behalf of the Brain Injury Association of America (BIAA), our national network of State affiliates, and hundreds of local chapters and support groups from across the country.

In the civilian population alone every year, more than 1.7 million people sustain brain injuries from falls, car crashes, assaults and contact sports. Males are more likely than females to sustain brain injuries. Children, teens and seniors are at greatest risk.

Recently, we are seeing an increasing number of service members returning from the conflicts in Iraq and Afghanistan with TBI, which has been termed one of the signature injuries of the war. Many of these returning service members are undiagnosed or misdiagnosed and subsequently they and their families will look to community and local resources for information to better understand TBI and to obtain vital support services to facilitate successful reintegration into the community.

For the past 13 years Congress has provided minimal funding through the HRSA Federal TBI Program to assist States in developing services and systems to help individuals with a range of service and family support needs following their loved one's brain injury. Similarly, the grants to State Protection and Advocacy Systems to assist individuals with traumatic brain injuries in accessing services through education, legal and advocacy remedies are woefully underfunded. Rehabilitation, community support and long-term care systems are still developing in many States, while stretched to capacity in others. Additional numbers of individuals with TBI as the result of war-related injuries only adds more stress to these inadequately funded systems.

BIAA respectfully urges you to provide States with the resources they need to address both the civilian and military populations who look to them for much needed support in order to live and work in their communities.

With broader regard to all of the programs authorized through the TBI Act, BIAA specifically requests:

—$10 million (+$4 million) for the Centers for Disease Control and Prevention TBI Registries and Surveillance, Brain Injury Acute Care Guidelines, Prevention and National Public Education/Awareness

—$8 million (+$1 million) for the Health Resources and Services Administration (HRSA) Federal TBI State Grant Program

—$4 million (+$1 million) for the HRSA Federal TBI Protection & Advocacy (P&A) Systems Grant Program

*CDC—National Injury Center.*—The Centers for Disease Control and Prevention's National Injury Center is responsible for assessing the incidence and prevalence of TBI in the United States. The CDC estimates that 1.7 million TBIs occur each year

and 3.4 million Americans live with a life-long disability as a result of TBI. In addition, the TBI Act as amended in 2008 requires the CDC to coordinate with the Departments of Defense and Veterans Affairs to include the number of TBIs occurring in the military. This coordination will likely increase CDC's estimate of the number of Americans sustaining TBI and living with the consequences.

CDC also funds States for TBI registries, creates and disseminates public and professional educational materials, for families, caregivers and medical personnel, and has recently collaborated with the National Football League and National Hockey League to improve awareness of the incidence of concussion in sports. CDC plays a leading role in helping standardize evidence based guidelines for the management of TBI and $1 million of this request would go to fund CDC's work in this area.

*HRSA TBI State Grant Program*.—The TBI Act authorizes the HHS, Health Resources and Service Administration (HRSA) to award grants to (1) States, American Indian Consortia and territories to improve access to service delivery and to (2) State Protection and Advocacy (P&A) Systems to expand advocacy services to include individuals with traumatic brain injury. For the past 13 years the HRSA Federal TBI State Grant Program has supported State efforts to address the needs of persons with brain injury and their families and to expand and improve services to underserved and unserved populations including children and youth; veterans and returning troops; and individuals with co-occurring conditions

In fiscal year 2009, HRSA reduced the number of State grant awards to 15, in order to increase each monetary award from $118,000 to $250,000. This means that many States that had participated in the program in past years have now been forced to close down their operations, leaving many unable to access brain injury care.

Increasing the program to $8 million will provide funding necessary to sustain the grants for the 15 States currently receiving funding along with the 3 additional States added this year and to ensure funding for 4 additional States. Steady increases over 5 years for this program will provide for each State including the District of Columbia and the American Indian Consortium and territories to sustain and expand State service delivery; and to expand the use of the grant funds to pay for such services as Information & Referral (I&R), systems coordination and other necessary services and supports identified by the State.

*HRSA TBI P&A Program*.—Similarly, the HRSA TBI P&A Program currently provides funding to all State P&A systems for purposes of protecting the legal and human rights of individuals with TBI. State P&As provide a wide range of activities including training in self-advocacy, outreach, information and referral and legal assistance to people residing in nursing homes, to returning military seeking veterans benefits, and students who need educational services.

Effective Protection and Advocacy services for people with traumatic brain injury is needed to help reduce Government expenditures and increase productivity, independence and community integration. However, advocates must possess specialized skills, and their work is often time-intensive. A $4 million appropriation would ensure that each P&A can move toward providing a significant PATBI program with appropriate staff time and expertise.

*NIDRR TBI Model Systems of Care*.—Funding for the TBI Model Systems in the Department of Education is urgently needed to ensure that the Nation's valuable TBI research capacity is not diminished, and to maintain and build upon the 16 TBI Model Systems research centers around the country.

The TBI Model Systems of Care program represents an already existing vital national network of expertise and research in the field of TBI, and weakening this program would have resounding effects on both military and civilian populations. The TBI Model Systems are the only source of non-proprietary longitudinal data on what happens to people with brain injury. They are a key source of evidence-based medicine, and serve as a "proving ground" for future researchers.

In order to make this program more comprehensive, Congress should provide $11 million (+$1.5 million) in fiscal year 2011 for NIDRR's TBI Model Systems of Care program, in order to add one new Collaborative Research Project. In addition, given the national importance of this research program, the TBI Model Systems of Care should receive "line-item" status within the broader NIDRR budget.

We ask that you consider favorably these requests for the CDC, the HRSA Federal TBI Program, and the NIDRR TBI Model Systems Program to further data collection, increase public awareness, improve medical care, assist States in coordinating services, protect the rights of persons with TBI, and bolster vital research.

PREPARED STATEMENT OF THE CAEAR COALITION

On behalf of the tens of thousands of individuals living with HIV/AIDS to whom members of the Communities Advocating Emergency AIDS Relief (CAEAR) Coalition provide care, I thank Chairman Harkin and Ranking Member Shelby for affording us the opportunity to submit testimony regarding increased funding for the Ryan White HIV/AIDS Program.

The Communities Advocating Emergency AIDS Relief (CAEAR) Coalition is a national membership organization which advocates for sound Federal policy, program regulations, and sufficient appropriations to meet the care, treatment, support service and prevention/wellness needs of people living with HIV/AIDS and the organizations that serve them, focusing on ensuring access to high quality healthcare and the evolving role of the Ryan White Program.

*A Wise Investment in a Program That Works*

The Ryan White Program works. In its Program Assessment Rating Tool (PART), the White House Office of Management and Budget (OMB) gave the Ryan White Program its highest possible rating of "effective"—a distinction shared by only 18 percent of all programs rated. According to OMB, effective programs "set ambitious goals, achieve results, are well-managed and improve efficiency." Even more impressively, OMB's assessment of the Ryan White Program found it to be in the top 1 percent of all Federal programs in the area of "Program Results and Accountability." Out of the 1,016 Federal programs rated—98 percent of all Federal programs—the Ryan White Program was one of seven that received a score of 100 percent in "Program Results and Accountability."

The Ryan White Program serves as the indispensable safety net for thousands of low-income, uninsured or underinsured people living with HIV/AIDS.

—Part A provides much-needed funding to the 52 major metropolitan areas hardest hit by the HIV/AIDS epidemic with severe needs for additional resources to serve those living with HIV disease in their communities.

—Part B assists States and territories in improving the quality, availability, and organization of healthcare and support services for individuals and families with HIV.

—The AIDS Drug Assistance Program (ADAP) in Part B provides life-saving, urgently needed medications to people living with HIV/AIDS in all 50 States and the territories.

—Part C provides grants to 349 faith- and community-based primary care health clinics and public health providers in 49 States, Puerto Rico and the District of Columbia. These clinics play a central role in the delivery of HIV-related medical services to underserved communities, people of color, and rural areas where Part C funded clinics provide the only HIV specific medical services available in the region.

—Part F AETC supports training for healthcare providers to identify, counsel, diagnose, treat, and manage individuals with HIV infection and to help prevent high-risk behaviors that lead to infection. It has 130 program sites with coverage in all 50 States.

CAEAR Coalition's fiscal year 2012 funding requests for Part A, Part B base and ADAP, and Part C reflect the amounts authorized by Congress in the most recent authorization of the program.

There continues to be an increasing gap between the number of people living with HIV/AIDS in the United States in need of care and the Federal resources available to serve them. Between 2001 and 2008 the number of people living with AIDS grew 35 percent and yet funding for medical care and support services in communities with the greatest burden of HIV disease grew less than 12 percent between 2001 and 2011. Similarly, funding for Part C-funded, faith and community-based primary care clinics, which provide medical care for people living with HIV/AIDS in remote, rural and geographically isolated, urban communities nationwide, grew by only 11 percent between 2001 and 2011 as the number of people they care for grew by 52 percent. The authorized amounts we request would not fully address these funding deficiencies, but would begin to reduce the still growing gaps in funding.

We thank you in advance for your consideration of our comments and our request for:

—$751.9 million for Part A to support grants to the cities where most people with HIV/AIDS live and receive their care and treatment.

—$495 million for Part B base to provide additional needed resources to the States to bolster the public health response statewide regardless of location.

—$991 million in funding for the ADAP line item in Part B so uninsured and underinsured people with HIV/AIDS can access the anti-HIV and other prescribed medications they need to survive.
—$272.2 million for Part C to support grants to faith- and community-based organizations, healthcare agencies, and clinics.
—$50 million to fund the 11 regional centers funded under by Part F AETC to offer specialized clinical education and consultation to frontline providers.

*Sufficient Funding for Ryan White Programs Saves Money and Saves Lives*

Increased funding for Ryan White Programs will reap a significant health return for minimal investment. Data show that Part A and Part C programs have reduced HIV-related hospital admissions by 30 percent nationally and by up to 75 percent in some locations. The programs supported by the Ryan White HIV/AIDS Program also have been critical in reducing AIDS mortality by 70 percent. The Ryan White Program works, resulting in both economic stimulus and social savings by helping keep people, stable, healthy and productive.

*Growing Needs as More Tested and Entering Care*

The Centers for Disease Control and Prevention (CDC) estimates that as of 2006 there were 1,106,400 persons living with HIV/AIDS in the United States. Approximately one-half were not in care and receiving treatment. New CDC recommendations for routine HIV testing have increased the influx of newly diagnosed individuals into care, but with 56,000 newly diagnosed individuals per year, the Federal resources have not kept pace with the burgeoning need.

The fiscal year 2012 appropriation presents a crucial opportunity to provide the Ryan White Program with the levels of funding needed to address a growing epidemic in young men, as the CDC continues to increase efforts to expand HIV testing so people living with HIV know their status, control their health, and protect others.

CAEAR Coalition supports efforts to help individuals infected with HIV learn their status at the earliest possible time. However, CAEAR Coalition is concerned about the unmet demand for services created by insufficient resources at the Federal level. Researchers estimate that CDC's expanded HIV testing guidelines will bring an additional 46,000 people into care over 5 years and significantly reduce the 21 percent of people living with HIV who do not know they are infected and therefore are not in care. Bringing these individuals into care will save large sums of money in the long run, but requires an initial investment now. Research clearly shows that averting a single HIV infection saves $221,365 in lifetime healthcare costs [1], and getting people on anti-HIV treatment early lowers levels of HIV circulating in the body and reduces potential transmissions [2]—saving lives and money in the long term—but we must invest now in care and treatment to reap those rewards. Caring for individuals early in their disease will increase the cost of care by $2.7 billion over 5 years and the majority of those costs will fall to Federal discretionary programs like the Ryan White Program and will not be offset by entitlement programs.[3]

Community-based providers are stretched to provide high-quality care with the scarce resources available. CAEAR Coalition is concerned that many HIV expert medical staff are scheduled to retire and the persistent financial pressures may accelerate the loss of trained professionals in the field. This additional pressure on an already overburdened system will leave many of the more than 200,000 HIV-infected individuals who do not know their HIV status without access to the care they need.

State budget cuts have created a continuing and growing ADAP funding crisis as a record number of people are in need of ADAP services due to the economic downturn. As of May 2011, there are 8,100 people on ADAP waiting lists in 13 States. Additionally, ADAP waiting lists and other cost-containment measures, including limited formularies, reducing eligibility, or removing already enrolled people from the program, are clear evidence that the need for HIV-related medications continues to outstrip availability. ADAPs are forced to make difficult trade-offs between serving a greater number of people living with HIV/AIDS with fewer services or serving

[1] Holtgrave DR, Briddell K, Little E, Bendixen AV, Hooper M, Kidder DP, et al. Cost and threshold analysis of housing as an HIV prevention intervention. AIDS & Behavior.(2007)11(Suppl 2), S162–S166.

[2] Montaner J, Lima VD, Barrios R, et al. Association of highly active antiretroviral therapy coverage, population viral load, and yearly new HIV diagnoses in British Columbia, Canada: a population-based study. The Lancet (2010) 376(9740): 532–539.

[3] Martin EG, Paltiel AD, Walensky, RP, Schackman BR, Expanded HIV Screening in the United States: What Will It Cost Government Discretionary and Entitlement Programs? A Budget Impact Analysis. Value in Health (2010) 13: 893—902.

fewer people with more services. Additional resources are needed to reduce and prevent further use of cost-containment measures to limit access to ADAPs and to allow all State ADAPs to provide a full range of HIV antiretrovirals and treatment for opportunistic infections.

The number of clients entering the 349 Part C community health centers and outpatient clinics has consistently increased over the last 5 years. Over 247,000 unduplicated persons living with HIV/AIDS receive medical care in Part C-funded community health centers and clinics each year. These faith- and community-based HIV/AIDS providers are staggering under the burden of treatment and care after years of funding cuts prior to the modest increase in recent years. The success of the CDC's routine HIV testing recommendations has generated new clients for Part C-funded health centers and clinics too, but unfortunately with no increase in funding to provide the high quality healthcare services and treatment access people with HIV/AIDS require.

*Ryan White-Funded Programs are Economic Engines in their Communities*

Ryan White—funded programs, including many community health centers, are small businesses providing jobs, vendor contracts and other types of economic development to low-income, urban and rural communities, frequently serving as anchors for existing and new businesses and investments. These organizations employ people in their communities, providing critical entry-level jobs, community-based training and career building.

For example, a large, urban community health center brings an estimated economic impact of $21.6 million, employing 281 people, and a small, rural health center has an estimated economic impact of $3.9 million, employing 52 people. Investing in AIDS care and treatment is an investment in jobs and community development in communities that need it most.

*Ryan White Program Key to Meeting the Goals of the National HIV/AIDS Strategy*

CAEAR Coalition is eager to work with Congress to meet the challenges posed by the HIV/AIDS epidemic. In 2012, we have the collective chance to implement the community-embraced healthcare goals and policies in the National HIV/AIDS Strategy (NHAS). The National Strategy is an opportunity to reinvigorate the Nation's response to the HIV/AIDS epidemic and stop its relentless movement into our communities. The Ryan White HIV/AIDS Program is key to reaching the NHAS goals of reducing new HIV infections, increasing access to care and improving health outcomes for people living with HIV/AIDS, and reducing HIV-related health disparities. Ryan White provides HIV/AIDS care and treatment services to a significantly higher proportion of racial/ethnic minorities and women than their representation among reported AIDS cases—suggesting the programs and resources are targeted to underserved and marginalized populations. Early care and treatment are more critical than ever because we can help those infected learn their status and get into care and treatment in order to improve their own health and the health of their communities.

The Ryan White Program's history of accomplishments for public health and people living with HIV/AIDS is a wonderful legacy for the U.S. Congress. There continues to be a vast need for additional resources to address the healthcare and treatment needs of people living with HIV across the country. In recognition of its high level of effectiveness and validation over time from credible Federal Government institutions, CAEAR urges the committee to provide the Ryan White HIV/AIDS Program with the funding levels authorized by Congress for fiscal year 2012.

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## PREPARED STATEMENT OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) COALITION

The CDC Coalition is a nonpartisan coalition of more than 140 organizations committed to strengthening our Nation's prevention programs. Our mission is to ensure that health promotion and disease prevention are given top priority in Federal funding, to support a funding level for the Centers for Disease Control and Prevention (CDC) that enables it to carry out its prevention mission, and to assure an adequate translation of new research into effective State and local programs. Coalition member groups represent millions of public health workers, clinicians, researchers, educators, and citizens served by CDC programs.

The CDC Coalition believes that Congress should support CDC as an agency—not just the individual programs that it funds. In the best judgment of the CDC Coalition—given the challenges and burdens of chronic disease, a potential influenza pandemic, terrorism, disaster preparedness, new and reemerging infectious diseases and our many unmet public health needs and missed prevention opportunities—we

believe the agency will require funding of at least $7.7 billion for CDC's "core programs" in fiscal year 2012. This request represents a 36 percent increase over fiscal year 2011 and a 31 percent increase over the President's fiscal year 2012 request. We are deeply disappointed with the more than $740 million in cuts to CDC's budget authority included in the proposed fiscal year 2011 continuing resolution (CR). While CDC programs will receive significant new funding from the Prevention and Public Health Fund in fiscal year 2011, we are concerned that this funding would essentially supplant cuts made to CDC's budget authority. As you know the Prevention and Public Health Fund was intended to supplement and not supplant the base funding of our public health agencies and programs.

By translating research findings into effective intervention efforts, CDC has been a key source of funding for many of our State and local programs that aim to improve the health of communities. Perhaps more importantly, Federal funding through CDC provides the foundation for our State and local public health departments, supporting a trained workforce, laboratory capacity and public health education communications systems.

CDC also serves as the command center for our Nation's public health defense system against emerging and reemerging infectious diseases. With the potential onset of a worldwide influenza pandemic, in addition to the many other natural and man-made threats that exist in the modern world, the CDC has become the Nation's—and the world's—expert resource and response center, coordinating communications and action and serving as the laboratory reference center. States and communities rely on CDC for accurate information and direction in a crisis or outbreak.

*The Multiple Roles of CDC*

CDC serves as the lead agency for bioterrorism and other public health emergency preparedness and must receive sustained support for its preparedness programs in order for our Nation to meet future challenges. Given the challenges of terrorism and disaster preparedness, and our many unmet public health needs and missed prevention opportunities we urge you to provide adequate funding for State and local capacity grants. We ask the Subcommittee to ensure that our States and local communities are prepared in the event of an act of terrorism or other public health threat this year and in future years. Unfortunately, this is not a threat that is going away.

*Addressing the Leading Causes of Death and Disability*

The President's fiscal year 2012 budget proposes to consolidate a number of chronic disease programs within CDC. Members of the CDC Coalition are currently engaged in conversations with CDC and members of Congress to better understand what this consolidation will mean for the funding that is passed on to our State and local health and education agencies and the various programs our members have supported in the past. We look forward to working with Congress, the administration and CDC to ensure that any effort to consolidate programs leads to the best health outcomes for the American people. We must ensure that CDC's National Center for Chronic Disease Prevention and Health Promotion has the resources it needs to assist our States and communities in their efforts to reduce the burden of chronic disease.

Heart disease remains the Nation's No. 1 killer. In 2007, over 616,000 people in the United States died from heart disease, accounting for nearly 25 percent of all U.S. deaths. More women than men die of heart disease each year, and in 2007, females had higher rates of inpatient heart attack mortality than males. Stroke is the third leading cause of death and is a leading cause of disability. In 2007, stroke killed more than 135,000 people (61 percent of them women), accounting for about 1 of every 18 deaths.

Cancer is the second most common cause of death in the United States. There were an estimated 1,529,560 new cancer cases and 569,490 deaths from cancer in 2010. The financial cost of cancer is also significant. According to the National Institutes of Health (NIH), in 2008 the overall cost for cancer in the United States was more than $228.1 billion: $93.2 billion for direct medical costs, $18.8 billion for lost worker productivity due to illness, and $116.1 billion for lost worker productivity due to premature death.

Among the ways CDC is fighting cancer, is through funding the National Breast and Cervical Cancer Early Detection Program that helps low-income, uninsured and medically underserved women gain access to lifesaving breast and cervical cancer screenings and provides a gateway to treatment upon diagnosis. CDC also funds grants to States to develop Comprehensive Cancer Control (CCC) plans, bringing together a broad partnership of public and private stakeholders to set joint priorities

and implement specific cancer prevention and control activities customized to address each State's particular needs.

Although more than 25.8 million Americans have diabetes, nearly 7 million cases are undiagnosed. In 2010, about 1.9 million people aged 20 years or older were newly diagnosed with diabetes. Diabetes is the leading cause of kidney failure, nontraumatic lower-limb amputations, and new cases of blindness among adults in the United States. The total direct and indirect costs associated with diabetes were $178 billion in 2007. Preventive care such as routine eye and foot examinations, self-monitoring of blood glucose, and glycemic control could reduce these numbers.

Over the last 25 years, obesity rates have doubled among adults and children, and tripled in teens. Obesity, diet and inactivity are cross-cutting risk factors that contribute significantly to heart disease, cancer, stroke and diabetes. CDC funds programs to encourage the consumption of fruits and vegetables, encourage sufficient exercise, and to develop other habits of healthy nutrition and activity.

An estimated 443,000 people die prematurely every year due to tobacco use. CDC's tobacco control efforts seek to prevent tobacco addition in the first place, as well as help those who want to quit. We must continue to support these vital programs and reduce tobacco use in the United States.

Each day more than 3,900 young people initiate cigarette smoking. At the same time, according to CDC, only 3.8 percent of elementary schools, 7.9 percent of middle schools and 2.1 percent of high schools provide daily physical education or its equivalent for the entire school year. Almost 90 percent of young people do not eat the recommended number of servings of fruits and vegetables, while nearly 30 percent of young people are overweight or at risk of becoming overweight. And every year, almost 800,000 adolescents become pregnant and nearly 4 million teens are infected with a sexually transmitted disease. CDC plays a critical role in ensuring good public health and health promotion in our schools.

CDC provides national leadership in helping control the HIV epidemic by working with community, State, national, and international partners in surveillance, research, prevention and evaluation activities. CDC estimates that about 1.1 million Americans are living with HIV, 21 percent of who are undiagnosed. Also, the number of people living with HIV is increasing, as new drug therapies are keeping HIV-infected persons healthy longer and dramatically reducing the death rate. Prevention of HIV transmission is the best defense against the AIDS epidemic that has already killed more than 617,000 in the United States and dependant areas and is devastating populations around the globe.

The United States has the highest rates of sexually transmitted diseases (STDs) in the industrialized world. More than 19 million new infections occur each year, almost half of them among young people. CDC estimates that STDs, including HIV, cost the U.S. healthcare system as much as $15.3 billion annually. Over the past several years, significant ground has been lost in the fight against STDs. While syphilis was on the verge of elimination in the United States at the start of the decade, rates have increased by 114 percent since 2000. An adequate investment in STD prevention could save millions in annual healthcare costs in the future.

CDC and its National Center for Health Statistics collect data on chronic disease prevalence, health disparities, emergency room use, teen pregnancy, infant mortality and causes of death. The health data collected through the Behavioral Risk Factor Surveillance System, Youth Risk Behavior Survey, Youth Tobacco Survey, National Vital Statistics System, and National Health and Nutrition Examination Survey are an essential part of the Nation's statistical and public health infrastructure. Adequate funding for these activities is essential for tracking America's health as a nation and developing targeted and appropriate public health policies and prevention interventions.

We must address the growing disparity in the health of racial and ethnic minorities. CDC is helping States address serious disparities in infant mortality, breast and cervical cancer, cardiovascular disease, diabetes, HIV/AIDS and immunizations. Our members are committed to ending the disparities and we encourage the Subcommittee to provide adequate funds for these efforts.

CDC oversees immunization programs for children, adolescents and adults, and is a global partner in the ongoing effort to eradicate polio worldwide. The value of adult immunization programs to improve length and quality of life, and to save healthcare costs, is realized through a number of CDC programs, but there is much work to be done and a need for sound funding to achieve our goals. Influenza vaccination levels remain low for adults. Levels are substantially lower for pneumococcal vaccination and significant racial and ethnic disparities in vaccination levels persist among the elderly. In addition, developing functional immunization registries in all States will be less costly in the long run than maintaining the incomplete systems currently in place.

Childhood immunizations provide one of the best returns on investment of any public health program. For every dollar spent on seven vaccines recommended in the childhood series, $16.50 is saved in direct and indirect costs. An estimated 14 million cases of childhood disease and 33,000 deaths are prevented each year through timely immunization. Despite the incredible success of the program, it faces serious financial challenges.

Injuries are the leading causes of death for persons aged 1–44 years. Unintentional injuries and violence such as older adult falls, unintentional drug poisonings, child maltreatment and sexual violence accounts for over 35 percent of emergency department visits annually. Annually, injury and violence cost the United States approximately $406 billion in direct and indirect medical costs including lost productivity. Unintentional injury consistently remains the leading cause of death among young Americans ages 1–34 with 37.1 percent of unintentional fatal injuries caused by motor vehicle traffic fatalities. Conversely, violence related injuries are also substantial with homicide being the second leading cause of death for persons 15–24 years, while suicide is the 11th leading cause of death across all age groups. The consequences of these injuries can be far reaching from physical, emotional, financial turmoil to long term disability. CDC's Injury Center works to prevent unintentional and violence-related injuries to minimize the consequences of injuries when they occur by researching the problem; identifying the risk and protective factors; developing and testing interventions; ensuring widespread adoption of proven strategies and gathering data to assist States and communities to develop prevention programs and practices through the use of surveillance systems like the National Violent Death Reporting System.

One in every 33 babies born each year in the United States is born with one or more birth defects. Birth defects are the leading cause of infant mortality. Children with birth defects who survive often experience lifelong physical and mental disabilities. More than 50 million people in the United States currently live with a disability, and 17 percent of children under the age of 18 have a developmental disability. The National Center on Birth Defects and Developmental Disabilities at CDC conducts programs to protect and improve the health of children and adults by preventing birth defects and developmental disabilities; promoting optimal child development and health and wellness among children and adults with disabilities.

We also encourage the Subcommittee to provide adequate funding for CDC's Center for Environmental Health to revitalize environmental public health services at the national, State and local level and sustain current programs. These services are essential to protecting and ensuring the health and well being of the American public from threats associated with West Nile virus, climate change, terrorism, E. coli, lead-based paint and other hazards.

We appreciate the Subcommittee's past support for CDC programs in a climate of competing priorities. We thank you for considering our fiscal year 2012 request for $7.7 billion for CDC's "core programs."

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## PREPARED STATEMENT OF THE CHARLES R. DREW UNIVERSITY OF MEDICINE AND SCIENCE

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to present you with testimony. The Charles Drew University is distinctive in being the only dually designated Historically Black Graduate Institution and Hispanic Serving Institution in the Nation. We would like to thank you, Mr. Chairman, for the support that this subcommittee has given to our University to produce minority health professionals to eliminate health disparities as well as do groundbreaking research to save lives.

The Charles Drew University is located in the Watts-Willowbrook area of South Los Angeles. Its mission is to prepare predominantly minority doctors and other health professionals to care for underserved communities with compassion and excellence through education, clinical care, outreach, pipeline programs and advanced research that makes a rapid difference in clinical practice. The Charles Drew University has established a national reputation for translational research that addresses the health disparities and social issues that strike hardest and deepest among urban and minority populations.

*Health Resources and Services Administration*

*Title VII Health Professions Training Programs*.—The health professions training programs administered by the Health Resources and Services Administration (HRSA) are the only Federal initiatives designed to address the longstanding under representation of minorities in healthcareers. HRSA's own report, "The Rationale for

Diversity in the Health Professions: A Review of the Evidence," found that minority health professionals disproportionately serve minority and other medically underserved populations, minority populations tend to receive better care from practitioners of their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health professions institutions, they are significantly more likely to: (1) serve in medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

*Minority Centers of Excellence*.—The purpose of the COE program is to assist schools, like Charles Drew University, that train minority health professionals, by supporting programs of excellence. The COE program focuses on improving student recruitment and performance; improving curricula and cultural competence of graduates; facilitating faculty and student research on minority health issues; and training students to provide health services to minority individuals by providing clinical teaching at community-based health facilities. For fiscal year 2012, the funding level for COE should be $24.602 million.

*Health Careers Opportunity Program*.—Grants made to health professions schools and educational entities under HCOP enhance the ability of individuals from disadvantaged backgrounds to improve their competitiveness to enter and graduate from health professions schools. HCOP funds activities that are designed to develop a more competitive applicant pool through partnerships with institutions of higher education, school districts, and other community based entities. HCOP also provides for mentoring, counseling, primary care exposure activities, and information regarding careers in a primary care discipline. Sources of financial aid are provided to students as well as assistance in entering into health professions schools. For fiscal year 2012, the HCOP funding level of $22.133 million is recommended.

*National Institutes of Health*

*National Institute on Minority Health and Health Disparities*.—The NIMHD is charged with addressing the longstanding health status gap between under-represented minority and non minority populations. The NIMHD helps health professional institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, telemedicine technology and other learning resources. The NIMHD also supports biomedical research focused on eliminating health disparities and developed a comprehensive plan for research on minority health at NIH. Furthermore, the NIMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities through the COE program and HCOP. For fiscal year 2012, an increase proportional to NIH's increase is recommended for NIMHD to support these critical activities.

*Research Centers At Minority Institutions*.—RCMI at the National Center for Research Resources (NCRR) has a long and distinguished record of helping institutions like The Charles Drew University develop the research infrastructure necessary to be leaders in the area of translational research focused on reducing health disparities research. Although NIH has received some budget increases over the last 5 years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2012.

*Department of Health and Human Services*

*Office of Minority Health*.—Specific programs at OMH include: assisting medically underserved communities, supporting conferences for high school and undergraduate students to interest them in healthcareers, and supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions. For fiscal year 2012, I recommend a funding level of $65 million for OMH to support these critical activities.

*Department of Education*

*Strengthening Historically Black Graduate Institutions*.—The Department of Education's Strengthening Historically Black Graduate Institutions program (Title III, Part B, Section 326) is extremely important to MMC and other minority serving health professions institutions. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2012, an appropriation of $65 million is suggested to continue the vital support that this program provides to historically black graduate institutions.

*Conclusion*

Despite all the knowledge that exists about racial/ethnic, socio-cultural and gender-based disparities in health outcomes, the gap continues to widen. Not only are minority and underserved communities burdened by higher disease rates, they are less likely to have access to quality care upon diagnosis. As you are aware, in many minority and underserved communities preventative care and research are inaccessible either due to distance or lack of facilities and expertise. As noted earlier, in just one underserved area, South Los Angeles, the number and distribution of beds, doctors, nurses and other health professionals are as parlous as they were at the time of the Watts Rebellion, after which the McCone Commission attributed the so-named "Los Angeles Riots" to poor services—particularly access to affordable, quality healthcare. The Charles Drew University has proven that it can produce excellent health professionals who 'get' the mission—years after graduation they remain committed to serving people in the most need. But, the university needs investment and committed increased support from Federal, State and local governments and is actively seeking foundation, philanthropic and corporate support.

Even though institutions like The Charles Drew University are ideally situated (by location, population, community linkages and mission) to study conditions in which health disparities have been well documented, research is limited by the paucity of appropriate research facilities. With your help, the Life Sciences Research Facility will translate insight gained through research into greater understanding of disparities and improved clinical outcomes. Additionally, programs like Title VII Health Professions Training programs will help strengthen and staff facilities like our Life Sciences Research Facility.

We look forward to working with you to lessen the huge negative impact of health disparities on our Nation's increasingly diverse populations, the economy and the whole American community.

Mr. Chairman, thank you again for the opportunity to present testimony on behalf of The Charles Drew University. It is indeed an honor.

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## PREPARED STATEMENT OF THE CHILDREN'S ENVIRONMENTAL HEALTH NETWORK

On behalf of the Children's Environmental Health Network (CEHN), a national multi-disciplinary organization whose mission is to protect the fetus and the child from environmental health hazards and promote a healthy environment, I thank you for the opportunity to submit testimony in support of fiscal year 2012 appropriations for U.S. Department of Health and Human Services (HHS) for activities that protect children from environmental hazards.

CEHN appreciates the wide range of needs that you must consider for funding. We urge you to give priority to those programs that directly protect and promote children's environmental health. In so doing, you will improve not only our children's health and development, but also their educational outcomes and their future.

The world in which today's children live has changed tremendously from that of previous generations, including a phenomenal increase in the substances to which children are exposed. Every day, children are exposed to a mix of chemicals, most of them untested for their effects on developing systems. In general, children have unique vulnerabilities and susceptibilities to toxic chemicals. In some cases, an exposure which may cause little or no harm to an adult may lead to irreparable damage to a child. Exposure to neurotoxicants in utero or early childhood can result in life-long learning and developmental delays.

Investments in programs that protect and promote children's health will be repaid by healthier children with brighter futures. Protecting our children—those born as well as those yet to be born—from environmental hazards is truly a national security issue. Cutting or weakening programs that protect children from harmful chemicals in their environment is not only very costly to our Nation (for example, the Clean Air Act Amendments of 1990 have saved $1 trillion in healthcare costs[1]), such cuts will reduce the number of exceptionally bright children in future generations. Our Nation's future will depend upon its future leaders. As our experience with removing lead from gasoline illustrates (removing lead in gasoline has saved the United States an estimated $200 billion each year since 1980 in the form of

[1] Health and Welfare Benefits Analyses to Support the Second Section 812 Benefit-Cost Analysis of the Clean Air Act, Final Report, prepared by Industrial Economics for the U.S. EPA, February 2011.

higher IQs for that year's newborns)[2], when we protect children from harmful chemicals in their environment, we help to assure that they will reach their full potential. We have a responsibility to our Nation's children, and to the Nation that they will someday lead, to provide them with a healthy environment.

Additionally, American competiveness depends on having healthy educated children who grow up to be healthy productive adults. Yet, growing numbers of our children are diagnosed with chronic and developmental illnesses and disabilities. The National Academy of Sciences estimates that toxic environmental exposures play a role in 28 percent of neurobehavioral disorders in children and this does not include other conditions such as asthma or cancers. Thus it is vital that the Federal programs and activities that protect children from environmental hazards receive adequate resources. Key programs in your jurisdiction which CEHN urges you to support include:

*Centers for Disease Control and Prevention (CDC)*

The CDC is the Nation's leader in public health promotion and disease prevention, and should receive top priority in Federal funding. CDC continues to be faced with unprecedented challenges and responsibilities. CEHN applauds your support for CDC in past years and urges you to support a funding level of $7.7 billion for CDC's core programs in fiscal year 2012.

Within CDC, the National Center for Environmental Health (NCEH) is particularly important to protecting the environmental health of young children. NCEH programs, such as its efforts to continue and expand biomonitoring and its national report card on exposure information, are key national assets. CEHN is thus deeply concerned about the proposed severe cuts to CDC's environmental public health programs in the President's fiscal year 2012 budget. We join with many others in strongly opposing the proposal to consolidate CDC's Healthy Homes/Lead Poisoning Prevention and the National Asthma Control Programs and reducing funding for these programs by more than half.

The CDC's National Environmental Public Health Tracking Program helps to track environmental hazards and the diseases they may cause and to coordinate and integrate local, State and Federal health agencies' collection of critical health and environmental data. Public health officials need integrated health and environmental data so that they can protect the public's health. We urge you to reverse the CDC operating plan for fiscal year 2011, which eliminates all budget authority for this vital program. We urge you to support additional funding for the program in fiscal year 2012.

The Built Environment and Health Program (also known as the Healthy Community Design Initiative) would be abolished. Other cuts to the center's core environmental work include its radiation activities and building capacity in local health departments. We urge you to oppose these cuts.

CEHN also strongly supports CDC's Environmental Health Laboratory and its biomonitoring activities, which allow us to measure with great precision the actual levels of more than 450 chemicals and nutritional indicators in people's bodies. This information helps public health officials to determine which population groups are at high risk for exposure and adverse health effects, assess public health interventions, and monitor exposure trends over time.

*National Institutes of Health (NIH)*

CEHN joins others in the health field in requesting that the Committee provide $35 billion for the National Institutes of Health (NIH) in fiscal year 2012, including $779.4 million for the National Institute of Environmental Health Sciences (NIEHS).

NIEHS is the leading institute conducting research to understand how the environment influences the development and progression of human disease. Children are uniquely vulnerable to harmful substances in their environment, and the NIEHS plays a critical role in uncovering the connections between environmental exposures and children's health. Thus it plays a vital role in our efforts to understand how to protect children, whether it is identifying and understanding the impact of substances that are endocrine disruptors or understanding childhood exposures that may not affect health until decades later.

CEHN therefore urges you to provide $779.4 million for NIEHS in fiscal year 2012.

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[2] "Economic Gains Resulting from the Reduction in Children's Exposure to Lead in the United States," Grosse SD, Matte TD, Schwartz J, Jackson RJ, Environ Health Perspectives 2002, 110(6): doi:10.1289/ehp.02110563

*Children's Environmental Health Research Centers of Excellence*

The Children's Environmental Health Research Centers, jointly funded by the NIEHS and the EPA, play a key role in providing the scientific basis for protecting children from environmental hazards. With their modest budgets, which have been unchanged for more than 10 years, these centers generate valuable research. A unique aspect of these Centers is the requirement that each Center actively involves its local community in a collaborative partnership, leading both to community-based participatory research projects and to the translation of research findings into child-protective programs and policies. The scientific output of these centers has been outstanding. For example, findings from four Centers clearly showed that prenatal exposure to a widely used pesticide affected developmental outcomes at birth and early childhood. This was important information to EPA's decision makers in their regulation of this pesticide.

Several Centers have established longitudinal cohorts which have resulted in valuable research results. The Network is concerned that as a Center's multi-year grant ends and the Center is shuttered, these cohorts and the invaluable information they can provide are being lost. The Network urges the Committee to assure that NIEHS has the funding and the direction to support Centers in continuing these cohorts.

The work of these Centers has also shown us that, in addition to research regarding a specific pollutant or health outcome, research is desperately needed in understanding the totality of the child's environment—for example, all of the exposures the child experiences in the home, school, and child care environment—and how to evaluate those multiple factors. CEHN urges you to support these Centers, to assure they receive full funding and are extended and expanded as described above.

*National Children's Study*

CEHN urges the Committee to assure stable support for the National Children's Study (NCS) for all Institutes involved in this landmark, evidence-based longitudinal study examining the effects of environmental influences on the health and development of more than 100,000 children across the United States. This study may be the only means that we will have to understand the links between exposures and the health and development of children and to identify the antecedents for a healthy adulthood. 2012 will be a critical year for the NCS. It is vital that the funding is in place to launch the main study involving all of the centers. Already approximately 700 babies have been born into the study.

We urge the Committee to assure that the NCS retains on its original focus on environmental chemicals. While the NCS is housed at NIH, it must be a multi-agency study and it must be responsive to its mission and to the lead agencies, in and out of NIH

CEHN also asks the Committee to direct NIH to ensure that protocols are in place within NCS for measuring exposures in child care and school settings; it is critically important to understand how school and child care exposures differ from home exposures very early in the study process.

*Pediatric Environmental Health Specialty Units*

Funded jointly by the Agency for Toxic Substances and Disease Registry (ATSDR) and the U.S. Environmental Protection Agency (EPA), the Pediatric Environmental Health Specialty Units (PEHSUs) form a valuable resource network, with a center in each of the U.S. Federal regions. PEHSU professionals provide medical consultation to healthcare professionals on a wide range of environmental health issues, from individual cases of exposure to advice regarding large-scale community issues. PEHSUs also provide information and resources to school, child care, health and medical, and community groups to help increase the public's understanding of children's environmental health, and help inform policymakers by providing data and background on local or regional environmental health issues and implications for specific populations or areas. For example, following the gulf oil spill in 2010, the PEHSUs quickly produced and released a series of factsheets and advisories in multiple languages for local patients and health professionals. We urge the Committee to fully fund ATSDR's portion of this program in fiscal year 2012.

In conclusion, investments in programs that protect and promote children's health will be repaid by healthier children with brighter futures, an outcome we can all support. That is why CEHN asks you to give priority to these programs. Thank you for the opportunity to comment. CEHN's staff and I would be happy to answer any questions you may have.

PREPARED STATEMENT OF THE COALITION FOR HEALTH FUNDING

The Coalition for Health Funding is pleased to provide the Senate Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittee with a statement for the record on fiscal year 2012 funding levels for health agencies and programs. Since 1970, the Coalition for Health Funding has advocated for sufficient and sustained discretionary funding for the public health continuum to meet the mounting and evolving health challenges confronting the American people.

Our Nation's strength is inextricably linked to our health. Evidence abounds—from the Department of Defense to the U.S. Chamber of Commerce—that healthy Americans are stronger on the battlefield, have higher academic achievement, and are more productive in school and on the job. Federal funding helps discover cures and fuel innovation, ensure the safety of our drugs, food, water, and air, prevent disease, protect and respond in times of crisis, train healthcare professionals, and provide care to our Nation's most vulnerable. Much of what public health does—and the impact of Federal investment in it—is such a part of Americans' daily living that it is often invisible and almost always taken for granted. For example, Federal health funding has:

—Improved and saved the lives of many of those suffering from illnesses through scientific innovation and discovery.
—Prevented unnecessary and costly injuries through seat belt and helmet laws, mandatory airbags, and car seats for infants and toddlers.
—Promoted safe and healthy foods through dietary guidelines and food labeling that help Americans better understand what we eat and how to eat better.
—Improved the health of mothers and reduced birth defects and infant deaths through recommendations to take folic acid during early stages of pregnancy, place babies on their backs to prevent Sudden Infant Death Syndrome, and avoid tobacco and alcohol use during pregnancy.
—Combated tobacco addiction by regulating advertisements, imposing age limits on tobacco purchases, and instituting smoking bans in public places, cutting smoking rates by nearly half and reducing the number of smoking-related deaths and illnesses and the opportunity and real costs associated with them.
—Treated and eradicated infectious diseases through vaccines, preventing epidemics and saving lives.
—Improved the environment through bans on asbestos in household products and lead in paint and gasoline.
—Protected the American people in all communities from infectious, occupational, environmental, and terrorist threats.

These are just some of the ways in which Federal funding for public health has changed our lives and those of our children for the better. Still, Federal funding is necessary to further improve, save, and protect those in America and around the world. The treatments and cures for many devastating diseases are just out of reach. Racial, socioeconomic, and geographic health disparities persist. Costly and often preventable chronic conditions such as asthma, diabetes, heart disease and obesity—particularly among young people—are on the rise and threaten military readiness, academic achievement, and societal productivity. The failure to prioritize behavioral health issues continues to have stunning, debilitating social and economic consequences. Oral health is still not widely recognized as a healthcare priority in spite of the fact that tooth decay remains a common chronic disease among all ages and is preventable.

The Coalition for Health Funding's 70 national, member organizations—representing the interests of more than 100 million patients, healthcare providers, public health professionals, and scientists—support the belief that the Federal Government is an essential partner with State and local governments and the nonprofit and private sectors in improving health. A pressing and immediate goal is to build the capacity of our public health system to address America's mounting health needs under the weight of a fragile economy, an aging population, a health workforce shortage, and persisting declines in health status.

Given current fiscal challenges, the Coalition for Health Funding appreciates the efforts of the President and Congress to maintain funding for many critical health programs in the final fiscal year 2011 spending legislation. Nevertheless, the Coalition remains concerned about prospects for future cuts to health programs. The Coalition supports fiscal responsibility, but not at the expense of America's health and well-being. Cuts to federally funded health services and scientific research will not significantly reduce the deficit, nor make a dent in the national debt; discretionary health spending represents less than 2 percent of all Federal spending. These cuts adversely affect American families, cost jobs, and ultimately compromise America's global competitiveness and economic growth.

The Coalition for Health Funding organized more than 470 national, State, and local organizations and six former Surgeons General in a letter that urged Congress to increase discretionary health funding. The following list summarizes the Coalition for Health Funding's fiscal year 2012 funding recommendations for health agencies under the subcommittee's jurisdiction.

*National Institutes of Health (NIH)*

The Coalition supports $35 billion in fiscal year 2012 for NIH, a 14.4 percent increase over the fiscal year 2011 funding level and a 10 percent increase over the President's fiscal year 2012 request. The partnership between NIH and America's scientific research community is a national investment in improving the health and quality of life of all Americans. As the primary Federal agency responsible for conducting and supporting medical research, NIH-funded research drives scientific innovation and develops new and better diagnostics, improved prevention strategies, and more effective treatments.

NIH-funded research also contributes to the Nation's economic strength by creating skilled, high-paying jobs; new products and industries; and improved technologies. More than 83 percent of NIH research funding is awarded to more than 3,000 universities, medical schools, teaching hospitals, and other research institutions, located in every State. The Nation's longstanding, bipartisan commitment to NIH has established the United States as the world leader in medical research and innovation. Other countries, such as China and India, are increasing their funding of scientific research because they understand its critical role in spurring technological advances and other innovations. If the United States is to continue to compete in a global, information-based economy, it too must continue to invest in research programs such as NIH.

*Centers for Disease Control and Prevention (CDC)*

The Coalition for Health Funding recommends a level of $7.7 billion for CDC's core programs in fiscal year 2012, a 36 percent increase over fiscal year 2011 and a 31 percent increase over the President's fiscal year 2012 request. This amount is representative of what CDC needs to fulfill its core mission in fiscal year 2012; activities and programs that are essential to protect the health of the American people. CDC continues to be faced with unprecedented challenges and responsibilities, ranging from chronic disease prevention, eliminating health disparities, bioterrorism preparedness, to combating the obesity epidemic. In addition, CDC funds community programs in injury control; health promotion efforts in schools and workplaces; initiatives to prevent diabetes, heart disease, cancer, stroke, and other chronic diseases; improvements in nutrition and immunization; programs to monitor and combat environmental effects on health; prevention programs to improve oral health; prevention of birth defects; public health research; strategies to prevent antimicrobial resistance and infectious diseases; and data collection and analysis on a host of vital statistics and other health indicators. It is notable that more than 70 percent of CDC's budget flows out to States and local health organizations and academic institutions, many of which are currently struggling to meet growing needs with fewer resources.

*Health Resources and Services Administration (HRSA)*

The Coalition for Health Funding recommends an overall funding level of $7.65 billion for HRSA in fiscal year 2012, a 22 percent increase over fiscal year 2011 and a 12 percent increase over the President's fiscal year 2012 request. HRSA operates programs in every State and thousands of communities across the country. It is a national leader in providing health services for individuals and families, serving as a health safety net for the medically underserved.

Over the past several years, HRSA has received mostly level funding, undermining the ability of its successful programs to grow. Additionally, the deep cuts made to the agency in the final fiscal year 2011 continuing resolution will likely have negative consequences for public health. Therefore, the requested minimum level of funding for fiscal year 2012 is critical to allow the agency to carry out critical public health programs and services that reach millions of Americans, including developing the public health and healthcare workforce; delivering primary care services through community health centers; improving access to care for rural communities; supporting maternal and child healthcare programs; providing healthcare to people living with HIV/AIDS; and many more. However, much more is needed for the agency to achieve its ultimate mission of ensuring access to culturally competent, quality health services; eliminating health disparities; and rebuilding the public health and healthcare infrastructure.

*Substance Abuse and Mental Health Services Administration (SAMHSA)*

The Coalition for Health Funding recommends an overall funding level of $3.671 billion for SAMHSA in fiscal year 2012, an 8.6 percent increase over fiscal year 2011 and an 8.4 percent increase over the President's fiscal year 2012 request. According to recent results from a national survey conducted by SAMHSA, 45.1 million American adults in the United States have experienced mental illness over the past year. However, only two-thirds of adults in the United States with mental illness in the past year received mental health services.

In fact, suicide claims over 34,000 lives annually, the equivalent of 94 suicides per day; one suicide every 15 minutes. In the past year, 8.4 million adults aged 18 or older thought seriously about committing suicide, 2.3 million made a suicide plan, and 1.1 million attempted suicide. The funding for community mental health services from SAMHSA has never been more critical especially in light of the $2.2 billion reduction in State mental health funding for programs serving this vulnerable population.

*Agency for Healthcare Research and Quality (AHRQ)*

The Coalition for Health Funding recommends an overall funding level of $405 million for AHRQ in fiscal year 2012, a 9 percent increase over fiscal year 2011 and a 10 percent increase over the President's fiscal year 2012 request. AHRQ funds research and programs at local universities, hospitals, and health departments that improve healthcare quality, enhance consumer choice, advance patient safety, improve efficiency, reduce medical errors, and broaden access to essential services—transforming people's health in communities in every State around the Nation. Specifically, the science funded by AHRQ provides consumers and their healthcare professionals with valuable evidence to make the right healthcare decisions for themselves and their families. AHRQ's research also provides the basis for protocols that reduce hospital-acquired infections, and improve patient confidence, experiences, and outcomes.

The Coalition for Health Funding appreciates this opportunity to provide its fiscal year 2012 discretionary health funding recommendations and looks forward to working with the Subcommittee in the coming weeks and months.

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PREPARED STATEMENT OF THE COALITION FOR HEALTH SERVICES RESEARCH

The Coalition for Health Services Research (Coalition) is pleased to offer this testimony regarding the role of health services research in improving our Nation's health. The Coalition's mission is to support research that leads to accessible, affordable, high-quality healthcare. As the advocacy arm of AcademyHealth, the Coalition represents the interests of more than 4,000 scientists and policy experts throughout the country and 160 organizations that produce and use research that improves health and healthcare. We advocate for the funding to support health services research and health data; better access to data and information to use in producing this research; and more transparent dissemination of the results of this research.

Health services research studies how to make the healthcare system work better and deliver improved outcomes for more people, at great value. These scientific findings improve healthcare by informing patient and healthcare provider choices; enhancing the quality, efficiency, and value of the care patients receive; and improving patients' access to care. Health services research both uncovers critical challenges confronting our Nation's healthcare system, and seeks ways to address them. For example, health services research tells us:

—Only 55 percent of adults receive recommended care and 47 percent of children receive indicated care (McGlynn et al, 2003; Mangione-Smith et al, 2007).

—The increased prevalence of obesity is responsible for almost $40 billion of increased medical spending through 2006, including $7 billion in Medicare prescription drug costs (Finkelstein, 2009).

—How hospitals were able to achieve more than 60 percent reduction in rates of bloodstream infections in very sick patients (Pronovost et al, 2006).

—More than 83,000 excess deaths each year could be prevented in the United States if the health disparities could be eliminated (Satcher et al, 2005).

—The percentage of heart attack patients receiving needed angioplasties within the recommended 90 minutes of arriving at the hospital improved from just 42 percent in 2005 to 81 percent by 2008 (Agency for Healthcare Research and Quality, 2011).

The primary economic rationale for a Government role in funding health services research is that the private market would not adequately supply for it, since the

full economic value of the evidence is unlikely to accrue solely to its discoverer. Like any corporation making sure it is developing and providing high quality products through R&D, the Federal Government has a responsibility to get the most out of every taxpayer dollar it spends on Federal health programs—Medicare, Medicaid, veterans' and service members' healthcare—by funding research that helps enhance their performance.

Finding new ways to get the most out of every healthcare dollar is critical to our Nation's long-term fiscal health. Funding for research on the quality, value, and organization of the health system will deliver real savings for the Federal Government, employers, insurers, and consumers. Research into the merits of different policy options for delivery system transformation, patient-centered quality improvement, community health, and disease prevention offers policymakers in both the public and private sectors the information they need to improve quality and outcomes, identify waste, eliminate fraud, increase efficiency and value, and promote personal responsibility.

Despite the positive impact health services research has had on the U.S. healthcare system, and the potential for future improvements in quality and value, the United States spends less than 1 cent of every healthcare dollar on this research; research that can help Americans spend their healthcare dollars more wisely and make more informed healthcare choices.

The Coalition for Health Services Research greatly appreciates the subcommittee's efforts to increase the Federal investment in health services research and health data. We respectfully ask that the subcommittee further strengthen capacity of health services research to address the pressing challenges America faces in providing access to high-quality, efficient care for all its citizens. The following list summarizes the Coalition's fiscal year 2012 funding recommendations for agencies that support health services research and health data under the subcommittee's jurisdiction.

*Agency for Healthcare Research and Quality (AHRQ)*

AHRQ funds research and programs at local universities, hospitals, and health departments that improve healthcare quality, enhance consumer choice, advance patient safety, improve efficiency, reduce medical errors, and broaden access to essential services—transforming people's health in communities in every State around the Nation. The science funded by AHRQ provides consumers and their healthcare professionals with valuable evidence to make the right healthcare decisions for themselves and their families. AHRQ's research also provides the basis for protocols that prevent medical errors and reduce hospital-acquired infections, and improve patient confidence, experiences, and outcomes in hospitals, clinics, and physician offices.

The Coalition joins the Friends of AHRQ—an alliance of more than 250 health professional, research, consumer, and employer organizations that support the agency—in recommending an overall funding level of $405 million for AHRQ in fiscal year 2012, a 9 percent increase over fiscal year 2011 and a 10 percent increase over the President's fiscal year 2012 request. Within the funding provided to AHRQ, the Coalition recommends that the subcommittee support:

—*A Breadth of Research Topics*.—During the last decade, AHRQ's research portfolio has focused predominantly on patient safety and healthcare quality. There has been less investment in research that provides evidence to improve the efficiency and value of the healthcare system itself. The Coalition is grateful to the subcommittee for its leadership in building a more balanced research agenda at AHRQ, and requests continued support for all aspects of research outlined in AHRQ's statutory mission, including the ways in which healthcare services are organized, delivered, and financed.

—*Innovation through Competition*.—Many of the sentinel studies that have changed the face of health and healthcare in the United States—diagnosis-related groups for hospital payments, check-lists for improved patient safety, geographic variation in healthcare, re-hospitalizations among Medicare beneficiaries—are the result of ingenuity on the part of investigators and rigorous, scientific competition. Federal support for innovative approaches to problem solving increases opportunities for constructive competition and creative solutions. The Coalition is grateful to the subcommittee for its leadership in recognizing the value of investigator-initiated research at AHRQ and requests sustained momentum for these competitive, innovative grants that advance discovery and the free marketplace of ideas.

—*The Next Generation of Researchers*.—At the direction of the subcommittee, AHRQ has doubled its investment in training grants for the next generation of researchers. Still, training grants for new researchers—both physicians and

non-physicians—fall far short of what is needed to meet growing public and private sector demands for health services research. The Coalition appreciates the subcommittee's continuing support of the next generation of researchers and requests that funding for training grants be increased to ensure America stays competitive in the global research market.

—*Research Translation and Dissemination*.—Health services research has great potential to improve health and healthcare when widely used by patients, providers, and policymakers. The Coalition recommends that the subcommittee support AHRQ's research translation and dissemination activities, including patient forums, practice-based research centers, and learning networks. These programs are designed to move the best available research and decisionmaking tools into healthcare practice and thus enhance patient choice and improve healthcare delivery.

*Centers for Disease Control and Prevention (CDC)*

The National Center for Health Statistics (NCHS) is the Nation's principal health statistics agency. Housed within CDC, NCHS provides critical data on all aspects of our healthcare system through data cooperatives and surveys that serve as a gold standard for data collection around the world. The Coalition appreciates the subcommittee's leadership in securing steady and sustained funding increases for NCHS in recent years. Such efforts have allowed NCHS to reinstate some data collection and quality control efforts, continue the collection of vital statistics, and enhance the agency's ability to modernize surveys to reflect changes in demography, geography, and health delivery.

We join the Friends of NCHS—a coalition of more than 250 health professional, research, consumer, industry, and employer organizations that support the agency—in endorsing the President's fiscal year 2012 request of $162 million, a funding level that will build on previous investments and put the agency on track to become a fully functioning, 21st century, national statistical agency.

The Patient Protection and Affordable Care Act recognizes the need for linking the medical care and public health delivery systems by authorizing a new CDC research program to study public health systems and service delivery. If funded in fiscal year 2012, this program will identify effective strategies for organizing, financing, and delivering public health services in real-world community settings by, for example, comparing State and local health department structures and systems in terms of effectiveness and costs. The Coalition urges you to appropriate $35 million in fiscal year 2012 for Public Health Services and Systems Research at CDC, enabling us to study ways to improve the efficiency and effectiveness of public health service delivery.

*National Institutes of Health (NIH)*

NIH reports that it spent $1.1 billion on health services research in fiscal year 2010—roughly 3.6 percent of its entire budget—making it the largest Federal sponsor of health services research. For fiscal year 2012, the Coalition joins the Ad Hoc Group for Medical Research in requesting $35 billion for NIH in fiscal year 2012, which would, based on historical funding levels, provide roughly $1.3 billion for the agency's health services research portfolio. The Coalition believes that NIH should increase the proportion of its overall funding that goes to health services research to ensure that discoveries from clinical trials are effectively translated into health services. We also encourage NIH to foster greater coordination of its health services research investment across its institutes.

*Centers for Medicare and Medicaid Services (CMS)*

Steady funding reductions for the Office of Research, Development and Information have hindered CMS's ability to meet its statutory requirements and conduct new research to strengthen public insurance programs—including Medicare, Medicaid, and the Children's Health Insurance Program—which together cover nearly 100 million Americans and comprise almost half of America's total health expenditures. As these Federal entitlement programs continue to pose significant budget challenges for both Federal and State governments, it is critical that we adequately fund research to evaluate the programs' efficiency and effectiveness and seek ways to manage their projected spending growth.

The Coalition supports an fiscal year 2012 base funding level of $40 million for CMS's discretionary research and development budget. This funding is a critical down payment to help CMS restore research to evaluate its programs, analyze pay for performance and other tools for updating payment methodologies, and further refine service delivery methods.

In conclusion, the accomplishments of health services research would not be possible without the leadership and support of this subcommittee. Health services re-

search will continue to yield valuable scientific evidence in support of improved quality, accessibility, and affordability of healthcare. We urge the subcommittee to accept our fiscal year 2012 funding recommendations for the Federal agencies funding health services research and health data.

If you have questions or comments about this testimony, please contact our Washington, DC, representative, Emily Holubowich at eholubowich@dc-crd.com.

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PREPARED STATEMENT OF THE COALITION FOR INTERNATIONAL EDUCATION

Mr. Chairman and Members of the Subcommittee: We are pleased to submit the views of the Coalition for International Education on fiscal year 2012 funding for the Higher Education Act, Title VI and the Mutual Educational and Cultural Exchange Act, Section 102(b)(6), commonly known as Fulbright-Hays. The Coalition for International Education consists of over 30 national higher education organizations with interest in the U.S. Department of Education's international and foreign language education programs. The Coalition represents the Nation's 3,300 colleges and universities, and organizations encompassing various academic disciplines, as well as the international exchange and foreign language communities.

We express our deep appreciation for the Subcommittee's long-time support for the U.S. Department of Education's premier international and foreign language education programs noted above. We recognize the difficult decisions Congress and the Administration faced on education spending cuts for the remainder of fiscal year 2011, and now face for fiscal year 2012. However, we are deeply concerned over the severe and disproportionate $50 million or 40 percent cut to the Title VI/Fulbright-Hays programs under H.R. 1473, the final fiscal year 2011 Continuing Resolution agreement. Title VI/Fulbright-Hays contain 14 small "pipeline" programs, 12 of which are under $20 million. A cut of this magnitude will seriously weaken our Nation's world-class international education capacity, which has taken decades to build and would be impossible to easily recapture. Among the first casualties likely will be the high-cost, low-enrollment critical language programs needed for national security, such as Pashto or Urdu.

Today we strongly urge the Appropriations Committee to safeguard these programs by providing funding for them that is equal to their fiscal year 2010 funding levels in the fiscal year 2012 appropriations bill. For the International and Foreign Language Studies account, we urge a total of $125.881 million, which includes $108.360 million for Title VI–A&B; $15.576 million for Fulbright-Hays 102(b)(6); and $1.945 million for the Institute for International Public Policy, Title VI–C.

After 9/11, Congress began a decade of enhancements to Title VI/Fulbright because of the sudden awareness of an urgent need to improve the Nation's in-depth knowledge of world areas and transnational issues, and fluency of U.S. citizens in foreign languages. Unfortunately these gains and many program enhancements on strategic world areas will be eliminated unless funding is restored to fiscal year 2010 levels.

We believe maintaining a strong Federal role in these programs is critical to supporting our Nation's long-term national security, global leadership, economic competitiveness capabilities, as well as mutual understanding and collaboration around the world. Successful U.S. engagement in these areas, at home or abroad, relies on Americans with global competence, including foreign language skills and the ability to understand and function in different cultural and business environments.

*Background and Federal Role*

In 1958 at the height of the cold war, Congress created NDEA-Title VI out of a sense of crisis about U.S. ignorance of other countries and cultures. Fulbright 102(b)(6) was created in 1961 and placed with Title VI to provide complementary overseas training. These programs have served as the lynchpin for producing international specialists for more than five decades, and continue to do so. Improving over time to address new global challenges and expanded needs across the Nation's workforce, 14 Title VI/Fulbright-Hays programs support activities to improve capabilities and knowledge throughout the educational pipeline, from K–12 through the graduate levels and advanced research, with emphasis on the less commonly-taught languages and areas, such as China, Russia, India and the Muslim world. Today they are the Federal Government's most comprehensive programs supporting the development of high quality national capacity in international, foreign language and business education and research. A March 2007 report by the National Academies of Sciences (NAS) concluded, "Title VI/Fulbright-Hays serve as our Nation's foundational programs for building U.S. global competence."

This Federal-university partnership ensures resources and knowledge are available to meet national needs that are not priorities of individual States or universities. Federal resources are essential incentives to develop and sustain high-cost programs in the less commonly-taught languages and world areas, and provide extensive outreach and collaboration among educational institutions, government agencies, and corporations. Most of these programs would not exist without Federal support, especially at a time when State/local governments and institutions of higher education are financially strapped.

*Why Investing in Title VI/Fulbright-Hays Is Important*

The NAS reported in 2007: "A pervasive lack of knowledge about foreign cultures and foreign languages in this country threatens the security of the United States as well as its ability to compete in the global marketplace and produce an informed citizenry."

*Government Needs*.—The quantity, level of expertise, and availability of U.S. personnel with high-level expertise in foreign languages, cultures, and political, economic and social systems throughout the world do not match our national strategic needs at home or abroad. Some 80 Federal agencies depend in part on proficiency in more than 100 foreign languages; in 1985, only 19 agencies identified such requirements.

"Foreign language skills are vital to effectively communicate and overcome language barriers encountered during critical operations and are an increasingly key element to the success of diplomatic efforts, military operations, counterterrorism, law enforcement and intelligence missions, as well as to ensure access to Federal programs and services to Limited English Proficient (LEP) populations within the United States." *David Maurer Testimony on Foreign Language Capabilities. Departments of Homeland Security, Defense, and State Could Better Assess their Foreign Language Needs and Capabilities and Address Shortfalls, GAO, July 2010*

"As of October 31, 2008, 31 percent of Foreign Service officers in overseas language-designated positions (LDP) did not meet both the foreign languages speaking and reading proficiency requirements for their positions. State continues to face foreign language shortfalls in regions of strategic interest—such as the Near East and South and Central Asia, where about 40 percent of officers in LDPs did not meet requirements. Past reports by GAO, State's Office of the Inspector General, and others have concluded that foreign language shortfalls could be negatively affecting U.S. activities overseas." *Comprehensive Plan Needed to Address Persistent Foreign language Shortfalls, GAO, September 2009.*

*Workforce Needs*.—National security is increasingly linked to commerce, and U.S. business is widely engaged around the world with joint ventures, partnerships, and economic linkages that require its employees to have international expertise both at home and abroad.

"Most of the growth potential for U.S. businesses lies in overseas markets. Already, one in five U.S. manufacturing jobs is tied to exports. Foreign consumers, the majority of whom primarily speak languages other than English, represent significant business opportunities for American producers, as the United States is home to less than 5 percent of the world's population. American companies lose an estimated $2 billion a year due to inadequate cross-cultural guidance for their employees in multicultural situations." *Education for Global Leadership, Committee for Economic Development, 2006.*

*Education Needs*.—Education institutions at all levels are challenged to keep up with rapidly expanding 21st century needs for global competence.

— Although higher education foreign language enrollments have increased and diversified over the past decade, according to the Modern Language Association's 2010 survey, enrollments are only 8.7 percent of total student enrollments, well behind the 1960 high point of 16 percent.
— Only 5 percent of all higher education students taking foreign languages study non-European languages spoken by roughly 85 percent of the world's population.
— Less than 2 percent of students in U.S. postsecondary education study abroad, and only about half studied outside Western Europe. Yet, an educational experience abroad is an essential element for achieving foreign language fluency, learning how to function in other cultures, and developing mutual understanding with others beyond our borders.
— U.S. educational institutions from K–16 face a shortage of teachers and faculty with international knowledge and expertise across the professions and across

types of higher education institutions. This problem is especially acute for foreign language teachers of the less commonly taught languages.

*What Title VI/Fulbright-Hays Programs Do*

Title VI/Fulbright programs produce U.S. experts, prepare Americans for the global workplace, and generate knowledge on the foreign languages and business, economic, political, social, cultural and regional affairs of other countries and world areas. Grantees also engage in extensive outreach and collaboration across the educational spectrum, and with business, government, the media and the general public. Title VI-funded centers are relied upon for their expertise by Federal agencies, corporations, and local school districts. Their many accomplishments include the following:

*Language and Culture*

Through several pipeline programs, Title VI institutions provide the major, and often the only, source of national expertise and research on non-European countries and their languages.

Title VI institutions account for 21 percent of undergraduate enrollment and 56 percent of graduate enrollment in the less commonly taught languages (LCTLs) such as Arabic and Chinese. For the least commonly taught languages such as Pashto and Urdu, Title VI institutions account for 49 percent of undergraduate and 78 percent of graduate enrollments.

Title VI institutions provide instruction and R&D in over 130 languages and in all world areas, and have the capacity to teach over 200 languages. Because of the high cost per student, many of these languages would not be taught on a regular basis but for Title VI/Fulbright support. In contrast, the Defense Language Institute (DLI) and the Foreign Service Institute (FSI) together offer instruction in only 75 LCTLs.

Title VI/Fulbright programs support advanced research abroad in international, area and language studies—such as through the Fulbright programs and overseas research centers—that otherwise would have few or no other funding sources.

Title VI programs support the development and maintenance of world class digital information resources in international, area and foreign language studies—using modern technologies for accessibility—that exist no where else in the world.

Title VI/Fulbright programs provide opportunity and access to all types of institutions of higher education, including minority-serving institutions, community colleges, and small and medium-sized 4-year institutions. With seed funding from the Undergraduate International Studies and Foreign Language, Institute for International Public Policy and Fulbright programs, training, fellowship, scholarship and study abroad opportunities are provided to students, faculty and administrators.

With enhancements provided by Congress between 2000–08, Title VI National Resource Centers increased annual job placements in key sectors. 2008 placements and percent increase over 2000: Federal Government 1,515 (+32 percent), U.S. military 552 (+20 percent), international organizations 1,567 (+22 percent), and higher education 3,414 (+51 percent).

During this same period, the NRCs have seen triple digit increases in courses and enrollments in critical languages. Between 2000 and 2008, enrollments in Arabic increased from 5,218 to 16,721, in Chinese from 9,637 to 23,724, in Persian from 1,231 to 3,878, in Turkish from 594 to 1,602, and in Urdu from 221 to 904.

Examples of renowned graduates include Secretary of Defense Robert Gates, General John Abizaid, former Ambassador to Russia James Collins, advisor to six Secretaries of State Aaron David Miller, and NY Times Pulitzer prize-winning journalist Anthony Shadid.

*International Business*

Title VI supports two important programs that internationalize business education, train Americans for the global workplace, and help U.S. small and mid-size businesses engage emerging markets: Centers for International Business Education and Research (CIBERs) and Business and International Education (BIE).

CIBERs offer training at all levels of education in all 50 States, including training for managers already active in the workforce, and research on cutting edge issues affecting the U.S. business environment, the Nation's global economic competitiveness and homeland security.

Before these programs were established, few business education programs in the United States incorporated a global dimension. Over 2 million students have taken international business courses through CIBER programs and over 160,000 faculty have gained international business and cultural expertise through faculty programs, domestically and abroad.

Over 42,000 language faculty have participated in over 900 international business language workshops, and 4.5 million students across the United States have benefited from enhanced commercial foreign language instruction.

*Outreach*

Title VI/Fulbright grantees provide access to international knowledge to other institutions of higher education, government, business, K–12 and the public through web resources, seminars, training and other means. Many educators, government agencies, nonprofit groups and corporations depend on these resources. Without Title VI/Fulbright funding, this outreach would disappear.

Title VI National Resource Centers provide training and consultation for foreign language and area staff in many government agencies. For example, the U.S. Army Foreign Area Officer (FAO) Program sends its officers to Title VI centers for their M.A. in language and area studies training and has done so since the inception of the FAO program three decades ago.

Title VI Language Resource Centers (LRC) train an estimated 2,000 teachers annually, and develop resources in critical languages used by educators and government agencies. For example, an LRC recently developed a free iPad app that provides tutorials in Pashto for U.S. soldiers in Afghanistan.

CIBER and BIE grantees work closely with the U.S. Department of Commerce and with the local District Export Councils on export development. In response to President Obama's 2010 National Export Initiative (NEI), the CIBERs continue to expand the global knowledge base of U.S. companies, enabling and assisting them to export their goods and services especially to the BRIC and other emerging markets. By enabling small and mid-sized U.S. business to increase exports, CIBER/BIE activities support job creation in America and reduction of the trade deficit.

Title VI grantees also work extensively with minority-serving institutions of higher education, community colleges and K–12 on language and culture programs, as well as with the media to promote citizen understanding of complex global issues.

Clearly, this Federal-higher education partnership pays dividends that vastly outweigh the small 0.2 percent investment within the Department of Education's budget.

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PREPARED STATEMENT OF THE COALITION FOR WORKFORCE SOLUTIONS

I represent The Coalition for Workforce Solutions (CWS), a national organization exclusively representing employers, workforce development providers, vendors and service organizations that operate and utilize One-Stop Career Centers, Temporary Assistance for Needy Families initiatives, career and technical education programs and workforce investment services. Members of CWS are proud to play a role in our workforce system as it promotes economic growth while giving unemployed, underemployed and disadvantaged workers an opportunity to gain new skills.

Today, while the Nation faces many complex challenges in light of mass layoffs and business realignments, the private sector is showing signs of recovery and businesses new and old need increased assistance in addressing their workforce needs. And our national network of WIA supported workforce services is in a unique position not only to train workers for economic recovery, but to match large and small employers with qualified workers in advanced manufacturing, healthcare, energy and other high-growth sectors. As the economy grows, our workforce system should be maintained and strengthened, not reduced or targeted for elimination.

We understand the budget issues and the need for debt reduction. We are confident that through integration of workforce services there is the capacity to maintain the existing level of service to the job seekers and employers. We look to the State of Florida and Texas as the model of integrated services for replication nationwide. This will ensure our workforce development and job-training system continues its vital support for businesses of all sizes to create and retain jobs, provide needed skills and transition assistance to workers, and enhance economic growth through the private sector in thousands of communities around the country.

Our Nation's workforce systems funded through WIA have become critical partners in regional economic development efforts—from directly supporting efforts to recruit new businesses (by offering access to skilled workers and employment and training incentives), to saving money for local businesses as they begin to rehire workers. The programs also assist businesses to avert layoffs through skills upgrading, and support businesses that are closing or downsizing. These partnerships with employers and economic development services are critical to helping businesses survive and contribute to regional economic growth and prosperity. Now is not the time

to take away these vital services when economic growth is paramount to our recovery and competitiveness.

WIA has experienced a 234 percent increase in demand for services since the onset of the recession and demand remains steady as the economy grows. It is easy to see why this is so: the one-stop system supported with WIA funds fosters community partnerships that drive job creation and economic recovery efforts while also providing vital labor market information, skills assessments, career guidance, counseling, employment assistance, support and training services to jobseekers and workers who need help in getting good jobs.

In every State and region, the workforce system addresses the needs of business so that local companies can remain competitive. By building relationships with community development organizations and local officials, businesses are provided with a collaborative network of support that is best-suited to the needs of employers. Only this system can provide businesses with the resources they can use to survive and thrive in this difficult economic time.

In fact, the workforce system is the only system of its kind to engage employers and address the kind of compelling challenges that business face in the following areas:

—Reducing turnover in entry level occupations in high growth industries such as healthcare through early immersion and career ladder programs.

—Finding the talent that advanced manufacturing companies need to compete by training workers in new skills and providing the next generation of workers a path to the modern workforce.

—Supporting economic development and business attraction activities so that new employers and manufacturers get assistance in determining local infrastructure, specific fits for training needs, and whatever it takes to be successful.

—Preparing youth in high demand IT careers as well as providing soft skills training, job search preparation, coaching and the life transforming skills that businesses need to develop a stable, high-quality workforce.

—Improving hiring efficiency such that employers improve their application conversion rate by 50 percent through collaborative partnerships with the workforce system that produce qualified candidates with the right skill-sets, dedication and motivation that employers need.

Businesses as well as jobseekers and workers benefit from WIA services. Research indicates that the workforce system produces a high return on investment. Last year, over 8 million job-seekers utilized the workforce system and over 4.3 million of them got jobs. While this is less than the normal 80 to 85 percent placement rate common in stronger economic times, the recent job environment had four jobseekers for every one vacancy. However, when jobs were simply not available, the system placed many of the unemployed in education and training programs that will lead to good new jobs.

The system is also effective. According to an Upjohn Institute Study, positive and statistically significant results were found for WIA Adult Program participants and for the Dislocated Worker Program. Furthermore, these employment and training services were shown to reduce reliance on public assistance. The average duration on TANF public assistance also was reduced by several percentage points for those participating in WIA or TANF welfare-to-work programs. One can conclude from a variety of studies that WIA training services raise employment rates and earnings while reducing reliance on TANF.

Many CWS members are private businesses that struggle everyday with budgets, so we can appreciate the need to make tough decisions. Since job creation is a priority for the Congress and since workers pay taxes and reduce pressure on public programs, maintaining support for the workforce system should remain a top priority. The workforce system is a critical partner in the Nation's economic recovery as it trains and retrains workers to meet the demands of our changing economy. In our judgment, this system is essential to addressing the employment needs of the more than 14 million unemployed in this country—we cannot afford to lose this valuable resource.

Nevertheless, Congress recently reduced WIA's three State/local program sections by about $307 million below the fiscal year 2010 levels enacted in Public Law 111–117. Overall, the last CR provides about $2.8 billion for job-training State grants for adult employment, youth activities, and dislocated workers. The more than $1 billion in reductions to key job training and education programs equate to more than 10 percent less than fiscal year 2010 enacted levels.

While funding for Program Year 2011 is now set, the spending agreement covers only the first quarter of the next WIA program year ending September 30, 2011. Funding for the final three quarters will be contained in the fiscal year 2012 appropriations.

Many WIA programs have received funding reductions in real dollar terms in recent years—these programs are significantly underfunded already relative to their mission. Congress should use the findings of duplication and overlap in workforce programs not to make further reductions but rather to work with the House Education and Workforce Committee to achieve better coordination and integration of services.

Despite the significant cuts in the latest CR, the bill represents substantial progress for thousands of jobseekers and employers across the country who informed their policymakers on the critical benefits of our workforce system. We are encouraged to see that Congress has rejected the severest cuts proposed early this year and we hope there is a more accurate picture for fiscal year 2012 emerging of how WIA programs help employers find qualified workers and train workers for new careers.

In short, CWS will work with Members of this Committee, the authorizing committees and other Members of Congress as they consider policies to better align planning and service delivery, and strengthen the overall system. As issues develop, there will be discussions about expectations for the future of the workforce system. Here are some issues of primary importance to CWS:

—Enhancing WIA accountability and driving high performance;
—Empowering Workforce Investment Boards to play a strategic role that promotes coordination and integration of services across federally funded systems;
—Serving disadvantaged and underserved populations; and
—Sharing and promoting best practices throughout the system.

CWS believes that WIA's core services and training have paid off in terms of higher employment rates and improved earnings for dislocated workers, the unemployed and disadvantaged youth and adults. As Members of the Committee examine the facts concerning WIA services, we trust that they will agree that the workforce system provides vital services to businesses and jobseekers. Thank you for your consideration of my testimony.

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PREPARED STATEMENT OF THE COALITION FOR THE ADVANCEMENT OF HEALTH THROUGH BEHAVIORAL AND SOCIAL SCIENCE RESEARCH

Mr. Chairman and Members of the Subcommittee, the Coalition for the Advancement of Health Through Behavioral and Social Science Research (CAHT–BSSR) appreciates and welcomes the opportunity to comment on the fiscal year 2012 appropriations for the National Institutes of Health (NIH). CAHT–BSSR includes 14 professional organizations, scientific societies, coalitions, and research institutions concerned with the promotion of and funding for research in the social and behavioral sciences. Collectively, we represent more than 120 professional associations, scientific societies, universities, and research institutions.

CAHT–BSSR would like to thank the Subcommittee and the Congress for their continued support of the NIH. Strong sustained funding is essential to national priorities of better health and economic revitalization. Providing adequate resources in fiscal year 2012 that allow the NIH to keep up with the rising costs of biomedical, behavioral, and social sciences research will help NIH begin to prepare for the era beyond recovery. We recognize that these are difficult times for our Nation, but at the same time, it is essential that funding in fiscal year 2012 and beyond allow the agency to resume steady, sustainable growth of the foundation of knowledge built through NIH-funded research at more than 3,000 universities, medical schools, teaching hospitals, and research institutions. CAHT–BSSR supports the NIH fiscal year 2012 request of $31.7 billion, at a minimum, and joins the Ad Hoc Group for Medical Research in its request for $35 billion in funding for NIH in fiscal year 2012.

*NIH Behavioral and Social Sciences Research*.—NIH supports behavioral and social science research throughout most of its 27 institutes and centers. The behavioral and social sciences regularly make important contributions to the well-being of this Nation. Due in large part to the behavioral and social science research sponsored by the NIH, we are now aware of the enormous contribution behavior makes to our health. At a time when genetic control over diseases is tantalizingly close but not yet possible, knowledge of the behavioral influences on health is a crucial component in the Nation's battles against the leading causes of morbidity and mortality: obesity, heart disease, cancer, AIDS, diabetes, age-related illnesses, accidents, substance use and abuse, and mental illness.

As a result of the strong congressional commitment to the NIH in years past, our knowledge of the social and behavioral factors surrounding chronic disease health outcomes is steadily increasing. The NIH's behavioral and social science portfolio

has emphasized the development of effective and sustainable interventions and prevention programs targeting those very illnesses that are the greatest threats to our health, but the work is just beginning.

From global warming to unlocking the secrets of memory; from self destructive behavior, such as addiction, to lifestyle factors that determine the quality of life, infant mortality rate and longevity; the grandest challenge we face is understanding the brain, behavior, and society. Nearly 125 million Americans are living with one or more chronic conditions, like heart disease, cancer, diabetes, kidney disease, arthritis, asthma, mental illness and Alzheimer's disease. Significant factors driving the increase in healthcare spending in the United States are the aging of the U.S. population, and the rapid rise in chronic diseases, many of which can be caused or exacerbated by behavioral factors. Obesity may be the result of sedentary behavior and poor diet; and addictions, resulting in health problems caused by tobacco and other drug use. Behavioral and social sciences research supported by NIH is increasing our knowledge about the factors that underlie positive and harmful behaviors, and the context in which those behaviors occur.

CAHT–BSSR continues to applaud the Congress' and NIH's recognition that the "scientific challenges in developing an integrated science of behavior change are daunting." The agency's efforts to launch the basic behavioral and social science research trans-NIH initiative, Opportunity Network for Basic Behavioral and Social Sciences Research (OppNet), likewise, is applauded. OppNet is designed to examine the important scientific opportunities that cut across the structure of NIH and designed to look for strategic opportunities to build areas of research where there are gaps that have the potential to affect the missions of multiple institutes and centers. Research results could lead to new approaches for reducing risky behaviors and improving health.

Equally, we commend the agency's support of the "Science of Behavior Change" Common Fund Initiative included in the third cohort of research areas for the Common Fund. We agree with the goals of this Common Fund Pilot to "establish the groundwork for a unified science of behavior change that capitalizes on both the emerging basic science and the progress already made in the design of behavioral interventions in specific disease areas. By focusing basic research on the initiation, personalization, and maintenance of behavior change, and by integrating work across disciplines, this Common Fund effort and subsequent trans-NIH activity could lead to an improved understanding of the underlying principles of behavior change. This should drive a transformative increase in the efficacy, effectiveness, and (cost) efficiency of many behavioral interventions."

With the recent passage of healthcare reform legislation, there has been the accompanying and appropriate attention to the issue of personalized healthcare. CAHT–BSSR believes that personalization needs to reflect genes, behaviors, and environments. And as the agency has acknowledged with its recent support of the Science of Behavior Change initiative, assessing behavior is critical to helping individuals see how they can improve their health. It is also critical to helping healthcare systems see where to put resources for behavior change. Fortunately, the NIH acknowledges the need to focus less on finding the "magic answer" and, at the same time, recognizes that healthcare is different from region to region across the country. Full personalization needs to consider the environmental, community, and neighborhood circumstances that govern how individuals' genes and behavior will influence their health. For personalized healthcare to be realized, we need a sophisticated understanding of the interplay between genetics and the environment, broadly defined.

In fiscal year 2012, NIH priorities include establishment of the National Center for Advancing Translational Sciences (NCATS) intended to align and bring together a number of trans-NIH programs that do not have a specific disease focus in one organization. As with development of more effective drugs, surgical techniques and medical devices, the development of more powerful health-related behavioral interventions is dependent on improving the understanding of human behavior, and then translating that knowledge into new and more effective interventions with enduring effects. It is critical that the NIH support for translational research extends to translation research designed to adapt findings from basic behavioral and/or social science research to develop behavioral interventions directed at improving health-related behaviors such as adequate physical activity and nutrition, learning and learning disabilities, and preventing or reducing health-risking behaviors including tobacco, alcohol, and/or drug abuse, and unprotected sexual activity. CAHT–BSSR strongly believes that the translation of behavioral interventions is a critical part of the NCATS initiative and must be accompanied by sufficient staff expertise and resources to manage research on the translation of behavioral interventions into communities.

CAHT–BSSR applauds the NIH's recognition of a unique and compelling need to promote diversity in health-related research. The agency expects these efforts to lead to: the recruitment of the most talented researchers from all groups; an improvement in the quality of the educational and training environment; a balanced perspective in the determination of research priorities; an improved ability to recruit subjects from diverse backgrounds into clinical research; and an improved capacity to address and eliminate health disparities. Numerous studies provide evidence that the biomedical and educational enterprise will directly benefit from broader inclusion.

NIH recognizes that developing a more diverse and academically prepared workforce of individuals in STEM (science, technology, engineering, and math) disciplines will benefit all aspects of scientific and medical research and care. CAHT–BSSR applauds the agency's recognition that, to remain competitive in the 21st century global economy, the Nation must foster new opportunities, approaches, and technologies in math and science education.

This recognition extends to the need for a coordinated effort to bolster STEM education nationwide, starting at the earliest stages in education. Unfortunately, the narrow perception of "science" persists, and the social and behavioral sciences are often excluded in discussion of STEM issues and remain outside of the science education curriculum. The considerable activity on STEM education provides the opportunity to improve the recognition of social and behavioral sciences as "science."

In 2010, the NIH commissioned the Institute of Medicine (IOM) to do a study surrounding LGBT (lesbian, gay, bisexual, and transgender) health issues, research gaps and opportunities. The recently released study, The Health of Lesbian, Gay, Bisexual, and Transgender People, examined the current state of knowledge on LGBT health, including general health concerns and health disparities, identified research gaps and opportunities; and outlined a research agenda which reflects the most pressing areas, specifically demographic research, social influences, healthcare inequities, intervention research, and transgender-specific health needs.

### NIH OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

The NIH Office of Behavioral and Social Sciences Research (OBSSR), authorized by Congress in the NIH Revitalization Act of 1993 and established in 1995, serves as a convening and coordinating role among the institutes and centers at NIH. In this capacity, OBSSR develops, coordinates, and facilitates the social and behavioral science research agenda at NIH; advises the NIH director and directors of the 27 institutes and centers; informs NIH and the scientific and lay publics of social and behavioral science research findings and methods; and trains scientists in the social and behavioral sciences. For fiscal year 2012, CAHT–BSSR supports a budget of $38.2 million for OBSSR. This sum reflects the Administration's request of $28 million for OBSSR and includes the $10 million needed to support the NIH-wide commitment to carry out OppNet, an initiative strongly supported by the Subcommittee. The OppNet initiative has made significant progress since its start. Thus far, OppNet has awarded 35 competitive revisions to add basic science projects to existing research project grants. Eight competitive revisions to Small Business Innovation Research/Small Business Technology and Transfer projects have been awarded. OppNet has also provided the much-needed training in basic social and behavioral sciences research.

In fiscal year 2012, OBSSR intends partner with the NIH institutes and centers and other Federal agencies to fund Mobile Technology Research (mHealth) to Enhance Health. Recent advances in mobile technologies and the use of these technologies in daily life have created opportunities for research applications that were not previously possible, such as assessing behavioral and psychological states in real time. To make use of this technology as effective as possible there is a need to integrate the behavioral, social sciences, and clinical research fields. The NIH mHealth Summer Institute is designed to address the lack of integration of these fields.

Over the years, OBSSR has sponsored summer training institutes for scientists interested in social and behavioral science research areas. The interest in these training sessions have been overwhelming and have exceeded the Office's capacity to provide the opportunity for scientists and researchers to gain critical training in these areas. These institutes include training in: systems science methodology and health; randomized clinical trials involving behavioral interventions; dissemination and implementation research in health; and mobile health. The Dissemination and Implementation Research in Health training institute, for example, features a faculty of leading experts from a variety of behavioral and social science disciplines and is designed to empower scientists to conduct this research. Drawing from these disciplines, dissemination and implementation research uses approaches and methods

that in the past have not been taught comprehensively in most graduate degree programs. Given the demand for the training these institutes provide and the potential this research has for propelling the science forward, CAHT–BSSR believes that greater collaboration with the NIH institutes and centers is needed to meet the demand.

CAHT–BSSR would be pleased to provide any additional information on these issues. Below is a list of coalition member societies. Again, we thank the Subcommittee for its generous support of the National Institutes of Health and for the opportunity to present our views.

CAHT–BSSR

American Association of Geographers
American Educational Research Association
American Psychological Association
American Sociological Association
Association of Population Centers
Consortium of Social Science Associations
Council on Social Work Education
Federation of Associations in Behavioral & Brain Sciences
National Association of Social Workers
National Communication Associations
Population Association of America
Society for Behavioral Medicine
Society for Research in Child Development
The Alan Guttmacher Institute (AGI)

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PREPARED STATEMENT OF THE COALITION OF HERITABLE DISORDERS OF CONNECTIVE TISSUE

Chairman Tom Harkin, Chairman, and Richard Ranking Member Shelby, and members of the Subcommittee: the Coalition of Heritable Disorders of Connective Tissue thanks you for the opportunity to submit testimony regarding the fiscal year 2012 budget for the National Heart, Lung and Blood Institute (NHLBI), the National Institute of Arthritis, Musculoskeletal and Skin Diseases, (NIAMS), and the NIH Office of Research Information Services/Office of Extramural Research. We are extremely grateful for the Subcommittee's strong support of the NIH, particularly as it relates to life threatening genetic disorders such as Heritable Disorders of Connective Tissue. Thanks to your leadership, we are at a time of unprecedented hope for patients with these diseases.

It is estimated that over 1 million people in the United States are affected by Heritable Disorders of Connective Tissue (HDCT). These disorders manifest themselves in many areas of the body, including the heart, eyes, skeleton, lungs and blood vessels. Connective tissue is the "glue" that holds the body together. These disorders are progressive conditions caused by genetic mutations and cause deterioration in each of these body systems. The most life-threatening are those which affect the aorta and the heart—the most disabling are orthopedic and ophthalmological.

Some 60 years ago, Victor McKusick, the "father" of modern medical genetics, described and coined the term "heritable disorders of connective tissues." These disorders included over 200 such rare disorders, among which were the Marfan syndrome, Weill-Marchesani syndrome, Ehlers-Danlos syndrome, Cutis Laxa, Osterogenesis imperfecta, the chondrodysplasias, and Pseudoxanthoma elasticum (Heritable Disorders of Connective Tissue, McKusick, Va 1972).

Awareness of these disorders has grown through the years due to collaborative research. Clues to the underlying causes of these diseases were obtained from the major manifestations found in the connective tissue and elaboration of connective tissue pathways involving identified disease genes and their protein products uncovered additional disease genes with related connective tissue manifestations. Identification of disease genes have led to surprising new information regarding important connective tissue pathways depending on the history of the particular disorder. Thus, the concept of the heritable disorders of connective tissue have reiterated and epitomized important lessons regarding how the connective tissue integrates cellular and organ function.

*National Heart Lung and Blood Institute*

Thanks to research funded by the NHLBI, we have seen amazing responses to HDCT disorders with cardiovascular disease. In the 1960s there was no intervention available, not even surgery for heart defects and dissection, this before the development of the "heart-lung" machine. It was not so long ago, when in the early 1960s, a 13 year old girl with Marfan syndrome was sent home from the hospital to die since there was no surgical intervention possible for her dissecting aneurysm. Early on, surgery required replacing the aortic valve with an animal's heart, further re-

search used a mechanical valve, and then came the sturdy composite graft, which became the "Cadillac" of surgical repair. Although the valve sparing method was used throughout this time, it has been continually improved to address the compromised tissue regarding longevity. Now we are seeing additional "translational" clinical trials, which look at therapies for prevention as well as surgical response. It is important to remember these amazing leaps and bounds in medical, surgical and technological advancement.

NHLBI support has been essential in promoting research collaboration. The Pediatric Heart Network, a cooperative network of pediatric cardiovascular clinical research centers, serves as a data coordinating center to promote the exchange of information to evaluate therapeutic and management strategies for children and adults with congenital and genetic heart defects.

NHLBI funded Clinical Trials in the use of Losarton have led to exciting new findings and pointed the way in future research directions. It has inspired current concepts of architectural and signaling pathways underlying the various heritable disorders of connective tissue in order to integrate these concepts in new productive ways. For example, can the recent advances in treating Marfan syndrome with TGF beta inhibitors and Losarton be applied to other heritable disorders of connective tissue? Does TGF beta signaling play pathological roles in other disorders? For another example, is there an important adhesion junction of architectural pathway that connects the vascular smooth muscle cell to the extracellular matrix? And, again: How do cell surface receptors (integrin and growth factor receptors) coordinate architectural and signaling pathways in connective tissue disorders? All pointing to future research avenues.

*National Institute of Arthritis, Musculoskeletal and Skin Diseases*

The collaboration of NHLBI and NIAMS has provided an even greater overview of the information gleaned from the Losarton clinical trial and a global view of these mult-system disorders. The muscular and orthopedic involvement is being addressed by the NIAMS. Through NIAMS support, there is a meeting in July, which is devoted to "Translational" avenues grown of current research progress in the understanding of heritable disorders of connective tissue. Great progress in the understanding of HDCT has been made over the past 15 years through NIAMS supported workshops on Heritable Disorders of Connective Tissue. Symposia have been convened in 1990, 1995, and 2000. In 1990 and 1995, the emphasis was on finding the genes for the various heritable disorders and understanding whether mutations could be correlated with specific phenotypes. Many of these goals have been met, due to research supported in large part by the NIAMS. In 2000, meeting themes were intentionally broader, focusing on multidisciplinary approaches and common themes in matrix biology in order to (1) promote a better understanding of pathogenesis of connective tissue disorders, (2) stimulate new collaborations between investigators, and (3) identify areas in which rapid progress could be made. In the decade since the 2000 Workshop, tremendous progress has been made, leading notably to new therapies. An example of this is Marfan syndrome, for which a clinical trial is underway to test for a therapy, which may prove to play a pivotal role in preventing heart disease. Epidermolysis bullosa is another disease—for which a research has improved prospects for new therapies, as well as for a number of other heritable disorders of connective tissue.

Research has emphasized an understanding of the role of cells in developing treatments for connective tissue disorders. The success of bone marrow transplantation in treating Epidermolysis Bullosa has called attention to this area. While connective tissue researchers have been interested in stem cell treatments—Osteogenesis imperfecta, for example—more discussion and emphasis in this area are needed.

The impact of this collaboration between these similar disease entities in heritable disorders of connective tissue continues to be of major importance. We are moving rapidly from the "bench to the patient," from basic research to the important translational benefit of research findings to treatments which directly benefit the patient. The collaboration between the basic research and clinical studies is what we are able to focus on in these disorders for the benefit of all disease groups.

*NIH/Office of Research Information Services/Office of Extramural Research—RePorter*

The National Institute of Health (NIH) has established the NIH RePorter, or research/condition/disease category (RCDC) which provides easy retrieval of information on scientific projects and studies. This excellent new tool provides information on research results, expediting access and the avoidance of duplication and is located in the Office of Research Information Services/Office of Extramural Research. It provides access to research information on all disease groups. We urge the inclu-

sion of the category "Heritable Disorders of Connective Tissue" (HDCT) in order to facilitate the exchange of information in the research community of these similar disorders.

What is so important about the study of these disorders is their very complexity—with genetic origins, requiring basic science for understanding, and clinical trials in order to maximize the translational advantages of this research. The mutations of HDCT affect all body systems and require particular depth of investigation. This very complexity informs the researcher, as well as contributes to the understanding of other more common disorders. Research on these disorders in all of the body systems, will "spill" over into research into many of the categories identified in both the short range and the long range strategic plans for NHLBI and NIAMS, and provide benefits for many diseases beyond the scope of HDCT.

*About the Coalition of Heritable Disorders of Connective Tissue (CHDCT)*

The CHDCT is a nonprofit voluntary health organization founded in 1989, dedicated to saving lives and improving the quality of life for individuals and families affected by any 1 of the over 200 Heritable Disorders of Connective Tissue. The mission is to raise awareness of these disabling and often deadly disorders and to support and promote research and collaboration between researchers in the field.

We thank you for this opportunity to thank the Committee for its past support and to voice the interests and concerns of the CHCDT member organizations relating to future priorities of NHLBI and the NIAMS.

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## PREPARED STATEMENT OF THE COMMISSIONED OFFICERS ASSOCIATION OF THE U.S. PUBLIC HEALTH SERVICE

On behalf of the Commissioned Officers Association of the U.S. Public Health Service, Inc. (COA), and in the context of the President's fiscal year 2012 budget request, I respectfully ask to submit this statement for the record. I speak for our Association's members, all of whom are active-duty or retired officers of the Commissioned Corps of the U.S. Public Health Service (USPHS).

We respectfully make two funding requests: Support for a pilot program to recruit and train public health doctors, dentists, and nurses for careers in the Commissioned Corps of the U.S. Public Health Service (USPHS), and support for the establishment of a USPHS Ready Reserve component. Congress authorized both programs last year, and directed the Department of Health and Human Services to implement them.

### U.S. PUBLIC HEALTH SCIENCES TRACK

First, we ask this subcommittee to approve $30 million to establish a scaled-back version of the public health workforce training program for would-be USPHS officers that was authorized by the Patient Protection and Affordable Care Act (Public Law 111–148). This pilot program would be based first at the Uniformed Services University of the Health Sciences (USUHS), which is the dedicated medical school and research institute for uniformed services personnel (Army, Navy, Air Force, Public Health Service.) Additional schools would be selected by the Surgeon General as provided for in law.

*Background and Rationale*

USPHS health professionals serve the health needs of the Nation's most underserved populations. They also serve side-by-side with Armed Forces personnel at home and abroad, on joint training missions, and even in forward operating bases in combat zones. USPHS psychiatric nurses have treated injured soldiers under fire in Afghanistan. At home, USPHS psychologists and other mental health specialists have been detailed to the military to treat returning soldiers and Marines suffering from traumatic brain injury and post-traumatic stress disorder. The PHS Commissioned Corps is a public health and national security force multiplier.

The original proposal, set forth in Section 5315 of PPACA, would have established a "U.S. Public Health Sciences Track" providing for a total of 850 annual scholarships for medical, dental, nursing, and public health students who commit to public service careers in the USPHS. Such a program would be the first of its kind, the first dedicated pipeline into the USPHS Commissioned Corps.

*Funding*

The PPACA provisions authorizing the U.S. Public Health Sciences Track also identified an existing source of funds within the Department of Health and Human Services (DHHS). Support was to come from the Public Health and Social Services Emergency Fund. The law directed the DHHS Secretary to "transfer from the Public

Health and Social Services Emergency Fund such sums as may be necessary" (Sec. 274). The language in the PPACA is clear and straightforward, but, for reasons unknowable to this Association, the directed funding transfer has not occurred.

USPHS READY RESERVE

This Association's second request is for sufficient funding to establish a Ready Reserve component within the USPHS Commissioned Corps. We ask the subcommittee to appropriate $12,500,000 annually through fiscal year 2014 for this purpose. Creation of a USPHS Ready Reserve was approved by Congress last year as part of the PPACA (Section 5210). Lawmakers wanted to bring the structure of the USPHS into line with that of its sister services in the Department of Defense; that objective is articulated several times in the text of the legislation.

The text of the law speaks to congressional intent with unusual specificity. Lawmakers wanted to establish a USPHS Ready Reserve Corps "for service in time of national emergency;" that is, to enhance the capability of the USPHS to respond to natural disasters, terrorist incidents, and other public health emergencies "both foreign and domestic." This reflects the growing realization that protection of the public's health is a fundamental component of national security.

Congress intended that USPHS Ready Reserve personnel would be "available on short notice." They would be "available and ready for involuntary calls to active duty during national emergencies and public health crises." They would be available for "backfilling critical positions left vacant" when active-duty USPHS personnel are deployed in response to public health emergencies, both foreign and domestic" and, finally, they would also "be available for service assignments in isolated, hardship, and medically underserved communities." Absent the appropriated funding necessary to meet these legal obligations, the Nation has no public health emergency response capacity.

CONCLUSION

This Association recognizes, of course, that start-up and even continued funding of various provisions of PPACA are a matter of ongoing debate and very much in doubt. But these two provisions—creation of a USPHS Ready Reserve and establishment of a pilot program at USUHS—warrant broad bipartisan support. They are modest, practical, and well thought-through, and they speak to the short-term and long-term national security needs of this country.

I would be pleased to expand on these points or to answer any questions. I can be reached at the COA offices at 301–731–9080, ext. 211.

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## PREPARED STATEMENT OF THE COUNCIL OF ACADEMIC FAMILY MEDICINE

On behalf of the Council of Academic Family Medicine (CAFM) (Association of Departments of Family Medicine, Association of Family Medicine Residency Directors, North American Primary Care Research Group, and Society of Teachers of Family Medicine), we are pleased to submit testimony on behalf of several programs under the jurisdiction of the Health Resources and Services Administration (HRSA) and the Agency for Healthcare Research and Quality (AHRQ). We thank you for your continued support for programs that encourage the development of primary care physicians to serve our countries healthcare needs. Your fiscal year 2011 committee passed budget was encouraging as a signal of your recognition for the need to invest in these important health professions and workforce programs.

Members of both parties agree there is much that must be done to support primary care production and nourish the development of a high quality, highly effective primary care workforce to serve as a foundation for our healthcare system. Providing strong funding for these programs is essential to the development of a robust workforce needed to provide this foundation.

*Primary Care Training and Enhancement*

The Primary Care Training and Enhancement Program (Title VII Section 747 of the Public Health Service Act) has a long history of providing indispensible funding for the training of primary care physicians. With each successive reauthorization, Congress has modified the Title VII health professions programs to address relevant workforce needs. The most recent authorization directs the Health Resources and Services Administration (HRSA) to prioritize training in the new competencies relevant to providing care in the patient-centered medical home model. It also calls for the development of infrastructure within primary care departments for the improvement of clinical care and research critical to primary care delivery, as well as inno-

vations in team management of chronic disease, integrated models of care, and transitioning between healthcare settings.

Key advisory bodies such as the Institute of Medicine (IOM) and the Congressional Research Service (CRS) have also called for increased funding. The IOM (December 2008) pointed to the drastic decline in Title VII funding and described these health professions workforce training programs as "an undervalued asset." The CRS found that reduced funding to the primary care cluster has negatively affected the programs during a time when more primary care is needed (February 2008).

According to the Robert Graham Center, (Title VII's decline: Shrinking investment in the primary care training pipeline, Oct. 2009), "the number of graduating U.S. allopathic medical students choosing primary care declined steadily over the past decade, and the proportion of minorities within this workforce remains low." Unfortunately, this decline coincides with a decline in funding of primary care training funding—funding that we know is associated with increased primary care physician production and practice in underserved areas. The report goes on to say that "the Nation needs renewed or enhanced investment in programs like Title VII that support the production of primary care physicians and their placement in underserved areas."

Title VII has a profound impact on States across the country and is vital to the continued development of a workforce designed to care for the most vulnerable populations and meet the needs of the 21st century. Attached are just a few examples of the impact Title VII has across the country in States like Alabama, Kansas, Ohio, Rhode Island, Tennessee, Texas, and Washington. Included are examples of opportunities lost through the lack of robust funding for the program.

We urge the Congress to appropriate at least $140 million for the health professions program, Primary Care Training and Enhancement authorized under Title VII, Section 747 of the Public Health Service Act in fiscal year 2012 as requested in the President's budget.

*Rural Physician Training Grants*

"Rural Physician Training Grants," Title VII Section 749B of the Public Health Service Act, were developed to increase the supply of rural physicians by authorizing grants to medical schools which establish or expand rural training. The program would provide grants to produce rural physicians of all specialties. It would help medical schools recruit students most likely to practice medicine in underserved rural communities, provide rural-focused training and experience, and increase the number of medical graduates who practice in underserved rural communities.

According to a July 2007 report of the Robert Graham Center (Medical school expansion: An immediate opportunity to meet rural healthcare needs), data show that although 21 percent of the U.S. population lives in rural areas, only 10 percent of physicians practice there. The Graham Center study describes the educational pipeline to rural medical practice as "long and complex." There are multiple tactics needed to reverse this situation, and this grant program includes several of them. Strategies to increase the number of physicians practicing in rural areas include "increasing the number of rural-background students in medical school, selecting the "right" students and giving them the "right" content and experiences to train them for rural practice." This is exactly what this grant program is designed to do.

We request the Committee provide the fully authorized amount of $4 million in fiscal year 2012 for Title VII Section 749B Rural Physician Training Grants.

*Teaching Health Centers*

Teaching Health Centers (THC) are community health centers or other similar venues that sponsor residency programs and provide residents with their ambulatory training experiences in the health center. This training in the community, rather than solely at the hospital bedside is one of the hallmarks of family medicine training. However, payment issues have always caused a tension and struggle between the hospital, which currently receives reimbursement for residents it sponsors when they train in the hospital, and programs that require training in non-hospital settings. This program is designed to provide residency programs and community health centers grant funding to plan for a transition in sponsorship, or the establishment of new programs. There are already 11 community-based entities from states across the country that have committed to train 44 primary care residents, demonstrating early success in this program.

We are pleased that THC's operations are currently funded through a mandatory appropriations trust fund of $230 million over 5 years, and it is essential that these important centers continue to be funded through this mandatory appropriation. Despite the positive impact that family medicine and other primary care residency

training programs have on those community-based entities that initiate them, a multitude of challenges make it clear that many of these entities would have difficulty doing the same without adequate and predictable financing. Converting this program to discretionary funding also would deter other entities from making the business decisions necessary to expand residency training (e.g., securing commitments from key stakeholders to agree to train new or additional residents, applying for accreditation if not already part of an eligible consortia, and hiring new faculty) since funding over the next few years would be subject to the annual appropriations process.

*Teaching Health Center Development Grants*

If this program is to be effective, there must be funds for the planning grants to establish newly accredited or expanded primary care residency programs. Teaching Health Center Development Grants are important to help establish these innovative programs.

We recommend the Committee appropriate the full authorized amount for the new Title VII Teaching Health Centers development grants of at least $10 million for fiscal year 2012.

*AHRQ*

Research related to the most common acute, chronic, and comorbid conditions that primary care clinicians care for on a daily basis is lacking. Research in these areas is vital because the overall health of a population is directly linked to the strength of its primary healthcare system. AHRQ supports research to improve healthcare quality, reduce costs, advance patient safety, decrease medical errors, and broaden access to essential services. This research is key to helping create a robust primary care system for our Nation—one that delivers higher quality of care and better health while reducing the rising cost of care. Despite this need, little is known about how patients can best decide how and when to seek care, introduce and disseminate new discoveries into real life practice, and how to maximize appropriate care. Ample funding for AHRQ can help researchers address these problems confronting our health system today.

We recommend the Committee fund AHRQ at a level of at least $405 million for fiscal year 2012

*Primary Care Extension Program*

The Primary Care Extension Program was modeled after the successful United States Agriculture Extension Service. This program, under Title III of the Public Health Service Act, is designed to support and assist primary care providers with the adoption and incorporation of techniques to improve community health. As the authors of an article describing this concept (JAMA, June 24, 2009) have stated, "To successfully redesign practices requires knowledge transfer, performance feedback, facilitation, and HIT support provided by individuals with whom practices have established relationships over time. The farming community learned these principles a century ago. Primary care practices are like small farms of that era, which were geographically dispersed, poorly resourced for change, and inefficient in adopting new techniques or technology but vital to the Nation's well-being."

Congress agreed with the authors that "practicing physicians need something similar to the agricultural extension agent who was so transformative for farming," and authorized this program at $120 million for fiscal year 2011 and 2012.

We recommend the Committee fund the Primary Care Extension program at the authorized level of $120 million for fiscal year 2012.

*Title VII Testimonials from the field*

*Brown University*.—"Our Title VII grant is devoted to training students in the care of the underserved. In our first year, we have already recruited two new Community Health Center clinical training sites for our medical students. Our first student at one of the two sites decided, after his family medicine rotation, to change his career path from Urology to Family Medicine." An additional grant has allowed for the development of a curriculum centered around the Patient Centered Medical Home and Practice transformation and has started transforming family medicine practices in Rhode Island. David Anthony, Director of Medical School Education, and Jeffrey Borkan, MD, PhD, Chair, Department of Family Medicine

*East Tennessee State University*.—We were able to use a Title VII grant to establish health fairs, including health screening exams, for rural and underserved communities in northeast Tennessee and southwest Virginia. We started small, but now there are 6 health fairs per year, including 2–3 days per event. During the fairs, the average number of visits per site is 180 and we estimate 27,000 visits in 11

years (1999–2010). John Franko MD, Chair and Professor, Department of Family Medicine

*The Ohio State University*.—With Title VII grants, "We were able to establish a four-track university program—university, academic, urban, and rural, which allowed us to provide a unique training experience involving a diverse population. We have been able to successfully match students in all tracks. We have also been able to provide primary care to the community in settings that were previously physician shortage areas. Finally, we were able to develop training modules for community medicine that address real issues, such as domestic violence, alcohol and substance abuse, teenage pregnancy, obesity, etc." W. Fred Miser, MD, Associate Professor of Family Medicine

*University of Kansas School of Medicine*.—The school applied for but did not receive funding for a program designed to help educate volunteer community physician educators. 29 percent of Kansas Medical students go into family medicine but the school has struggled with faculty development education, this is necessary to teach our community physicians the skills necessary to efficiently and effectively teach. Rick Kellerman MD, Professor and Chair, Department of Family and Community Medicine

*University of South Alabama*.—The Department of Family Medicine applied for but did not receive funding for a program designed to allow us to train residents in a simulated environment to ensure experiences with patients with disability, access and mental health problems. Allen Perkins, MD, MPH, Professor and Char, Department of Family Medicine

*University of Texas Health Science Center at San Antonio*.—Title VII grants are helping the program transition to be core transitional laboratories for the NIH's Clinical and Translational Science Awards (CTSA) efforts and have helped in getting support for a new a Practice Based Research Network Resource Center for community engagement. Carlos Roberto Jaen, MD PhD FAAFP, Professor of Epidemiology and Health Statistics

*WWAMI (a partnership between the University of Washington School of Medicine and the States of Wyoming, Alaska, Montana, and Idaho)*.—Title VII grants have helped fund over 30 faculty positions across the States of Washington, Wyoming, Alaska, Montana, and Idaho. These grants have helped fund the development of areas of scholarship for residency programs in Montana, assisted in the training of fellows that became Residency Directors at other programs, and funded faculty development programs delivered with televideo to rural areas in Wyoming. Ardis Davis MSW,University of Washington Department of Family Medicine, Teaching Associate

*Thomas Jefferson Medical School*.—Title VII grants have allowed us to expand our successful rural Physician Shortage Area and Urban Underserved Programs, teach all of our students about the Patient Centered Medical Home in all 4 years of medical school, and train over 1,400 students, residents, and faculty in community medicine and population health. We have also expanded the infrastructure and rigor of our research fellowship, doubling the publication outcomes of our research fellows over the past 2 years. Howard Rabinowitz, Department of Family and Community Medicine

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## PREPARED STATEMENT OF THE COUNCIL ON SOCIAL WORK EDUCATION

On behalf of the Council on Social Work Education (CSWE), I am pleased to offer this written testimony to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies for inclusion in the official Committee record. I will focus my testimony on the importance of fostering a skilled, sustainable, and diverse social work workforce to meet the healthcare needs of the Nation through professional education, training and financial support programs at the Department of Health and Human Services (HHS) and the Department of Education (ED).

CSWE is a nonprofit national association representing more than 3,000 individual members as well as 650 master's and baccalaureate programs of professional social work education. Founded in 1952, this partnership of educational and professional institutions, social welfare agencies, and private citizens is recognized by the Council for Higher Education Accreditation (CHEA) as the single accrediting agency for social work education in the United States. Social work education focuses students on leadership and direct practice roles helping individuals, families, groups, and communities by creating new opportunities that empower people to be productive, contributing members of their communities.

Social work is rooted in a tradition of social justice, with a central mission of eliminating inequities by helping vulnerable populations navigate societal and personal challenges. Social workers are embedded in a variety of settings, such as schools, hospitals, Veteran health facilities, rehabilitation centers, social service agencies, child welfare organizations, assisted living centers, nursing homes, and faith-based organizations, which allows us to reach diverse segments of the population and play a significant role in the lives of Americans from all walks of life. For example, we provide psychosocial support for individuals and families to help them cope with disease, such as Alzheimer's disease and cancer; we assist families who struggle with homelessness and un- or underemployment; we work with families dealing with domestic violence, including child and spousal abuse; and we work with children in school or afterschool settings to ensure that they meet their full academic potential and to help them cope with issues they may be experiencing in their home lives. As you can see, social workers have an important role to play in all aspects of daily life.

Unfortunately, recruitment and retention in social work continues to be a serious challenge that threatens the workforce's ability to meet societal needs. The U.S. Bureau of Labor Statistics estimates that employment for social workers is expected to grow faster than the average for all occupations through 2018, particularly for social workers specializing in the aging population and working in rural areas. In addition, the need for mental health and substance abuse social workers is expected to grow by almost 20 percent over the 2008–2018 decade.[1]

Recruitment into the social work profession faces many obstacles, the most prevalent being low wages coupled with high educational debt. For example, the median annual wage for child, family, and school social workers in May 2008 was $39,530, while the wage for mental health and substance abuse social workers was $37,210. While a bachelor's degree (BSW) is necessary for most entry-level positions, a master's degree (MSW) is the terminal degree for social work practice, which significantly contributes to the debt load of social work graduates entering careers with low starting wages. According to the 2007–2008 National Postsecondary Student Aid Study conducted by the National Center for Education Statistics at ED, 72 percent of students graduating from MSW programs incurred debt to earn their graduate degree. The average debt was approximately $35,500. The percentage of MSW students borrowing money is 17 percent higher than the average for all master's degrees and the amount borrowed is approximately $5,000 higher than the average for all master's degrees. These difficult realities have made recruitment and retention of social workers an ongoing challenge.

CSWE understands and appreciates the tough funding decisions Congress is faced with this year. However, we urge you to consider the needs of our frontline workforce if we are to see real progress in meeting the healthcare and societal demands of the Nation. The below recommendations for fiscal year 2012 would help to ensure that we are fostering a sustainable, skilled, and diverse workforce that will be able to keep up with the increasing demand for social work services.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA) TITLE VII AND TITLE VIII HEALTH PROFESSIONS PROGRAMS

CSWE urges the Subcommittee to provide $762.5 million for the Title VII and Title VIII health professions programs at HRSA in fiscal year 2012. HRSA's Title VII and Title VIII health professions programs represent the only Federal programs designed to train healthcare providers in an interdisciplinary way to meet the healthcare needs of all Americans, including the underserved and those with special needs. These programs also serve to increase minority representation in the healthcare workforce through targeted programs that improve the quality, diversity, and geographic distribution of the health professions workforce. The Title VII and Title VIII programs provide loans, loan guarantees and scholarships to students, and grants to institutions of higher education and nonprofit organizations to help build and maintain a robust healthcare workforce. Social workers and social work students are eligible for Title VII funding.

The Title VII and Title VIII programs were reauthorized in 2010, which helped to improve the efficiency of the programs as well as enhance efforts to recruit and retain health professionals in underserved communities. Allow me to highlight a few of the programs that are of critical importance to the training of social workers.

—*Mental and Behavioral Health Education and Training*.—Recognizing the severe shortages of mental and behavioral health providers within the healthcare

[1] U.S. Bureau of Labor Statistics. 2009. *Occupational Outlook Handbook, 2010–11 Edition: Social Workers*, http://data.bls.gov/cgi-bin/print.pl/oco/ocos060.htm. Retrieved April 13, 2011.

workforce, a new Title VII program was authorized in the Patient Protection and Affordable Care Act (Public Law 111–148). This program—Mental and Behavioral Health Education and Training Grants—would provide grants to institutions of higher education (schools of social work and other mental health professions) for faculty and student recruitment and professional education and training. The President's budget request includes $17.9 million for these grants in fiscal year 2012. This funding would allow for approximately 10 grants in graduate social work education, 17 grants in graduate psychology education, 12 grants for professional child and adolescent mental health education, and 6 grants for paraprofessional child and adolescent mental health. This is the only program in the Federal Government that is explicitly focused on recruitment and retention of social workers and other mental and behavioral health professionals. CSWE strongly urges the Subcommittee to provide $17.9 million for the Title VII Mental and Behavioral Health Education and Training Grants in fiscal year 2012.

—*Geriatrics Health Professions Training*.—Within the overall request for HRSA's Title VII and Title VIII programs, CSWE urges the Subcommittee to appropriate $46.5 million for Geriatrics Health Professions Programs. This includes the Geriatric Academic Career Incentive Awards (GACA), Geriatric Education Centers (GEC), and Geriatric Career Incentive Awards. As mentioned earlier, the reauthorization that occurred last year made enhancement to the Title VII and Title VIII programs. Specifically, the reauthorization enhanced the geriatrics programs to allow additional health professions—such as social workers and other mental healthcare providers—to participate. Rapid job growth is anticipated for gerontological social workers. In fact, the demand for geriatric social workers is expected to increase by 45 percent by 2015, faster than the average of all other occupations [2]. Additional funding for these programs is needed to ensure that the geriatric workforce is adequately equipped to deal with the aging population, which is only expected to grow to breaking-point levels within the next several years.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA) MINORITY FELLOWSHIP PROGRAM

The goal of the SAMHSA Minority Fellowship Program (MFP) is to achieve greater numbers of minority doctoral students preparing for leadership roles in the mental health and substance abuse fields. According to SAMHSA, minorities make up approximately one-fourth of the population, but only about 10 percent of mental health providers are ethnic minorities. CSWE is a grantee of this critical program and administers funds to exceptional minority social work students. For fiscal year 2012, CSWE urges the Subcommittee to appropriate $7.5 million to the SAMHSA Minority Fellowship Program. This would include $6.882 million for the Center for Mental Health Services, where the majority of MFP funds are administered; $71,000 for the Center for Substance Abuse Prevention; and $547,000 for the Center for Substance Abuse Treatment.

The program has helped support doctoral-level professional education for over 1,000 ethnic minority social workers, psychiatrists, psychologists, psychiatric nurses, and family and marriage therapists since its inception. Still, the program continues to struggle to keep up with the demands that are plaguing our health professions. Severe shortages of mental health professionals often arise in underserved areas due to the difficulty of recruitment and retention in the public sector. Nowhere are these shortages more prevalent than in Indian Country, where mental illness and substance abuse go largely untreated and incidences of suicide continue to increase. Studies have shown that ethnic minority mental health professionals practice in underserved areas at a higher rate than non-minorities. Furthermore, a direct positive relationship exists between the numbers of ethnic minority mental health professionals and the utilization of needed services by ethnic minorities.

The $7.5 million request would be used to substantially increase access to professional education and training for additional minority mental health and substance abuse professionals, in turn helping to ensure that underserved minority populations receive the mental health and substance abuse services they so desperately need. President Obama's fiscal year 2012 budget request includes flat funding for the MFP at about $4.9 million. Funding the MFP at $7.5 million would directly encourage more social workers of minority backgrounds to pursue doctoral degrees in

[2] Hooyman, N., and Unützer, J. 2011. "A Perilous Arc of Supply and Semand: How Can America Meet the Multiplying Mental Health Care Needs of an Again Populations." Generations 34 (4): 36–42.

mental health and substance abuse and will turnout more minority mental health professionals equipped to provide culturally competent, accessible mental health and substance abuse services to diverse populations.

DEPARTMENT OF EDUCATION STUDENT AID PROGRAMS

CSWE supports full funding to keep the maximum Pell Grant at $5,550 in fiscal year 2012. While Congress is understandably focused on identifying a solution that will place the Pell Grant program on solid ground in regards to its fiscal future, we urge you to remember that these grants help to ensure that all students, regardless of their economic situation, can achieve higher education. Moreover, as described above with regard to the SAMHSA Minority Fellowship Program, one goal of social work education is recruiting students from diverse backgrounds (which includes racial, economic, religious, and other forms of diversity) with the hope that they will return to serve diverse communities once they have completed their education. In many cases, this includes encouraging social workers to return to their own communities and apply the skills they have acquired through their social work education to individuals, groups, or families in need. Without support such as Pell Grants, many low-income individuals would not be able to access higher education, and in turn, would not acquire skills needed to best serve in the communities that would most benefit from their service.

The Graduate Assistance in Areas of National Need (GAANN) program provides graduate traineeships in critical fields of study. Currently, social work is not defined as an area of national need for this program; however it was recognized by Congress as an area of national need in the Higher Education Opportunity Act of 2008. We are hopeful that ED will recognize the importance of including social work in the GAANN program in future years. Inclusion of social work would help to significantly enhance graduate education in social work, which is critically needed in the country's efforts to foster a sustainable health professions workforce. CSWE urges the Subcommittee to provide $31 million for the GAANN Program. However, if social work was to be added by the Department as a new area of national need, additional resources would need to be provided so as not to take funding away from the already determined areas of national need.

Thank you for the opportunity to express these views. Please do not hesitate to call on the Council on Social Work Education should you have any questions or require additional information.

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PREPARED STATEMENT OF THE CROHN'S AND COLITIS FOUNDATION OF AMERICA

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to submit testimony on behalf of the 1.4 million Americans living with Crohn's disease and ulcerative colitis. My name is Gary Sinderbrand and I have the privilege of serving as the Chairman of the National Board of Trustees for the Crohn's and Colitis Foundation of America. CCFA is the Nation's oldest and largest voluntary organization dedicated to finding a cure for Crohn's disease and ulcerative colitis—collectively known as inflammatory bowel diseases.

Let me express at the outset how appreciative we are for the leadership this Subcommittee has provided in advancing funding for the National Institutes of Health.

Mr. Chairman, Crohn's disease and ulcerative colitis are devastating inflammatory disorders of the digestive tract that cause severe abdominal pain, fever and intestinal bleeding. Complications include arthritis, osteoporosis, anemia, liver disease and colorectal cancer. We do not know their cause, and there is no medical cure. They represent the major cause of morbidity from digestive diseases and forever alter the lives of the people they afflict—particularly children. I know, because I am the father of a child living with Crohn's disease.

Seven years ago, during my daughter, Alexandra's sophomore year in college, she was taken to the ER for what was initially thought to be acute appendicitis. After a series of tests, my wife and I received a call from the attending GI who stated coldly: Your daughter has Crohn's disease, there is no cure and she will be on medication the rest of her life. The news froze us in our tracks. How could our vibrant, beautiful little girl be stricken with a disease that was incurable and has ruined the lives of countless thousands of people?

Over the next several months, Alexandra fluctuated between good days and bad. Bad days would bring on debilitating flares which would rack her body with pain and fever as her system sought equilibrium. Our hearts were filled with sorrow as we realized how we were so incapable of protecting our child.

Her doctor was trying increasingly aggressive therapies to bring the flares under control.

Asacol, Steroids, Mercaptipurine, Methotrexate and finally Remicade. Each treatment came with its own set of side effects and risks. Every time A would call from school, my heart would jump before I picked up the call in fear of hearing that my child was in pain as the flares had returned. Ironically, the worst call came from one of her friends to report that A was back in the ER and being evaluated by a GI surgeon to determine if an emergency procedure was needed to clear an intestinal blockage that was caused by the disease. Several hours later, a brilliant surgeon at the University of Chicago, removed over a foot of diseased tissue from her intestine. The surgery saved her life, but did not cure her. We continue to live every day knowing that the disease could flare at any time with devastating consequences.

Mr. Chairman, I will focus the remainder of my testimony on our appropriations recommendations for fiscal year 2012.

RECOMMENDATIONS FOR FISCAL YEAR 2012

*Centers For Disease Control And Prevention*

*Inflammatory Bowel Disease Epidemiology Program*

As I mentioned earlier, CCFA estimates that 1.4 million people in the United States suffer from IBD, but there could be many more. We do not know the exact number due to the complexity of these diseases and the difficulty in identifying them. The Centers for Disease Control and Prevention's Inflammatory Bowel Disease Program is helping answer this and many other important questions related to these challenging conditions. This program is the only one of its kind and its accomplishments have been applauded by the CDC.

CCFA has been a proud partner with CDC in conducting the research funded under the epidemiology program. For the first 2 years of the project the Foundation worked collaboratively with Kaiser Permanente in California to better understand the incidence and prevalence of IBD, the natural history of the disease, and why patients respond differently to the same therapy. This research has resulted in 11 publications to date and another 11 papers to be submitted to high-quality peer-reviewed journals. Topics include but are not limited to the following:

—Incidence and Prevalence of IBD
—Patterns of Care and Outcomes in IBD
—Qualitative study of provider opinions
—Utilization of biologics (Infliximab)
—Disparities in Mortality
—Myelosuppression during Thiopurine Therapy for Inflammatory Bowel Disease: Implications for Monitoring Recommendations
—Severity and Flare Algorithms
—Disparities in Surveillance for Colorectal Cancer
—Pediatric Epidemiology

In 2007, our focus shifted to the establishment of the "Ocean State Crohn's & Colitis Area Registry" or OSCCAR. Under the leadership of Dr. Bruce Sands, this study is being conducted jointly by investigators at the Massachusetts General Hospital and Rhode Island Hospital/Brown University. The State of Rhode Island is an excellent location to conduct a population-based IBD study because; (1) it is a small State geographically; (2) it has a diverse ethnic and socioeconomic population that does not tend to migrate out of State: and (3) a small number of gastroenterologists treat essentially all IBD patients within the State. Since 2007, Dr. Sands has been able to recruit virtually all GI physicians in Rhode Island to refer patients into the study. To date, almost 310 patients have been recruited, 89 of whom are pediatric patients. All of this progress will be lost if the program is eliminated in 2012.

The goals of the OSCCAR study moving forward are to: (1) describe the age and sex adjusted incidence rate of Crohn's disease and ulcerative colitis; (2) describe variations in presenting symptoms among children, men and women with newly diagnosed disease; (3) identify factors that predict resistance to steroids, including clinical characteristics and blood test markers that could be useful to treating physicians; (4) identify predictors of the need for surgery; and (5) describe factors that predict either impaired quality of life or a benign course of disease. Mr. Chairman, to ensure that this important epidemiological work moves forward in fiscal year 2012, CCFA recommends an appropriation of $680,000 (fiscal year 2010 level).

*Pediatric Inflammatory Bowel Disease Patient Registry*

Mr. Chairman, the unique challenges faced by children and adolescents battling IBD are of particular concern to CCFA. In recent years we have seen an increased prevalence of IBD among children, particularly those diagnosed at a very early age. To combat this alarming trend CCFA, in partnership with the North American Soci-

ety for Pediatric Gastroenterology, Hepatology and Nutrition, has instituted an aggressive pediatric research campaign focused on the following areas:

—*Growth/Bone Development*.—How does inflammation cause growth failure and bone disease in children with IBD?

—*Genetics*.—How can we identify early onset Crohn's disease and ulcerative colitis?

—*Quality Improvement*.—Given the wide variation in care provided to children with IBD, how can we standardize treatment and improve patients' growth and well-being?

—*Immune Response*.—What alterations in the childhood immune system put young people at risk for IBD, how does the immune system change with treatment for IBD?

—*Psychosocial Functioning*.—How does diagnosis and treatment for IBD impact depression and anxiety among young people? What approaches work best to improve mood, coping, family function, and quality of life.

The establishment of a national registry of pediatric IBD patients is central to our ability to answer these important research questions. Empowering investigators with HIPPA compliant information on young patients from across the Nation will jump-start our effort to expand epidemiologic, basic and clinical research on our pediatric population. We encourage the Subcommittee to support our efforts to establish a Pediatric IBD Patient Registry with the CDC in fiscal year 2012.

*National Institutes of Health*

Throughout its 40 year history, CCFA has forged remarkably successful research partnerships with the NIH, particularly the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which sponsors the majority of IBD research, and the National Institute of Allergy and Infectious Diseases (NIAID). CCFA provides crucial "seed-funding" to researchers, helping investigators gather preliminary findings, which in turn enables them to pursue advanced IBD research projects through the NIH. This approach led to the identification of the first gene associated with Crohn's—a landmark breakthrough in understanding this disease.

Mr. Chairman, NIDDK-sponsored research on IBD has been a remarkable success story. In 2008, a consortium of researchers from the United States, Canada, and Europe identified 21 new genes for Crohn's disease. This discovery, funded in part by the NIDDK, brings the total number of known genes associated with Crohn's disease to more than 30 and provides new avenues for the development of promising treatments. We are grateful for the leadership of Dr. Stephen James, Director of NIDDK's Division of Digestive Diseases and Nutrition, for aggressively pursuing this and other promising areas of research.

CCFA's scientific leaders, with significant involvement from NIDDK, have developed an ambitious research agenda entitled "Challenges in Inflammatory Bowel Diseases." In addition, CCFA-affiliated investigators played a leading role in developing the recommendations on IBD in the new NIH National Commission on Digestive Diseases strategic plan. We look forward to working with the NIDDK to advance the cutting-edge science called for in these two roadmaps.

For fiscal year 2012, CCFA joins with other voluntary patient and medical organizations in recommending an appropriation of $35 billion for the NIH. Once again Mr. Chairman, thank you very much for the opportunity to submit our views for your consideration.

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## PREPARED STATEMENT OF THE CYSTIC FIBROSIS FOUNDATION

On behalf of the Cystic Fibrosis Foundation and the 30,000 Americans with cystic fibrosis (CF), we are pleased to submit the following testimony with our requests for fiscal year 2012 Labor, Health and Human Services, and Education Appropriations.

### ABOUT CYSTIC FIBROSIS

Cystic fibrosis is a life-threatening genetic disease for which there is no cure. People with CF have two copies of a defective gene, known as CFTR, which causes the body to produce abnormally thick, sticky mucus that clogs the lungs and results in fatal lung infections. The thick mucus in those with CF also obstructs the pancreas, making it difficult for patients to absorb nutrients from food.

Since its founding, the CF Foundation has maintained its focus on promoting research and improving treatments for CF. More than 30 drugs are now in development to treat CF; some treat the basic defect of the disease, while others target its symptoms. Through the research leadership of the Cystic Fibrosis Foundation, peo-

ple with CF are living into their 30s, 40s and beyond. This improvement in the life expectancy for those with CF can be attributed to research advances and to the teams of CF caregivers who offer specialized care. Although life expectancy has improved dramatically, we continue to lose young lives to this disease.

The promise for people with CF lies in research. In the past 6 years, the Cystic Fibrosis Foundation has invested over $1 billion in its medical programs of drug discovery, drug development, research, and care focused on life-sustaining treatments and a cure for CF. A greater investment is necessary, however, to accelerate the pace of discovery and development of CF therapies.

SUSTAINING THE FEDERAL INVESTMENT IN BIOMEDICAL RESEARCH

This Committee and Congress are to be commended for their support for biomedical research through the years. It is vital that we continue to sufficiently fund the NIH, so that it can capitalize on scientific advances and maintain the momentum generated by the doubling of funds and the infusion from the American Recovery and Reinvestment Act (ARRA). These increases in funding brought a new era in drug discovery that has benefited all Americans.

Cutting discretionary health spending by 13.5 percent, as has been proposed, would halt this progress. Deep cuts would have a detrimental effect on the fight against many of our most serious diseases, stifle scientific opportunities, and result in high-wage job loss in all 50 States. In 2007, NIH grants and contracts created and supported more than 350,000 jobs across the United States, an important contribution to the American economy.

We urge this Committee and Congress to maintain robust investment in biomedical research at the NIH so it can fund critical research today that will provide the care and cures of tomorrow.

STRENGTHENING CLINICAL RESEARCH AND DRUG DEVELOPMENT

The Cystic Fibrosis Foundation has been recognized for its unique research approach, which encompasses everything from basic research through Phase 4 postmarketing monitoring of drug safety, and has created the infrastructure required to accelerate the development of new CF therapies. As a result, we now have a pipeline of more than 30 potential therapies that are being examined to treat people with CF.

One such treatment is VX–770, a drug being developed by Vertex Pharmaceuticals that was discovered in collaboration with CFF. This promising therapy targets the physiological defect that causes CF in patients with a particular type of genetic mutation, as opposed to only addressing symptoms of the disease. In late February 2011 we learned that Phase 3 clinical trial data of VX–770 showed profound improvements in lung function and other health measures in CF patients, and a New Drug Application is expected to be submitted to the FDA for review later this year. This new treatment is a direct result of the Foundation's innovative research agenda, advancing from bench to bedside through the Foundation's research program which speeds the creation of new CF therapies.

The Foundation is a leader in creating a clinical trials network to achieve greater efficiency in clinical investigation. Because the CF population is small, a higher proportion of people with the disease must partake in clinical trials than in most other diseases. This unique challenge prompted the Foundation to streamline our clinical trials processes. As a result, research conducted by the Foundation is more efficient than ever before and we are a model for other disease groups.

While the CF Foundation has made great progress in creating a more efficient drug development process for cystic fibrosis, still more needs to be done for other rare diseases, many of which have no treatments available. The Federal Government has the opportunity to make a real difference in this regard, and we are hopeful that the Committee will direct the national health agencies to encourage all investigators and institutions receiving Federal funding to advance novel methodologies and mechanisms for translating basic research into therapies that can benefit patients.

*Advancing Translational Science*

The CF Foundation strongly urges this Committee and Congress to support funding for NIH's proposed National Center for Advancing Translational Sciences (NCATS), which will house the Institutes' existing translational science programs while establishing and providing a more focused, integrated, and systematic approach for linking basic discovery to therapeutic development.

The existing programs to be housed under NCATS are integral to translating basic science into treatments and will benefit from funding for the new center.

These programs include Clinical and Translational Science Awards (CTSA), discussed in further detail below, and the newly authorized Cures Acceleration Network (CAN), both designed to transform the way in which clinical and translational research is conducted and funded. The Therapeutics for Rare and Neglected Diseases (TRND) program will also be housed in the new center. NIH Director Collins has specifically cited the Cystic Fibrosis Foundation's Therapeutics Development Network (TDN), which plays a pivotal role in accelerating the development of new treatments for cystic fibrosis patients, as an exemplar for TRND's innovative therapeutics development model.

The Foundation's investment in pharmaceutical and biotech companies can also serve as a model for the new center's overall mission. NCATS, like CFF, will promote public-private partnerships and convene cross-sector collaborations between industry, government, academia, and others to advance drug development, as well as provide services and resources for high throughput screening, assay development, and preclinical modeling. Prioritizing these initiatives through a standalone center at NIH has the potential to greatly accelerate the development of drugs for diseases that have historically received little pharmaceutical industry attention. In addition, integrating translational science programs from throughout NIH into one center will help bring greater efficiency to the Institutes' pursuit of this important research. Once again, we applaud NIH Director Collins for spearheading NCATS and look forward to working with him as this new initiative is implemented.

*Clinical and Translational Science Awards (CTSA)*

The CTSA program, soon to be housed in NCATS, encourages novel approaches to clinical and translational research, enhances the utilization of informatics, and strengthens the training of young investigators. Key to the success of CTSAs is the parallel maintenance of infrastructure support for Clinical Research Centers (CRC). Without a mechanism to offset clinical research costs, young investigators or Principle Investigators (PIs) studying rare diseases for which there is limited funding will not be able to continue to conduct clinical research. It is important that all NIH institutes recognize that there is a significant cost associated with the conduct of well designed and safe clinical trials, and not all of these costs can be borne by the CTSAs. Congress should direct the NIH to cover costs that used to be borne by the General Clinical Research Centers (GCRCs) through individual research grants.

Support should also be directed toward the continuation and expansion of research networks, such as NIH's pediatric liver disease consortium at the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK). This successful collaboration is helping researchers discover treatments not only for CF liver disease but for other diseases that affect thousands of children each year.

SUPPORTING DRUG DISCOVERY

The Cystic Fibrosis Foundation's clinical research is fueled by a vigorous drug discovery effort comprised of early stage translational research into successful treatments for this disease. Several research projects at the NIH will expand our knowledge about the disease, and could eventually be the key to controlling or curing cystic fibrosis.

*Opportunities in Animal Models*

The Cystic Fibrosis Foundation is encouraged by the NIH's investment in a research program at the University of Iowa to study the effects of CF in a pig model. The program, funded through research awards from both the National Heart, Lung, and Blood Institute (NHLBI) and the Cystic Fibrosis Foundation, bears great promise to help make significant developments in the search for a cure. While a company has been established to produce the animals, the infrastructure and extensive animal husbandry required to keep the animals alive and conduct research on them is available at few academic institutions. Such barriers have greatly limited widespread adoption of these valuable research tools. We urge additional funding to create a common facility that would enable researchers from multiple institutions to conduct research with these models.

*Understanding CFTR Folding and Trafficking*

The data that emerged from the VX–770 Phase 2 and 3 clinical trials, discussed above, is proof that the way in which this drug targets the physiological defect that causes CF, called CFTR protein function modulation, is a viable therapeutic approach. However, this exciting data was obtained from patients with a specific CF mutation which affects only approximately 4 percent of CF patients. More research is needed to understand other genetic mutations, the most common of which is called F508del. F508del causes multiple negative effects, including misfolding and

poor activation properties of the CFTR protein. We encourage the Committee to increase investment in genetic research that can help scientists to better understand the F508del mutation. This will facilitate CF drug discovery and has the potential to benefit not just those with cystic fibrosis, but also those with other protein misfolding diseases.

*Personalized Medicine*

Strong Federal and private investment in research is bringing personalized medicine into the forefront. As we gain a deeper understanding of many diseases and their accompanying genetic profiles, we understand the great challenge of personalizing therapies. While exciting and promising for patients, it is also expensive, complex, and scientifically challenging. For instance, CF doctors are facing difficulties in delivering appropriate care to CF patients, as insurance providers will not cover certain combinations of medicines that clinicians have found are effective for cystic fibrosis in particular when there is no formal clinical data to support it. This puts patients in a difficult position, as these clinical trials are expensive and unlikely to be performed by pharmaceutical companies, especially for treatment of a small, targeted population. As such we urge the Committee to provide sustained Federal investment in personalized medicine, to help move this burgeoning field forward and advance exciting scientific discoveries.

SUPPORTING GREATER ACCESS TO QUALITY HEALTH CARE

We are making remarkable strides in our fight against cystic fibrosis, but people who live with it face greater obstacles each year, as high medical costs can prevent them from accessing appropriate medical care. Healthcare for a CF patient costs $64,000 per year on average, 15 times more than that of the average person. Because of high costs, nearly a quarter of CF patients delay getting medical care or skip treatments their providers recommend to enhance and lengthen their life.

The Foundation sees some promise in a number of provisions in the new healthcare reform law that increase access to health insurance coverage for those with rare and chronic diseases, a critical tool in decreasing out of pocket costs for patients. These provisions include those allowing children to remain on their parents' insurance until they are 26; prohibiting insurance companies from denying or rescinding coverage based on a pre-existing condition; banning annual and lifetime caps on coverage; and the expansion of Medicaid eligibility.

The new law is not perfect, however, and we are concerned that while the provisions listed above will ensure continuity of coverage and greater access to care for those with CF and other chronic diseases, more must be done to reduce the financial burden so many families face in affording their care, especially in these challenging economic times.

While we urge Congress to explore new options to help make care more affordable and reduce shifting costs to patients, we ask that provisions that have the potential to provide desperately needed relief to people with cystic fibrosis be retained, and that they are sufficiently funded so that those with rare and chronic diseases can access the care they need.

In addition, the Foundation wishes to applaud the formation of the Patient Centered Outcomes Research Institute (PCORI) and urges the Committee to support this important entity. PCORI, a private non-profit institute created by the Patient Protection and Affordable Care Act, will support and direct research that gives patients, doctors, and others the information they need make informed decisions about the most effective and appropriate methods for preventing and treating health conditions. The CF Foundation has had great success in improving quality of care for cystic fibrosis patients through the development and administration of a comprehensive patient registry and the collection of comprehensive data on outcomes and practice patterns for use in comparative effectiveness research, and we are confident that dedicating a national institute to such pursuits will improve care for all Americans.

The Cystic Fibrosis Foundation has devoted our own resources to developing treatments through drug discovery, clinical development, and clinical care. Several of the drugs in our pipeline show remarkable promise in clinical trials and we are increasingly hopeful that these discoveries will bring us even closer to a cure. However, sufficient investment in basic science, translational science, clinical research, and drug development programs at NIH is needed to continue these successes not only for CF but for all rare diseases. Additionally, funding for programs that promote access and quality of care will help achieve a greater quality of life for those living with chronic diseases like cystic fibrosis.

We urge the Committee to consider these factors as you craft the fiscal year 2012 Labor, Health and Human Services, and Education Appropriations legislation, and

stand ready to work with NIH and Congressional leaders on the challenging issues ahead. Thank you for your consideration.

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PREPARED STATEMENT OF THE DIGESTIVE DISEASE NATIONAL COALITION

*Summary of Fiscal Year 2012 Recommendations*

$35 billion for the National Institutes of Health (NIH) at an increase of 12 percent over fiscal year 2011. Increase funding for the National Cancer Institute (NCI), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Allergy and Infectious Diseases (NIAID) by 12 percent.

Continue focus on digestive disease research and education at NIH, including the areas of inflammatory bowel disease (IBD), hepatitis and other liver diseases, irritable bowel syndrome (IBS), colorectal cancer, endoscopic research, pancreatic cancer, and celiac disease.

$50 million for the Centers for Disease Control and Prevention's (CDC) hepatitis prevention and control activities.

$50 million for the Center for Disease Control and Prevention's (CDC) colorectal cancerscreening and prevention program.

Chairman Rehberg, thank you for the opportunity to again submit testimony to the Subcommittee. Founded in 1978, the Digestive Disease National Coalition (DDNC) is a voluntary health organization comprised of 29 professional societies and patient organizations concerned with the many diseases of the digestive tract. The DDNC promotes a strong Federal investment in digestive disease research, patient care, disease prevention, and public awareness. The DDNC is a broad coalition of groups representing disorders such as Inflammatory Bowel Disease (IBD), Hepatitis and other liver diseases, Irritable Bowel Syndrome (IBS), Pancreatic Cancer, Ulcers, Pediatric and Adult Gastroesophageal Reflux Disease, Colorectal Cancer, and Celiac Disease.

Mr. Chairman, the social and economic impact of digestive disease is enormous and difficult to grasp. Digestive disorders afflict approximately 65 million Americans. This results in 50 million visits to physicians, over 10 million hospitalizations, collectively 230 million days of restricted activity. The total cost associated with digestive diseases has been conservatively estimated at $60 billion a year.

The DDNC would like to thank the Subcommittee for its past support of digestive disease research and prevention programs at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

Specifically the DDNC recommends: $2.16 billion for the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK); and $35 billion for the NIH.

We at the DDNC respectfully request that any increase for NIH does not come at the expense of other Public Health Service agencies. With the competing and the challenging budgetary constraints the Subcommittee currently operates under, the DDNC would like to highlight the research being accomplished by NIDDK which warrants the increase for NIH.

*Inflammatory Bowel Disease*

In the United States today about 1 million people suffer from Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD). These are serious diseases that affect the gastrointestinal tract causing bleeding, diarrhea, abdominal pain, and fever. Complications arising from IBD can include anemia, ulcers of the skin, eye disease, colon cancer, liver disease, arthritis, and osteoporosis. The cause of IBD is still unknown, but research has led to great breakthroughs in therapy.

In recent years researchers have made significant progress in the fight against IBD. The DDNC encourages the subcommittee to continue its support of IBD research at NIDDK and NIAID at a level commensurate with the overall increase for each institute. The DDNC would like to applaud the NIDDK for its strong commitment to IBD research through the Inflammatory Bowel Disease Genetics Research Consortium. The DDNC urges the Consortium to continue its work in IBD research. Therefore the DDNC and its member organization the Crohn's and Colitis Foundation of America encourage the CDC to continue to support a nationwide IBD surveillance and epidemiological program in fiscal year 2012.

*Viral Hepatitis: A Looming Threat to Health*

The DDNC applauds all the work NIH and CDC have accomplished over the past year in the areas of hepatitis and liver disease. The DDNC urges that funding be focused on expanding the capability of State health departments, particularly to enhance resources available to the hepatitis State coordinators. The DDNC also urges

that CDC increase the number of cooperative agreements with coalition partners to develop and distribute health education, communication, and training materials about prevention, diagnosis and medical management for viral hepatitis.

The DDNC supports $50 million for the CDC's Hepatitis Prevention and Control activities. The hepatitis division at CDC supports the hepatitis C prevention strategy and other cooperative nationwide activities aimed at prevention and awareness of hepatitis A, B, and C. The DDNC also urges the CDC's leadership and support for the National Viral Hepatitis Roundtable to establish a comprehensive approach among all stakeholders for viral hepatitis prevention, education, strategic coordination, and advocacy.

*Colorectal Cancer Prevention*

Colorectal cancer is the third most commonly diagnosed cancer for both men and woman in the United States and the second leading cause of cancer-related deaths. Colorectal cancer affects men and women equally.

The DDNC recommends a funding level of $50 million for the CDC's Colorectal Cancer Screening and Prevention Program. This important program supports enhanced colorectal screening and public awareness activities throughout the United States. The DDNC also supports the continued development of the CDC-supported National Colorectal Cancer Roundtable, which provides a forum among organizations concerned with colorectal cancer to develop and implement consistent prevention, screening, and awareness strategies.

*Pancreatic Cancer*

In 2006, an estimated 33,730 people in the United States will be found to have pancreatic cancer and approximately 32,300 will die from the disease. Pancreatic cancer is the fifth leading cause of cancer death in men and women. Only lout of 4 patients will live 1 year after the cancer is found and only 1 out of 25 will survive 5 or more years.

The National Cancer Institute (NCI) has established a Pancreatic Cancer Progress Review Group charged with developing a detailed research agenda for the disease. The DDNC encourages the Subcommittee to provide an increase for pancreatic cancer research at a level commensurate with the overall percentage increase for NCI and NIDDK.

*Irritable Bowel Syndrome (IBS)*

IBS is a disorder that affects an estimated 35 million Americans. The medical community has been slow in recognizing IBS as a legitimate disease and the burden of illness associated with it. Patients often see several doctors before they are given an accurate diagnosis. Once a diagnosis of IBS is made, medical treatment is limited because the medical community still does not understand the pathophysiology of the underlying conditions.

Living with IBS is a challenge, patients face a life of learning to manage a chronic illness that is accompanied by pain and unrelenting gastrointestinal symptoms. Trying to learn how to manage the symptoms is not easy. There is a loss of spontaneity when symptoms may intrude at any time. IBS is an unpredictable disease. A patient can wake up in the morning feeling fine and within a short time encounter abdominal cramping to the point of being doubled over in pain and unable to function.

Mr. Chairman, much more can still be done to address the needs of the nearly 35 million Americans suffering from irritable bowel syndrome and other functional gastrointestinal disorders. The DDNC recommends that NIDDK increase its research portfolio on Functional Gastrointestinal Disorders and Motility Disorders.

*Digestive Disease Commission*

In 1976, Congress enacted Public Law 94–562, which created a National Commission on Digestive Diseases. The Commission was charged with assessing the state of digestive diseases in the United States, identifying areas in which improvement in the management of digestive diseases can be accomplished and to create a long-range plan to recommend resources to effectively deal with such diseases.

The DDNC recognizes the creation of the National Commission on Digestive Diseases, and looks forward to working with the National Commission to address the numerous digestive disorders that remain in today's diverse population.

*Conclusion*

The DDNC understands the challenging budgetary constraints and times we live in that this Subcommittee is operating under, yet we hope you will carefully consider the tremendous benefits to be gained by supporting a strong research and education program at NIH and CDC. Millions of Americans are pinning their hopes for a better life, or even life itself, on digestive disease research conducted through the

National Institutes of Health. Mr. Chairman, on behalf of the millions of digestive disease sufferers, we appreciate your consideration of the views of the Digestive Disease National Coalition. We look forward to working with you and your staff.

*Digestive Disease National Coalition*

The Digestive Disease National Coalition was founded 30 years ago. Since its inception, the goals of the coalition have remained the same: to work cooperatively to improve access to and the quality of digestive disease healthcare in order to promote the best possible medical outcome and quality of life for current and future patients with digestive diseases.

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PREPARED STATEMENT OF THE DYSTONIA MEDICAL RESEARCH FOUNDATION

Summary of recommendations for fiscal year 2012:

—$35 Billion for the National Institutes of Health (NIH) and concurrent percentage increases across its institutes and centers.

—Expand dystonia research at NIH through the National Institute on Neurological Disorders and Stroke (NINDS), the National Institute on Deafness and other Communication Disorders (NIDCD), the National Eye Institute (NEI), and the National Institute on Child Health and Human Development (NICHD).

—Continue to advance dystonia research through partnerships with the Office of Rare Diseases Research (ORDR) and the Rare Diseases Clinical Research Network (RDCRN).

—$100 million for the Cures Acceleration Network (CAN)

Dystonia is a neurological movement disorder characterized by involuntary muscle spasms that cause the body to twist, repetitively jerk, and sustain postural deformities. Focal dystonia affects specific parts of the body, while generalized dystonia affects multiple parts of the body at the same time. Some forms of dystonia are genetic but dystonia can also be caused by injury or illness. Although dystonia is a chronic and progressive disease, it does not impact cognition, intelligence, or shorten a person's life span. Conservative estimates indicate that between 300,000 and 500,000 individuals suffer from some form of dystonia in North America alone. Dystonia does not discriminate, affecting all demographic groups. There is no known cure for dystonia and treatment options remain limited.

Although little is known regarding the causes and onset of dystonia, two therapies have been developed and proved particularly useful to control patients' symptoms. Botulinum toxin (Botox/Myobloc) injections and deep brain stimulation (DBS) have shown varying degrees of success alleviating dystonia symptoms. Until a cure is discovered, the development of management therapies such as these remains vital, and more research is needed to fully understand the onset and progression of the disease in order to better treat patients.

*Dystonia Research at the National Institutes of Health (NIH)*

Currently, dystonia research at NIH is conducted through the National Institutes on Neurological Disorders and Stroke (NINDS), the National Institute on Deafness and Other Communication Disorders (NIDCD), the National Eye Institute (NEI), and the Office of the Director.

The majority of dystonia research at NIH is conducted through NINDS. NINDS has utilized a number of funding mechanisms in recent years to study the causes and mechanisms of dystonia. These grants cover a wide range of research including the genetics and genomics of dystonia, the development of animal models of primary and secondary dystonia, molecular and cellular studies in inherited forms of dystonia, epidemiology studies, and brain imaging. DMRF works to support NINDS in conducting critical research and advancing the understanding of dystonia.

NIDCD has funded many studies on brainstem systems and their role in spasmodic dysphonia. Spasmodic dysphonia is a form of focal dystonia which involves involuntary spasms of the vocal cords causing interruptions of speech and affecting voice quality. In addition, NEI focuses some of its resources on the study of blepharospasm. Blepharospasm is an abnormal, involuntary blinking of the eyelids which can cause blindness due to a patient's inability to open their eyelids. DMRF encourages partnerships between NINDS, NIDCD and NEI to further dystonia research.

When ORDR initiated the second phase of the Rare Disease Clinical Research Network at NIH, they provided funding for an additional 19 grants aimed at studying the natural history, epidemiology, diagnosis, and treatment of rare diseases. This includes the Dystonia Coalition, which facilitates collaboration between researchers, patients, and patient advocacy groups to advance the pace of clinical research on cervical dystonia, blepharospasm, spasmodic dysphonia, craniofacial

dystonia, and limb dystonia. Working primarily through NINDS and ORDR, the RDCRN holds great hope for advancing understanding and treatment of primary focal dystonias.

Treatment for dystonia is highly individualized, and many dystonia patients do not respond to the current available therapies. The study of potential dystonia therapies is critical for the community. The Cures Acceleration Network (CAN) promises to advance the development of "high need cures," particularly by reducing the barriers between research discovery and clinical trials in areas that the private sector is unlikely to pursue in an adequate or timely way. DMRF supports this initiative and asks that it be funded at $100 million, as requested in the President's budget.

In summary, the DMRF recommends the following for fiscal year 2012:

—$35 billion for NIH and a proportional increase for its Institutes and Centers.

—Increased portfolio of dystonia research at NIH through the National Institute on Neurological Disorders and Stroke, the National Institute on Deafness and Other Communication Disorders, the National Eye Institute, and the National Institute on Child Health and Human Development.

—Continued partnerships on dystonia research between the Office of Rare Diseases Research, other NIH Institutes and Centers, the Rare Diseases Clinical Research Network, and the dystonia patient community.

—$100 million for the Cures Acceleration Network

*The Dystonia Medical Research Foundation (DMRF)*

The Dystonia Medical Research Foundation was founded over 30 years ago and has been a membership-driven organization since 1993. Since our inception, the goals of DMRF have remained to advance research for more effective treatments of dystonia and ultimately find a cure; to promote awareness and education; and support the needs and well being of affected individuals and their families.

Thank you for the opportunity to present the views of the dystonia community, we look forward to providing any additional information.

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## Prepared Statement of the Elder Justice Coalition

The Elder Justice Coalition (EJC) thanks you for providing an opportunity to submit testimony as you consider an fiscal year 2012 Labor-HHS and Education Appropriations bill. The EJC is a 705 member strong, non-partisan organization dedicated to advocating for funding for the Elder Justice Act (EJA), a bipartisan bill authored by Rep. Pete King (NY) and sponsored by Rep. Tammy Baldwin (WI) and Rep. Janice Schakowsky (IL). Senator Orrin Hatch (UT) was the sponsor of the Senate version of the bill. The EJA was passed over a year ago. Authorized funding for the EJA is $195 million per year for 4 years, but first time funding has yet to be appropriated.

Since passage of the EJA, a year later, vulnerable older adults who should be protected by the law are confronted with the same threats they faced a year ago. This is a sad reality given the increasing severity of elder abuse in this country. The most recent study estimates that 14.1 percent of non-institutionalized older adults nationwide had experienced some form of elder abuse in the past year. According to a recent National Institute of Justice study, almost 11 percent of people ages 60 and older (5.7 million) faced some form of elder abuse in 2009. Financial exploitation of older adults is increasingly alarming. A 2009 report by the MetLife Mature Market Institute and the National Committee for the Prevention of Elder Abuse (NCPEA) estimates that seniors lose a minimum of $2.5 billion each year. A study of financially exploited older persons in one State found that 9 percent of the victims had to turn to Medicaid for their care after their own funds were stolen. Elder financial exploitation undoubtedly represents a large drain on Medicaid throughout the country.

In his proposed budget for fiscal year 2012, President Obama included $21.5 million for Elder Justice Act funding. The proposed funding would benefit States and local communities and create jobs. Of the $21.5 million, $16.5 million was included for State adult protective services, the first and front line responders to cases of elder abuse in the home. Of these funds, $1.5 million would be used to prevent and address elder abuse within Tribal nations.

APS workers are faced with increasing and complex caseloads while both Federal and State funding for these programs lag behind. Currently, there is no dedicated Federal funding stream for State APS agencies. A recently released report outlines the challenges APS faces and notes that Federal leadership on elder abuse prevention is lacking. Another report points to an overall increase in calls to adult protec-

tive services. Over $100 million is authorized for State APS programs in fiscal year 2012 and we urge the Subcommittee to use the President's budget proposal, $21.5 million, as the minimum amount for APS funding. Strengthening APS will enhance its ability to protect both older victims and their assets before it is too late.

The President also included an increase of $5 million for the Long-Term Care Ombudsman Program to improve resident advocacy to elders and adults with disabilities who reside in a long-term care setting. The Long-Term Care Ombudsman Program is a critical tool in the fight against elder abuse yet, consistently underfunded.

We urge you to include a minimum appropriation of $21.5 million for the Elder Justice Act in your fiscal year 2012 Labor-HHS Appropriations bill. We thank you for your consideration and please feel free to contact me with questions or concerns.

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PREPARED STATEMENT OF THE ELDERCARE WORKFORCE ALLIANCE

Mr. Chairman and Members of the Subcommittee: We are writing on behalf of the Eldercare Workforce Alliance (EWA), which is comprised of 28 national organizations united to address the immediate and future workforce crisis in caring for an aging America. As the Subcommittee begins consideration of funding for programs in fiscal year 2012, the Alliance [1] asks that you consider $54.9 million in funding for the geriatrics health professions and direct-care worker training programs that are authorized under Titles VII and VIII of the Public Health Service Act as follows: $46.5 million for Title VII Geriatrics Health Professions Programs; $3.4 million for direct care workforce training; and $5 million for Title VIII Comprehensive Geriatric Education Programs.

Geriatrics health profession and direct-care worker training programs are integral to ensuring that America's healthcare workforce is prepared to care for the Nation's rapidly expanding population of older adults.

The first of the baby boomers began to turn 65 this year. Within 20 years, one in five Americans will be over 65; 90 percent of those Americans will have one or more chronic conditions. Despite the growing need for services, there is a growing shortage of health professionals and direct-care workers with specialized training in geriatrics and an even greater shortage of the geriatrics faculty needed to train the entire workforce.

In 2008, the Institute of Medicine (IOM) issued a ground-breaking report, Retooling for an Aging America: Building the Health Care Workforce, which spotlighted these shortages and their impact on eldercare. The report called for an expansion of geriatrics faculty development awards to include additional professional disciplines, increased training for the direct-care workforce, and other efforts to create a healthcare workforce with adequate capacity to care for older adults. The Eldercare Workforce Alliance was established to encourage policymakers to act on the IOM's recommendations for addressing the eldercare workforce crisis.

The enactment of the Patient Protection and Affordable Care Act (ACA) was a historic moment for healthcare in this country. ACA makes important strides toward addressing the severe and growing shortages of healthcare providers with the skills and training to meet the unique healthcare needs of our Nation's growing aging population.

ACA includes provisions from the Retooling for an Aging America Act (S. 245 and H.R. 468 in the 111th Congress), sponsored by Senator Kohl (D-WI) and Representative Schakowsky (D-IL). These provisions enhance existing and establish new geriatrics programs in an effort to build the capacity of the healthcare workforce needed to care for older adults, as recommended in the IOM report.

We very much appreciate the funding for the Title VII Geriatrics Health Professions programs that President Obama included in his fiscal year 2012 budget. We urge you to appropriate adequate funds for geriatrics training programs in fiscal year 2012 so that we can immediately begin to realize the healthcare workforce goals set forth in health reform. Specifically, the Eldercare Workforce Alliance requests $54.9 million in total funding for the following programs under Title VII and VIII of the Public Health Service Act:

*Title VII Geriatrics Health Professions Appropriations Request: $46.5 Million*

Title VII Geriatrics Health Professions programs are the only Federal programs that: (1) increase the number of faculty with geriatrics expertise in a variety of dis-

[1] The positions of the Eldercare Workforce Alliance reflect a consensus of 75 percent or more of its members. This testimony reflects the consensus of the Alliance and does not necessarily represent the position of individual Alliance member organizations.

ciplines; and (2) offer critically important geriatrics training to the entire healthcare workforce.

—*Geriatric Academic Career Awards (GACA)*.—The goal of this program is to promote the development of academic clinician educators in geriatrics.

*Program Accomplishments*.—In Academic Year 2009–2010, GACA funded 84 non-competing continuation awards. GACA awardees provided approximately 60,000 health professionals with interdisciplinary geriatrics training. In turn, these trainees provided culturally competent quality healthcare to over 525,000 underserved and uninsured patients in acute care services, geriatric ambulatory care, long-term care, and geriatric consultation services settings.

In 2010, HRSA expanded the awards to be available to more disciplines. EWA advocated for this expansion and we now want to ensure that there is adequate funding for this vital program. Our request of $5.3 million, as reflected in the President's budget, includes necessary support for 68 Geriatric Academic Career Awardees, promoting the development of clinician educators.

—*Geriatric Education Centers (GEC)*.—The goal of the Geriatric Education Centers is to provide quality interdisciplinary geriatric education and training to geriatrics specialists and non-specialists, including family caregivers and direct care workers.

*Program Accomplishments*.—In Academic Year 2009–2010, the GEC grantees provided clinical training to 54,167 health professional students and to 20,791 interdisciplinary teams in multiple settings.

As part of the ACA, Congress authorized a supplemental grant award program that will train additional faculty through a mini-fellowship program. The program requires awarded faculty to provide training to family caregivers and direct care workers. Our funding request of $22.7 million, as reflected in the President's budget plus $2.7 million for the supplemental grants, includes support for the core work of 45 GECs and for the 24 GECs that would be funded to undertake development of mini-fellowships under the supplemental grants program included in ACA.

—*Geriatric Training Program for Physicians, Dentists, and Behavioral and Mental Health Professions*.—The goal of the GTPD is to increase the supply of quality and culturally competent geriatric clinical faculty and to retrain mid-career faculty in geriatrics. This program supports training additional faculty in medicine, dentistry, and behavioral and mental health so that they have the expertise, skills and knowledge to teach geriatrics and gerontology to the next generation of health professionals in their disciplines.

*Program Accomplishments*.—In Academic Year 2009–2010, 11 non-competing continuation grants were supported. Forty-nine physicians, dentists, and psychiatric fellows received support to provide geriatric care to 20,078 older adults across the care continuum. Geriatric physician fellows provided healthcare to 12,254 older adults. Geriatric dental fellows provided healthcare to 4,073 older adults. Geriatric psychiatry fellows provided healthcare to 3,751 older adults.

Our funding request of $8.5 million, as reflected in the President's budget, includes support for 13 institutions to continue this important faculty development program.

—*Geriatric Career Incentive Awards Program*.—Congress has authorized this new program created through the ACA, which offers grants to foster greater interest among a variety of health professionals in entering the field of geriatrics, long-term care, and chronic care management. President Obama included $10 million in his fiscal year 2012 budget to establish this awards program. Our funding request of $10 million, as reflected in the President's budget, includes support for implementation of this new program.

*Title VII Direct-Care Worker Training Program Appropriations Request: $3.4 million*

Direct-care workers help older adults who need long-term services and supports including assistance with activities of daily living (e.g. eating, bathing, dressing, toileting). Expanded training opportunities for these essential workers are critical to ensuring an adequate geriatrics workforce. According to current employment projections, more than 1 million new direct care workers will be needed by 2018 in order to meet the growing need for care.

—*Training Opportunities for Direct Care Workers*.—As part of the ACA, Congress approved an advanced training program for direct care workers, administered by HHS. Although President Obama's budget did not include this vital training program, EWA urges Congress to fund it in order to enhance direct care worker skills and knowledge, and thereby, improve the quality of care for older adults. EWA's funding request of $3.4 million includes support to establish this unique

grant program at community colleges as they look to increase the geriatrics knowledge and expertise of the direct care workforce.

*Title VIII Geriatrics Nursing Workforce Development Programs Appropriations Request: $5 million*

These programs, administered by the HRSA, are the primary source of Federal funding for advanced education nursing, workforce diversity, nursing faculty loan programs, nurse education, practice and retention, comprehensive geriatric education, loan repayment, and scholarship.

—*Comprehensive Geriatric Education Program*.—The goal of this program is to provide quality geriatric education to individuals caring for the elderly. This program supports additional training for nurses who care for the elderly; development and dissemination of curricula relating to geriatric care; and training of faculty in geriatrics. It also provides continuing education for nurses practicing in geriatrics.

*Program Accomplishments*.—In Academic Year 2009–2010, 27 CGEP grantees provided education and training to [suggest adding all of these together—total of *x* professionals in nursing, home health, as well as lay people] 3,030 Registered Nurses/Registered Nursing Students; 260 Advanced Practice Nurses; 221 Faculty; 110 Home Health Aides; 483 Licensed Practical/Vocational Nurses & LPN students; 730 Nurse Assistants/Patient Care Associates; 810 Allied Health Professionals and 929 lay persons, guardians, activity directors. The CGEP grantees provided 459 educational course offerings in the care of the elderly on a variety of topics to 6,846 participants.

—*Traineeships for Advanced Practice Nurses*.—Through the ACA, the Comprehensive Geriatric Education Program is being expanded to include advanced practice nurses who are pursuing long-term care, geropsychiatric nursing or other nursing areas that specialize in care of elderly.

Our funding request of $5 million, as reflected in the President's budget, includes funds that will continue the training of nurses caring for the elderly and offer 200 traineeships to nurses under the newly implemented traineeship program.

Without additional funds in these programs, we will fail to ensure that America's healthcare workforce will be prepared to care for older Americans. We understand that the Committee faces difficult budget decisions. However, we strongly believe that by investing in these programs, which create geriatrics faculty and offer the training that is needed to ensure a competent workforce, we will be delivering better care to America's older adults. Healthcare dollars will be saved from better care coordination and health outcomes, and the workforce will grow as more people are trained, recruited and retained in the field of geriatrics.

On behalf of the members of the Eldercare Workforce Alliance, we commend you on your past support for geriatric workforce programs and ask that you join us in expanding the geriatrics workforce at this critical time—for all older Americans deserve quality of care, now and in the future.

Thank you for your consideration.

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## PREPARED STATEMENT OF THE FSH SOCIETY, INC.

Honorable Senator Harkin, Mr. Chairman, Honorable Senator Shelby, Ranking Member, Subcommittee members and members of the U.S. Senate Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education and Related Agencies thank you for the opportunity to submit this testimony.

I am Daniel Paul Perez, of Bedford, Massachusetts, President and CEO of the FSH Society, Inc. and an individual who has lived with facioscapulohumeral muscular dystrophy (FSHD) for 48 years. FSHD is also known as facioscapulohumeral muscular disease, FSH muscular dystrophy and Landouzy-Dejerine muscular dystrophy. For hundreds of thousands of men, women, and children the major consequence of inheriting the most prevalent form of muscular dystrophy is a lifelong progressive and severe loss of all skeletal muscles. FSHD is a crippling and life shortening disease. No one is immune, it is genetically and spontaneously (by mutation) transmitted to children and it affects entire family constellations.

My testimony seeks to address the urgent need for NIH to redress and increase funding for research on FSHD.

A consortium of European partners known as Orphanet, led by the French government research agency, INSERM (Insitut National de la Santé et de la Recherche Medicale), that is comparable to the United States. NIH, which includes both government and private members, has issued new epidemiology and prevalence data

for hundreds of diseases that ranks FSHD as the first and most prevalent muscular dystrophy. The "Orphanet Series" report November 2010, "Prevalence of Rare Diseases" report can be found at Internet web site: (http://www.orpha.net/orphacom/cahiers/docs/GB/Prevalence__of__rare__diseases__by__alphabetical__list.pdf). FSHD is presented as the third most prevalent muscular dystrophy in the Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001 and 2008 (the MD–CARE Act). This new data changes the findings as listed in the MD–CARE Act. FSHD is 40 percent more prevalent than Duchenne muscular dystrophy (DMD), now recognized as the second most prevalent dystrophy.

| Estimated Prevalence | Cases/100,000 |
|---|---|
| Facioscapulohumeral muscular dystrophy (FSHD) | 7 |
| Duchenne (DMD) and Becker dystrophy (BMD) | 5 |
| Steinert myotonic dystrophy (DM) | 4.5 |

Figures from the online NIH database RCDC RePORT and the NIH Appropriations History for Muscular Dystrophy report provided by NIH/OD Budget Office & NIH OCPL show that from the inception of the MD CARE Act 2001, funding has more than quadrupled from $21 million to $86 million in fiscal year 2010 for muscular dystrophy. In fiscal year 2010, total muscular dystrophy funding grew by 3.6 percent ($3 million/$83 million) over the previous fiscal year.

In fiscal year 2010, FSHD funding represented 7 percent of the NIH-wide muscular dystrophy budget ($6 million/$86 million). In the previous year, FSHD represented 6 percent of the total muscular dystrophy funding ($5 million/$83 million). FSHD funding as a percentage of overall NIH muscular dystrophy funding has been level over the last 9 years.

NATIONAL INSTITUTES OF HEALTH (NIH) FSHD FUNDING AND APPROPRIATIONS

[Dollas in millions]

| Fiscal Year | FSHD Research | FSHD as a Percentage of Total NIH Muscular Dystrophy Funding |
|---|---|---|
| 2006 | $1.7 | 4 |
| 2007 | 3 | 5 |
| 2008 | 3 | 5 |
| 2009 | 5 | 6 |
| 2010 | 6 | 7 |

Sources: NIH/OD Budget Office & NIH OCPL & NIH RCDC RePORT.

We highly commend the NIH on the ease of use and the continued accuracy of the Research Portfolio Online Reporting Tool (RePORT) report "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)" with respect to reporting projects on muscular dystrophy.

Now that FSHD has been established as the most prevalent muscular dystrophy, and in light of recent advances in research it makes no sense that FSHD remains the most underfunded dystrophy by the NIH and in the Federal research agency system (CDC, DOD and FDA). Given FSHD's prevalence, disease burden, the overall percentage of funding of the muscular dystrophy research portfolio and major mechanistic breakthroughs on FSHD etiology in 2010 and 2011, we ask Congress to urge NIH to provide a catalyst for scientific opportunity in FSHD.

Inter-dystrophy funding changes and comparisons year after year clearly depicts that NIH FSHD funding needs to be increased and set right. Intra-dystrophy funding changes are misleading as a large change in a small number is still an anemic amount. In fiscal year 2010, the most prevalent muscular dystrophy, FSHD, received a $1 million increase from NIH to $6 million, up 20 percent from $5 million. In fiscal year 2010, the second most prevalent, Duchenne (DMD/BMD) type, received a $5 million increase from NIH to $38 million, up 15 percent from $33 million. In fiscal year 2010, the third most prevalent myotonic dystrophy (DM) type, received $1 million less from NIH to $12 million down 8 percent from $13 million. There is an obvious funding disparity as the first and third most prevalent dystrophies combined, each with major breakthroughs in the past 2 years, are receiving less than half of NIH funding that the second prevalent dystrophy with its disease causing gene being discovered 25 years ago.

The MD CARE Act mandates the NIH Director to intensify efforts and research in the muscular dystrophies, including FSHD, across the entire NIH. It should be very concerning that: (1) in the last 9 years muscular dystrophy has quadrupled to $86 million and that FSHD has remained on average at 5 percent of the NIH muscular dystrophy portfolio; (2) FSHD, the most prevalent muscular dystrophy is far underrepresented based on percentage of overall NIH dystrophy funding given its prevalence and disease burden; and (3) that both FSHD and DM have had extraordinary major breakthroughs in understanding the disease mechanism in the current and past fiscal years and NIH funding remains level in one and has declined in the other.

[Dollars in millions]

| Muscular Dystrophy Type | NIH Funding | | Percentage of Total MD funding at NIH | |
|---|---|---|---|---|
| | Fiscal Year 2009 | Fiscal Year 2010 | Fiscal Year 2009 | Fiscal Year 2010 |
| FSHD | $5 | $6 | 6 | 7 |
| DMD/BMD | 33 | 38 | 40 | 44 |
| DM | 13 | 12 | 16 | 14 |

Two major breakthroughs on FSHD occurred in fiscal year 2010 and fiscal year 2011 that make it urgent for the NIH to redress funding for FSHD. On August 19, 2010, a paper titled, "A Unifying Genetic Model for Facioscapulohumeral Muscular Dystrophy" [Science 24 September 2010: Vol. 329 no. 5999 pp. 1650–1653] was published online in the top-rated journal by a group of researchers who started their careers in FSHD research with post-doctoral fellowships from the FSH Society. This paper was a major breakthrough in understanding how FSHD works. It made the front page of the New York Times on the following day. The Times article "Reanimated 'Junk' DNA Is Found to Cause Disease," quoted Dr. Francis Collins, a human geneticist and Director of the National Institutes of Health saying, "If we were thinking of a collection of the genome's greatest hits, this would go on the list." Dr. Collins went on to say, "Well, my gosh, . . . here's a simple disease with an incredibly elaborate mechanism. To come up with this sort of mechanism for a disease to arise—I don't think we expected that." Professor David E. Housman, FSH Society Scientific Advisory Committee Chairman and a geneticist at Massachusetts Institute of Technology (M.I.T.), was quoted saying, "Scientists will now be looking for other diseases with similar causes, and they expect to find them. As soon as you understand something that was staring you in the face and leaving you clueless, the first thing you ask is, 'Where else is this happening?'"

Two months later, another paper was published that originated with seminal funding from the FSH Society that made a second critical advance in determining the cause of FSHD. "Facioscapulohumeral Dystrophy: Incomplete Suppression of a Retrotransposed Gene" was published in PLoS Genetics, October 28, 2010, that made a second critical advance in FSHD. The research shows that FSHD is caused by the inefficient suppression of a gene that may be normally expressed only in early development. The international team of researchers led by Stephen Tapscott, M.D., Ph.D., a member of the Hutchinson Center's Biology Division thinks that the work will lead to new approaches for therapy and new insights into human evolution of disease.

The international FSHD clinical and research community recently came together at the DHHS NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Boston Biomedical Research Institute Senator Paul D. Wellstone MD CRC for FSHD. Almost 90 scientists working on FSHD globally met at the 2010 FSH Society FSHD International Research Consortium, held October 21–22, 2010 to identify areas of scientific opportunity in FSHD that need funding. The summary and recommendations of the group state that given the recent developments in our definition of FSHD, that within 1 to 2 years evidence-based intervention strategies, therapeutics, and trials need to be planned and conducted. Our immediate priorities should be to confirm that the DUX4 gene hypothesis is valid. Then we must understand the normal DUX4 function. Finally, we must understand the naturally occurring variability to enable us to manipulate the disease in our favor. We need to be prepared for this new era in the science of FSHD by accelerating efforts in the following 10 areas: Shareable protocols; common and shareable materials and data by the whole community; corroborate and verify DUX4 finding; FSHD alleles in context of population genetics need to be defined; biomarkers; FSHD clinical evaluation scales/systems need be defined under one agreed standard; Working Groups/animal and mouse model working group consortium;

model systems for mechanistic, intervention work and advancement to clinical trials; Epigenetics/Genetics; clinical trials readiness.

To read the expanded summary and recommendations of the group please go to online file at: http://www.fshsociety.org/assets/pdf/IRCWorkshop2010WorkingConsensusOfPrioritiesGalley.pdf.

It is impossible to justify the current low level of FSHD funding in the current context of muscular dystrophy budget at the NIH. We have worked hard with our scientific colleagues and member patients and families to build the corpus of knowledge to understand FSHD. We have made great progress in understanding our own disease. We have worked side by side with the NIH directors, program and legislative staff the whole distance to these remarkable discoveries. Still, there has been a confounding and recalcitrant lack of traction at NIH for funding in FSHD. Our request to the NIH—increase FSHD funding now!

NIH constantly reminds us that the NIH system of peer-review delivers the best science from investigator initiated grant applications, thus delivering quality science to the American taxpayer. NIH is receiving more and more grant applications on FSHD. As a nonprofit volunteer health agency that funds breakthrough research based on peer-review mechanics and on a shoe-string compared to NIH, we appreciate the need for peer review, the need to fund the best science and also the need to recalibrate the process to ensure that pragmatic and necessary choices are being pursued in the advent of paradigmatic changes in a disease. We FSHD patients and fellow citizens appreciate this as taxpayers as well.

What it comes down to is—the choice of "the best science" in a disease area and how this has been achieved. This is difficult to measure except in hindsight e.g. what hypotheses represent the best science. The Director of NIH said, set this down, take note, this is 1 of the 10 greatest discoveries in human genomics and that we never expected diseases to be caused by unwanted RNA from reanimated junk DNA. The implications are enormous. FSHD has an incredibly elaborate mechanism that we did not expect. We now know that inadvertent expression of DUX4 from a stretch of reactivated "junk-DNA" causes muscle disease known as FSHD. It is clear that this type of research does not and has not done well in peer-review and it is obvious by the fact that funding is dwarfed. Looking back at the recent NIH Request For Proposals (RFAs) that covered FSHD we can see that all of the breakthrough D4Z4 DUX4 gene grant applications went unfunded by NIH. Perhaps the study sections need to be pulled apart and examined in the broader context of muscular dystrophy. Perhaps comparing Duchenne, Myotonic and FSHD is now much akin to determining the best science in computer science and biology combined. Computer science and biology seems an obvious apples to oranges comparison. We are saddened that the most brilliant work on FSHD was turned away by the NIH. It is crystal clear, if not completely black and white, that FSHD is not achieving the goals of parity in funding as set down in mandates set forth in the MD CARE Acts 2001/2008 and by the NIH Action Plan for the Dystrophies submitted to the Congress by the NIH.

As you know, we are impressed with the efforts of NIH staff and Muscular Dystrophy Coordinating Committee (MDCC) on behalf of the community of patients and their families with muscle disease and the research community pursuing solutions for all of us. We recognize in particular the efforts and hard work of the following NIH staff: Story Landis, Ph.D. and John D. Porter, Ph.D. of National Institute of Neurological Disorders and Stroke (NINDS); Stephen I. Katz, M.D., Ph.D. and Glen H. Nuckolls, Ph.D. and Vittorio Satorelli, Ph.D., National Institute of Arthritis and Musculoskeletal and Skin Disease (NIAMS); James W. Hanson, M.D. and Ljubisa Vitkovic, M.D., Ph.D., (NICHD).

The pace of discovery and numbers of experts in the field of biological science and clinical medicine working on FSHD are rapidly expanding. Many leading experts are now turning to work on FSHD not only because it is one of the most complicated and challenging problems seen in science, but because it represents the potential for great discoveries, insights into stem cells and transcriptional processes and new ways of treating human disease.

We request this year in fiscal year 2012, immediate help for those of us coping with and dying from FSHD. We ask NIH to fund research on facioscapulohumeral muscular dystrophy (FSHD) at a level of $35 million in fiscal year 2012. In view of the tremendous breakthroughs in FSHD research that may rewrite genetics, we implore the NIH to immediately address the inadequacy in FSHD muscular dystrophy funding.

We implore the Appropriations Committee to request that the Director of NIH, the Chair, and Executive Secretary of the Federal advisory committee MDCC to increase the amount of FSHD research and projects in its portfolios using all available passive and pro-active mechanisms and interagency committees.

We request that NIH be more proactive in facilitating grant applications (unsolicited and solicited) from new and existing investigators and through new and existing mechanisms, special initiatives, training grants and workshops—to bring knowledge of FSHD to the next level.

We ask NIH to consider increasing the scope and scale of the existing DHHS U.S. NIH Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers (U54) to double or triple their size—they are financially under-powered as compared to their potential. These centers have provided an excellent source of human biomaterials and are a catalyst for research, clinical research and training on muscular dystrophy. We ask NIH to develop funding mechanisms to help expand work from NIH Wellstone Centers outward to address needs and priorities of the scientific communities.

We ask NIH for more than one Wellstone center solely dedicated to FSHD. There needs to be one-half dozen groups with 6 to 10 people solely working on FSHD across the United States to assure continuity in FSHD efforts.

We strongly support research discovery through the use of post-doctoral and clinical training fellowships—a model that has worked very effectively for us. It produces results and progeny. Yet, NIH has only a few fellows in dystrophy. We request that NIH issue an RFA to exclusively fund 12 new post-doctoral fellows and four clinical fellows a year on an ongoing basis for the next 5 years on FSHD. We ask that FSHD be the pilot dystrophy for such initiative.

We request that the Director of the NIH initiate solely for FSHD an RFA for Specialized Centers (P50s) to encourage multidisciplinary research approaches on the complexity of FSHD.

We request that the Director of the NIH redress the low level of funding in FSHD by issuing an RFA exclusively for FSHD to allow it to be a prototype disease in the newly forming National Center for Advancing Translational Sciences. This will help advance the translational science in FSHD and catalyze the development of novel diagnostics and therapeutics for FSHD.

We request that the Directors of the NIH develop, through an RFA for FSHD, a central place where clinical trials can be designed and run on animal models of FSHD (mouse, dog, sheep, etc.). It is cost prohibitive to have each U54, P01, P50 funding infrastructure to support these resources. We ask that FSHD be the proof-of-concept disease for such a facility.

Thanks to your efforts and the efforts of your Committee, Mr. Chairman, the Congress, the NIH and the FSH Society are all working to promote progress in FSHD. Our successes are continuing and your support must continue and increase.

Mr. Chairman, thank you for this opportunity to testify before your committee.

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## PREPARED STATEMENT OF THE FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

The Federation of American Societies for Experimental Biology (FASEB) urges Congress to make investment in the National Institutes of Health (NIH) an urgent national priority and respectfully requests an appropriation of $35 billion for the agency in fiscal year 2012. This figure represents an increase that responds to the effects of inflation on the current program level and is needed to continue ongoing initiatives and prevent severe damage to the Nation's capacity for innovation in its fight against disease.

As a federation of 23 scientific societies, FASEB represents more than 100,000 life scientists and engineers, making it the largest coalition of biomedical research associations in the United States. FASEB's mission is to advance health and welfare by promoting progress and education in biological and biomedical sciences, including the research funded by NIH, through service to its member societies and collaborative advocacy. FASEB enhances the ability of scientists and engineers to improve—through their research—the health, well-being, and productivity of all people.

NIH is the driving force behind our Nation's leadership in biomedical science and the dramatic improvements in our health and quality of life. Because of NIH and the research it supports, we stand on the brink of an era of enormous potential progress against the ravages of disease. NIH funds the research of more than 325,000 scientists at over 3,000 universities, medical schools, and other research institutions across the United States. Eighty percent of NIH funding is distributed through competitive grants to researchers in nearly every congressional district and the U.S. territories. More than 130 Nobel Prize winners have received support from the agency. NIH considers many different perspectives in establishing scientific priorities and identifies and, within the limits of its budget, funds the most promising

and highest quality research to address them. NIH is also training the next generation of researchers to ensure that the United States continues to be a global leader in advancing medical science.

*Improving Health, Saving Lives*

Research funded by NIH has produced an outstanding legacy. NIH-funded discovery has meant that more than 1 million lives per year are saved due to therapies to prevent heart attacks and stroke. That alone has increased American life expectancy by 4 years. Biomedical research discovery has also meant that since 2002 deaths from cancer have steadily declined; and in the past 30 years, survival rates for childhood cancers have increased from less than 50 percent to over 80 percent. More recent advances include:

—*Improving Treatments for Acute Myeloid Leukemia (AML)*.—Investigators have discovered mutations in a gene that affects the treatment prognosis for some patients with AML, an aggressive blood cancer that kills 9,000 Americans annually. The findings may help guide future treatment strategies for individuals with AML, as well as lead to more effective therapies for patients who carry the mutations.

—*Increasing Pediatric Cancer Survival Rates*.—A new form of immunotherapy has significantly improved survival rates of children with neuroblastoma, a deadly nervous system cancer responsible for 12 percent of all cancer deaths in children under age 15. The new therapy has dramatically increased the percentage of children who were alive and free of disease progression after 2 years.

—*Reversing Aspects of Aging*.—Researchers have reversed age-related degeneration in a mouse model of aging. While the findings don't prove that natural aging could be halted or reversed, they may lead to new strategies to combat certain age-related conditions.

—*Rapidly Detecting Tuberculosis (TB)*.—Scientists have developed an automated test that can rapidly and accurately detect TB and drug-resistant TB in patients. The finding could pave the way for earlier diagnosis and more targeted treatment of this disease. TB kills about 1.8 million people each year, and drug-resistant TB is a growing threat. The new test makes it possible to detect TB and drug resistance in a single clinic visit and perhaps begin treatment immediately.

*Predictable and Sustainable Funding Will Drive Innovation and Progress*

Our leadership in biomedical research has made us the envy of the rest of the world. Our dominant position in the discovery of new drugs and therapies is the result of research conducted by scientists and engineers in academia and in the biotech firms that they have started.[1] A study published in the February 9 issue of the New England Journal of Medicine found that 153 new drugs approved by the U.S. Food and Drug Administration during the past 40 years were discovered at least in part by public sector research institutions (universities, research hospitals, nonprofit research institutes, and Federal laboratories), highlighting the increasingly important role of the public sector in the development of pharmaceuticals and other medical interventions.[2] At present, the NIH budget is insufficient to fund all of the promising research that needs to be done. Less than one in five research proposals can be funded. Over the past 6 years, the number of research project grants funded by NIH has declined in almost every year, and the agency is now funding 2,000 fewer grants that it did in 2004. Due to the extreme competition for support, NIH grant applicants have pared their funding requests to the bare minimum needed to fulfill the goal of their research.

If we fail to continue to capitalize on our investment, others will. We have built laboratories, trained young researchers, and initiated exciting new projects. Potentially revolutionary new avenues of research hold promise for earlier screening and better therapies, but these advances will not become a reality unless the NIH budget is sustained and enhanced to meet inflation's demands. Failure to continue our commitment to biomedical research will terminate important scientific investigations, stunt graduate training, and discourage young scientists who are the key to our future.

The NIH budget is currently $34 billion (including supplemental appropriations). Exciting new initiatives at NIH are poised to accelerate our progress in the search

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[1] R. Kneller, Nature Reviews: Drug Discovery 9 (November) 2010.

[2] Ashley J. Stevens, D.Phil., Jonathan J. Jensen, M.B.A., Katrine Wyller, M.B.E., Patrick C. Kilgore, B.S., Sabarni Chatterjee, M.B.A., Ph.D., and Mark L. Rohrbaugh, Ph.D., J.D. The Role of Public-Sector Research in the Discovery of Drugs and Vaccines, New England Journal of Medicine, February 9, 2011.

for cures, and it would be tragic if we could not capitalize on the many opportunities before us. A modest increase over the current program level is needed to continue ongoing initiatives and prevent severe damage to our capacity for innovation. Maintaining our current level of effort requires an increase equal to the biomedical research and development price index (BRDPI), which the Bureau of Economic Analysis in the U.S. Department of Commerce estimates will be 3 percent in fiscal year 2012.

A small fraction of our Federal budget, research funding generates an enormous return in new technologies and improved quality of life. Boom and bust cycles are wasteful and inefficient strategies for funding science. The Nations medical research agency needs sustainable and predictable budget growth to maximize the return on this investment in the health and longevity of all Americans. To that end, FASEB recommends an appropriation of $35 billion for NIH in fiscal year 2012. Thank you for the opportunity to offer FASEB's support for NIH.

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## PREPARED STATEMENT OF FRIENDS OF THE HEALTH RESOURCES AND SERVICES ADMINISTRATION

The Friends of HRSA is a nonprofit and non-partisan alliance of more than 180 national organizations, collectively representing millions of public health and healthcare professionals, academicians and consumers. The coalition's principal goal is to ensure that HRSA's broad health programs have continued support in order to reach the populations presently underserved by the Nation's patchwork of health services.

HRSA operates programs in every State and territory and thousands of communities across the country and is a national leader in providing health services for individuals and families. The agency serves as a health safety net for the medically underserved, including the 50 million Americans who were uninsured in 2009 and 60 million Americans who live in neighborhoods where primary healthcare services are scarce. To respond to these challenges, it is the best professional judgment of the members of the Friends of HRSA that the agency will require an overall funding level of at least $7.65 billion for fiscal year 2012.

While we recognize the reality of the current fiscal climate, our request of $7.65 billion represents the minimum amount necessary for HRSA to continue to meet the healthcare needs of the American public. Anything less will undermine the efforts of HRSA programs to improve access to quality healthcare for millions of our neediest citizens. Additionally, the Friends of HRSA coalition members remain concerned about the deep cuts made to the agency in the final fiscal year 2011 Continuing Resolution and the negative consequences for public health. Therefore, the requested minimum level of funding for fiscal year 2012 is essential to allow the agency to carry out critical public health programs and services that reach millions of Americans, including training for public health and healthcare professionals, providing primary care services through community health centers, improving access to care for rural communities, supporting maternal and child healthcare programs, and providing healthcare to people living with HIV/AIDS. However, much more is needed for the agency to achieve its ultimate mission of ensuring access to culturally competent, quality health services; eliminating health disparities; and rebuilding the public health and healthcare infrastructure.

Our $7.65 billion fiscal year 2012 HRSA funding request is based upon recommendations provided by coalition members to support HRSA programs including:

—Health Professions programs support the education and training of primary care physicians, nurses, dentists, dental hygienists physician assistants, nurse practitioners, public health personnel, mental and behavioral health professionals, optometrists, pharmacists, and other allied health providers; improve the distribution and diversity of health professionals in medically underserved communities; and ensure a sufficient and capable health workforce able to provide care for all Americans and respond to the growing demands of our aging and increasingly diverse population. In addition, the Patient Navigator Program helps individuals in underserved communities, who suffer disproportionately from chronic diseases, navigate the health system.

—Primary Care programs support community health centers operating in more than 8,000 communities in every State and territory, improving access to cost-effective and high-quality primary and preventive care in rural and urban underserved areas. In addition, the Health Centers program targets the country's most vulnerable populations, including migrant and seasonal farm workers, homeless individuals and families, and those living in public housing.

—Maternal and Child Health Flexible Maternal and Child Health Block Grants, Healthy Start and other programs provide services, including prenatal and postnatal care, newborn screening tests, immunizations, school-based health services, mental health services, and well-child care for more than 34 million uninsured and underserved women and children not covered by Medicaid or the Children's Health Insurance Program, including children with special needs.
—HIV/AIDS programs provide assistance to metropolitan and other areas most severely affected by the HIV/AIDS epidemic; support comprehensive care, drug assistance and support services for people living with HIV/AIDS; provide education and training for health professionals treating people with HIV/AIDS; and address the disproportionate impact of HIV/AIDS on women and minorities.
—Family Planning Title X programs provide reproductive healthcare and other preventive services for more than 5 million low-income women at over 4,500 clinics nationwide. These programs improve maternal and child health outcomes, prevent unintended pregnancies, and reduce the rate of abortions.
—Rural Health programs improve access to care for the 60 million Americans who live in rural areas. Rural Health Outreach and Network Development Grants, Rural Health Research Centers, Rural and Community Access to Emergency Devices Program, and other programs are designed to support community-based disease prevention and health promotion projects, help rural hospitals and clinics implement new technologies and strategies, and build health system capacity in rural and frontier areas.
—Special Programs include the Organ Procurement and Transplantation Network, the National Marrow Donor Program the C.W. Bill Young Cell Transplantation Program, and National Cord Blood Inventory. Strong funding would facilitate an increase in organ, marrow, and cord blood transplantation.

Greater investment is necessary to sufficiently fund HRSA services and programs that continue to face increasing demands. We urge you to consider HRSA's role in building the foundation for health service delivery and ensuring that vulnerable populations receive quality health services, while continuing to strengthen our Nation's health safety net programs. By supporting, planning for and adapting to change within our healthcare system, we can build on the successes of the past and address new gaps that may emerge in the future.

We appreciate the Subcommittee's hard work in advocating for HRSA's programs in a climate of competing priorities. The members of the Friends of HRSA thank you for considering our fiscal year 2012 request for $7.65 billion for HRSA in the fiscal year 2012 Labor, Health and Human Services, Education, and Related Agencies Appropriations bill and are grateful for this opportunity to present our views to the Subcommittee.

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## PREPARED STATEMENT OF FRIENDS OF THE NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES ADVOCACY COALITION

The Friends of NCBDDD Advocacy Coalition recommends that Congress provide at least $144 million in fiscal year 2012 to sustain the vital programs and activities funded by NCBDDD. Furthermore, we call on Congress to ensure any program modifications do no harm for children and adults currently served by the Center and that funds intended to directly benefit the targeted populations not be diverted.

CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD) works to prevent birth defects and developmental disabilities and help people with disabilities and blood disorders live the healthiest life possible. It is the only CDC Center whose primary mission is focused on birth defects, disability and blood disorders. 2011 marks the 10th year of the Center's accomplishments.

NCBDDD impacts millions of our Nation's most vulnerable: infants and children, people with disabilities, and people with blood disorders. During times of increasing fiscal constraint, NCBDDD is committed to finding strategic approaches to support and strengthen core public health activities for these vulnerable and underserved populations. Public health is the science and art of preventing disease and disability, promoting physical and behavioral wellness, supporting personal responsibility, and prolonging life in communities where people live, work, and learn. Building upon the latest science and evidence-based research, the Center has identified key priorities to these populations to ensure continued public health advancements are made, as well as demonstrating sound returns on investments.

*Child Health and Development—Assuring Child Health*

*Division of Birth Defects and Developmental Disabilities*

Success in this NCBDDD program area includes rapidly translating research findings into prevention strategies that prevent birth defects and developmental disabilities, focusing attention on the importance of early care and special intervention services for children born with a birth defect or developmental disability, and supporting parents in helping their children grow into healthy, safe, productive members of society.

*Health and Development for People with Disabilities—Improving the Health of People with Disabilities*

*Division of Human Development and Disability*

This spectrum of NCBDDD activities promotes healthy development and reduces health disparities across the life course for persons with or at risk of disability. Program goals include: Improving the health and developmental outcomes for children, improving the quality of life and life expectancy for people with disabilities, and eliminating health disparities faced by persons of all ages living with disabilities.

*Public Health Approach to Blood Disorders*

*Division of Blood Disorders*

The history of NCBDDD activities in this area includes bleeding and clotting disorders, hemoglobinopathies and blood product safety. The future of blood disorders is predicated on building upon our past successes and expanding our public health activities to begin addressing the most prevalent, costly, and debilitating bleeding and clotting disorders.

*CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD) Focus on Public Health-Social Impact-Safety Net Need of the Populations Served*

The Friends advocacy coalition calls on congressional appropriators and the administration to continue to focus the Center's programs on outcomes that affect positive public health, positive social impact, and the safety net purpose. These include:

*Assuring Child Health*

Decrease or eliminate birth defects and developmental disabilities occurring due to known causes.

Improve longer term outcomes of children with birth defects, autism, and other developmental disabilities, and eliminate racial/ethnic disparities in these outcomes.

Identify preventable risk factors of birth defects and developmental disabilities, and develop appropriate interventions to reduce these risks.

Increase early identification and intervention for infants and young children with disabling conditions.

Mediate the impact of poverty on developmental outcomes for young children.

*Improving the Health of People with Disabilities*

Change individual health behaviors to improve health in children, youth, and adults with disabilities.

Improve healthcare access and screening for children, youth, and adults with disabilities.

Reduce the incidence of secondary conditions by increasing health promotion and wellness interventions for children and adults with disabilities.

Improve public health surveillance systems to track the health, development, and participation of persons with disabilities across the life course.

Implement fully the Section 4302 "Patient Protection and Affordable Care Act" intent, expectations, and requirements in "Understanding Health Disparities: Data Collection and Analysis" including "disability status" as well as Section 5307 "Cultural Competency, Prevention, and Public Health" including "individuals with disabilities training."

*Public Health Approach to Blood Disorders*

Improve the life expectancy of people with Sickle Cell Disease.

Reduce the morbidity and mortality related to bleeding disorders in women.

Reduce the incidence of DVT/PE, and prevent related mortality and serious morbidity.

Prevent emerging morbidities of people with bleeding disorders.

*Positive Outcomes*

These outcomes should positively affect several social impact goals to improve the life situation of persons with disabilities and other challenges. These include:

—Seamless, positive, and helpful transitions from one of life's stages to the next stage in life, such as the transition from high school to adulthood and work.
—Promotion and support of independent living in the community—a community participation that encourages and promotes self-direction.
—Continued coordinated efforts to assist parents and consumers make informed medical and life decisions.
—Focused activities with the goal of reducing the severity of disability.

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PREPARED STATEMENT OF THE FRIENDS OF THE NATIONAL INSTITUTE ON AGING (NIA)

The Friends of the NIA is a coalition of 50 academic, patient-centered and not-for-profit organizations that conduct, fund or advocate for scientific endeavors to improve the health and quality of life for Americans as we age. As a coalition, we support the continuation and expansion of NIA research activities and seek to raise awareness about important scientific progress in the area of aging research currently sponsored by the Institute.

To ensure that progress in Nation's biomedical, social, and behavioral research is sustained, the Coalition endorses the NIH fiscal year 2012 request, $31.7 billion, as a floor and joins the Ad Hoc Group for Medical Research in supporting $35 billion for NIH as a ceiling. Given the unique funding challenges facing the NIA, and the range of promising scientific opportunities in the vast, diverse field of aging research, the Friends of NIA ask the subcommittee to recommend NIA receive $1.4 billion in fiscal year 2012—an amount endorsed by the Leadership Conference on Aging.

*The NIA Mission*

Established in 1974, NIA leads the national scientific effort to understand the nature of aging in order to promote the health and well being of older adults. NIA's mission is three-fold: (1) Support and conduct genetic, biological, clinical, behavioral, social, and economic research related to the aging process, diseases and conditions associated with aging, and other special problems and needs of older Americans; (2) Foster the development of research- and clinician-scientists for research on aging; and (3) Communicate information about aging and advances in research on aging with the scientific community, healthcare providers, and the public. The NIA fulfills this mission by supporting both extramural research at universities and medical centers across the United States and intramural research at laboratories in Baltimore and Bethesda, Maryland.

*Research Activities and Advances*

Adding to its strong record of progress throughout its 37-year history, recent NIA-supported activities and advances have contributed to improving the health and well-being of older people worldwide. Below is a summary of some of these most recent activities and advances.

*Alzheimer's Disease*

Alzheimer's disease (AD) is the most common cause of dementia in the elderly. Between 2.6 million and 5.1 million Americans aged 65 years and older may have AD, with a predicted increase to 13.2 million by 2050. While researchers have achieved greater understanding of the disease, there is no cure. In light of the exploding aging population, which by 2030 is expected to reach 72 million Americans ages 65 or older, scientists are in a race against time to prevent an unprecedented AD epidemic threatening our older population.

NIA is the lead Federal research agency for Alzheimer's disease (AD). In this regard, the Institute coordinates trans-NIH AD initiatives and encourages collaboration with other Federal agencies and private research entities. As illustration of its leadership role, NIA partnered with the McKnight Brain Research Foundation to support the 2010 Cognitive Aging Summit. This meeting, a follow-up to a 2007 summit, brought together experts in a variety of research fields to discuss advances in understanding brain and behavioral changes associated with normal aging, including clinical translational research for prevention of age-related cognitive decline.

As part of its ongoing AD Neuroimaging Initiative (ADNI), the largest public-private partnership currently in AD research, NIA-funded researchers continued to make important progress in 2010. Phase two is underway to define changes in brain structure and function as people transition from normal cognitive aging to mild cognitive impairment (MCI is often a precursor to Alzheimer's) to AD. Using imaging techniques and biomarker measures in blood and cerebrospinal fluid (CSF), ADNI investigators have already established a method and standard of testing levels of AD characteristic tau and beta-amyloid proteins in the CSF, correlated levels of

these proteins with changes in cognition over time, and determined that changes in these two protein levels in the CSF may signal the onset of mild AD.

Genetic research on AD is also yielding important insights into the disease. In 2009 and 2010, several new candidate risk factors gene, including CR1, CLU, PICALM and SORL1, were identified. Identification of new pathways that contribute to the development of AD will provide novel avenues for drug targeting. As part of another initiative, the AD Translational Initiative, 40 compounds are being studied. In addition, industry partners are considering several compounds that NIH funded in the pre-clinical phase for full-scale clinical testing. In total, NIH currently supports 38 clinical trials, including both pilot and large scale trials, of a wide range of interventions to prevent, slow, or treat AD and/or cognitive decline. Any one or more of these trials may hold the key to curing or preventing this terrible disease.

In a major announcement, revised clinical diagnostic criteria for AD dementia were published in the April 19, 2011 issue of Alzheimer's & Dementia: The Journal of the Alzheimer's Association, marking the first time in 27 years clinical diagnostic criteria and research guidelines for earlier stages of AD have been revised. The revised guidelines cover the full spectrum of the disease as it gradually changes over many years. They describe the earliest pre-clinical stages of the disease, mild cognitive impairment, and dementia due to AD's pathology. The guidelines also address the use of imaging and biomarkers in blood and spinal fluid that may help determine whether changes in the brain and those in body fluids are due to AD. The guidelines outline some new approaches for clinicians and provide scientists with more advanced guidelines for moving forward with research on diagnosis and treatments.

*Increasing Healthy Life Span*

Through its Division of Aging Biology, NIA supports research to improve understanding of the basic biological mechanisms underlying the process of aging and age-related diseases. The program's primary goal is to provide the biological basis for interventions in the process of aging, which is the major risk factor for many chronic diseases affecting older people. Recent significant findings that could help advance understanding of a range of chronic diseases, include the discovery of the drug rapamycin, which has been shown to extend median lifespan in a mouse model. Grantees supported by this program have also identified genetic pathways that regulate the maintenance of the stem cell microenvironment in aging tissues.

In fiscal year 2012, the Institute intends to continue supporting the Interventions Testing Program to extend median and/or maximal life span in a mouse model; an initiative to determine cell fates in various tissues of aged mammals, under both normal and injury conditions; and studies to identify neural, neuroendocrine, and other mechanisms that influence age-related changes in bone metabolism and health.

*Behavioral and Social Science Research*

The Division of Behavioral and Social Research Program supports social and behavioral research to increase understanding of the aging process at the individual, institutional, and societal levels. Research areas include the behavioral, psychological, and social changes individuals undergo throughout the adult lifespan; participation of older people in the economy, families, and communities; the development of interventions to improve the health and cognition of older adults; and the societal impact of population aging and of trends in labor force participation, including fiscal effects on the Medicare and Social Security programs. The Division also leads numerous trans-NIH behavioral and social science research initiatives, such as the ongoing Behavioral Economics initiatives.

One of the Division's signature projects, the Health and Retirement Study (HRS), is recognized as the Nation's leading source of combined data on health and financial circumstances of Americans over age 50. HRS data have been cited in over 1,700 scientific papers and have informed findings regarding the effects of early-life exposures on later-life health, variables associated with cognitive and functional decline in later life, and trends in retirement, savings, and other economic behaviors. In 2010, NIA expanded the HRS to increase minority representation and conduct genome-wide scans of a subset of participants. Also, in 2010, HRS data were used by scientists who found that older adults who survive hospitalization involving severe sepsis, a serious medical condition caused by an overwhelming immune response to severe infection, are at higher risk for cognitive impairment and physical limitations than older adults hospitalized for other reasons.

*Funding Challenges*

In November 2010, Nature magazine featured an article, "Funding crisis hits U.S. ageing research," describing funding challenges facing the NIA and the field of

aging research. The article reported that "in 2010, a researcher submitting a grant application for any single deadline had only an 8 percent chance of winning funding"—falling from 12 percent in 2009. Dr. Richard Hodes, NIA Director, is quoted as saying the currently funding dilemma "threaten[s] the viability of ageing research" and expresses concern, in particular, about the effect the declining success rates could have on the morale of the next generation of scientists and on their ability to compete successfully for an NIA grant. The dire implications of the Institute's declining success rates is one reason, among others, that the Friends of NIA ask the Subcommittee to support $1.4 billion, an increase of $300 million, for the Institute in fiscal year 2012.

*Conclusion*

We thank you, Mr. Chairman, and the Subcommittee for supporting the NIA and, again, for the opportunity to express our support for the Institute and its important research.

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PREPARED STATEMENT OF FUTURES WITHOUT VIOLENCE

Futures Without Violence, formerly Family Violence Prevention Fund, has worked for 30 years to end violence against women and children around the world, and is proud to be a co-chair the nonpartisan Funding to End Domestic and Sexual Violence Coalition, a coalition of over 30 national organizations committed to domestic violence, dating violence, sexual assault, and stalking. As the National Health Resource Center on Domestic Violence, we provide critical information to thousands of healthcare providers, institutions, domestic violence service providers, government agencies, researchers and policy makers each year. Our public education campaigns, conducted in partnership with The Advertising Council, have shaped public awareness and changed social norms for 15 years.

*Violence Against Women Health Initiative (HHS Office of Women' Health).*—I wish to request $3.375 million for the Violence Against Women Health Initiative as authorized by the Violence Against Women and Department of Justice Reauthorization Act of 2005 (Public Law 109–162); the President's fiscal year 2012 budget requested $3 million for this Initiative. The Violence Against Women Health Initiative is a consolidation of two Violence Against Women Act 2005 programs (Grants to Foster Public Health Partnerships and Education and Training of Health Care Providers), and a top LHHS priority by the Funding to End Domestic and Sexual Violence Coalition. The Violence Against Women Health Initiative through the Office of Women's Health, with additional support by the Administration on Children and Families, provides funding to public health programs that integrate domestic and sexual violence assessment and intervention into basic care, as well as encourages collaborations between healthcare providers, public health programs, and domestic and sexual violence programs. The field is already seeing impressive results. We strongly support the continued need to engage health providers to prevent and respond to violence and abuse. Our other priorities are listed at the end of my testimony.

Domestic and sexual violence is a critical healthcare problem and one of the most significant social determinants of health for women and girls. Nearly one in four women in the United States reports experiencing violence by a current or former spouse or boyfriend at some point in her life, and one in six women reported experiencing a completed sexual assault. The Centers for Disease Control and Prevention (CDC) conservatively estimates that intimate partner rape, physical assault and stalking costs the healthcare system $8.3 billion annually from direct injuries and services. In addition to the immediate trauma caused by abuse, it contributes to a number of chronic health problems. The CDC classifies violence and abuse as a "substantial public health problem in the United States."

Children who experience childhood trauma, including witnessing incidents of domestic violence, are at a greater risk of having serious adult health problems including tobacco use, substance abuse, cancer, heart disease, depression and a higher risk for unintended pregnancy. Twenty years of research links childhood exposure to violence with chronic health conditions including obesity, asthma, arthritis, and stroke. It is worth noting that victims, particularly of sexual violence, are linked with obesity. A meta-analysis of research on the impact of adult intimate partner violence finds that victims of domestic violence are at increased risk for conditions such as heart disease, stroke, hypertension, cervical cancer, chronic pain including arthritis, neck and pain, and asthma. In addition to injuries, adult intimate partner violence also contributes to a number of mental health problems including depression and PTSD, risky health behaviors such as smoking, alcohol and substance abuse, and poor reproductive health outcomes such as unintended pregnancy, pregnancy com-

plications, post partum depression, poor infant health outcomes and sexually transmitted infections including HIV.

But early identification and treatment of victims can financially benefit the healthcare system. Initial findings from one study found that hospital-based domestic violence interventions may reduce healthcare costs by at least 20 percent. Preventing abuse or associated health risks and behaviors clearly could have long term implications for decreasing chronic disease and costs. Because of the long-term impact of abuse on a patient's health, the Violence Against Women Health Initiative is integrating assessment for current and lifetime physical or sexual violence exposure and interventions into routine care. Regular, face-to-face screening of patients by skilled healthcare providers markedly increases the identification of victims of intimate partner violence, as well as those who are at risk for verbal, physical, and sexual abuse. Routine inquiry of all patients, as opposed to indicator-based assessment, increases opportunities for both identification and effective interventions, validates violence and abuse as a central and legitimate healthcare issue, and enables providers to assist both victims and their children.

When victims or children exposed to violence and abuse are identified early, providers may be able to break the isolation and coordinate with domestic or sexual violence advocates to help patients understand their options, live more safely within the relationship, or safely leave the relationship. Expert opinion suggests that such interventions in adult health settings may lead to reduced morbidity and mortality. Assessment for exposure to lifetime abuse has major implications for primary prevention and early intervention to end the cycle of violence.

Just as the healthcare system has always played an important role in identifying and preventing other serious public health problems, I believe it can and must play a pivotal role in domestic and sexual violence prevention and intervention. It is clear that by funding these innovative and life-saving health provisions, we can help save the lives of victims of violence and greatly reduce healthcare expenses.

In order to advance necessary and needed health goals, I urge you to fund the following LHHS programs accordingly:

*Violence Against Women Health Initiative at $3.375 million*

The existing program, entitled "Project Connect: A Coordinated Public Health Initiative to Prevent Violence Against Women," is working with two southern California tribes and eight States (Arizona, Georgia, Ohio, Iowa, Maine, Michigan, Texas, Virginia) to change how adolescent health, reproductive health, and home visiting programs respond to sexual and domestic violence. The Initiative is developing and distributing education and training materials to respond to abuse across the lifespan. Research demonstrates that women in these programs are at high risk for abuse, and that there are evidence-based interventions that can improve maternal and child health, and decreases the risks for unplanned pregnancy, poor pregnancy outcomes and further abuse. These sites provide much-needed services for women in abusive relationships including historically medically underserved communities that have high rates of domestic and sexual violence, such as rural/frontier areas, immigrant women, and Native Americans. UC Davis School of Medicine is implementing an evaluation plan to measure the effectiveness of both the clinical intervention and policy change efforts.

The approach includes creating and disseminating:

—Enhanced clinical interventions to respond to domestic and sexual violence, including training and supporting materials for providers and health systems,
—Patient education materials on the connection between abuse and their health,
—Policy and systems change at the local, State and national level,
—National training of providers through an eLearning platform,
—Pilot programs to offer basic health services within domestic and sexual violence programs, and
—Evaluation and research on the health impact of abuse and the impact of health-based interventions.

In the first year using fiscal year 2009 funding, the Initiative had a significant impact:

—With over 1,500 providers from 50 clinical sites receiving training, programs serving over 200,000 women will integrate assessment for abuse into routine care and offer help when needed, using an evidence-based and setting-specific clinical intervention.
—New education materials for providers and patients/clients have been developed, including:
—New training curriculum for home visitation programs
—New safety cards for adolescents talking about healthy relationships

—Twelve new video vignettes an electronic distance learning platform that will be used to train providers in adolescent, reproductive and maternal and child health programs nationwide.
—Coordinated State level teams of public health and domestic and sexual violence partners have been formed to create lasting health policy and coordinated response to victims. Examples of policy change include adding assessment of domestic and sexual violence into statewide nursing guidelines, and improving data collection by adding new questions about domestic and sexual violence to statewide surveillance systems.

This year, the sites are continuing this work but building on the momentum by:
—Implementing an e-learning platform to train tens of thousands of additional physicians, nurses, and students. Beginning in Spring 2011, the free online CME trainings will be offered to Project Connect sites, as well as national health associations, such as the American College of Obstetricians and Gynecologists.
—Offering basic health services on site in select domestic and sexual violence programs in each Project Connect site. Program strategies include: utilizing mobile health vans, stationing public health nurses in family violence programs, integrating basic health assessment questions into domestic violence shelter intake, and partnering with local providers for ongoing care.
—Evaluating the impact of Project Connect's clinical intervention on the health and safety of victims of abuse. In addition to the initiative-wide evaluation of provider behavior change, four sites have partnered with local universities to conduct an in-depth evaluation of the effect that integrating the assessment of domestic and sexual violence into clinical settings has on clients.
—Disseminating information on best practice models for integration in other States/tribes and service settings. Plans include an educational briefing and development of a report outlining model programs.

*Report Language under Centers for Disease Control and Prevention Injury Prevention and Control regarding Domestic and Sexual Violence*

In VAWA 2005, Congress approved a program entitled "Research on Effective Interventions to Address Violence Against Women" at $5 million through CDC and ARHQ to support research and evaluation on effective interventions in the healthcare setting to improve victim's health and safety and prevent initial victimization. This authorized program from Public Law 109–162 has not been funded. The President's fiscal year 2012 budget recommends $20 million of the Prevention and Public Health Fund go to unintentional injuries through CDCs Injury Prevention and Control. To fulfill the need recognized by the earlier VAWA program, I respectfully recommend the following report language:

"The Committee finds that domestic and sexual violence is a healthcare problem and one of the most significant social determinants of health for women and girls. In addition to the immediate trauma caused by abuse, it contributes to a number of chronic health problems. The CDC classifies violence and abuse as a "substantial public health problem in the United States." As part of the budget request to fund unintentional injury prevention activities from the Prevention and Public Health Fund, the Committee supports a portion of the funding support the prevention of intentional injuries from lifetime exposure to intimate partner violence, child maltreatment, youth violence, and sexual violence."

*Proposed Report Language under HHS Office of Adolescent Health regarding Teen Dating Violence and Communities of Color*

The work by the Office of Adolescent Health to create and administer the Teen Pregnancy Prevention Program in such a short time period has been remarkable. That said, adolescents from communities of color are disproportionately affected by teenage pregnancy, and research also shows that teenage dating violence and abuse are associated with higher levels of teenage pregnancy and unplanned pregnancy. Adolescent girls in physically abusive relationships are three times more likely to become pregnant than non-abused girls. To fulfill the promise of the Office of Adolescent Health to holistically address teen pregnancy prevention, I respectfully recommend the following report language:

"The Committee strongly urges the Secretary, through the Office of Adolescent Health, to include teen dating violence prevention and healthy relationship strategies within existing adolescent health working groups and better integrate preventing violence and abuse as a strategy to prevent teen and unplanned pregnancy within communities of color. Further, the Committee strongly urges the Secretary, though the Office of Adolescent Health, to conduct a review of the evidence-based programs chosen by the Teen Pregnancy Prevention Program and issue a report to

determine which programs address teen dating violence and healthy relationship strategies as a means to prevent teen pregnancy."

In addition, I ask that you at least meet the President's fiscal year 2012 request of $135 million for the Family Violence Prevention and Services Act (FVPSA) under ACF, the Nation's only designated Federal funding source for domestic violence shelters and services. As we are all committed to both the prevention of violence and abuse and to the health and safety of victims, I urge you to fund these critical programs.

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PREPARED STATEMENT OF THE GLOBAL HEALTH TECHNOLOGIES COALITION

Chairman Harkin, Ranking Member Shelby and members of the Committee, thank you for the opportunity to provide testimony on the fiscal year 2012 appropriations funding for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). We appreciate your leadership in promoting the importance of international development, in particular global health. We hope that your support will continue. I am submitting this testimony on behalf of the Global Health Technologies Coalition (GHTC), a group of nearly 40 nonprofit organizations working together to advance U.S. policies which can accelerate the development of new global health innovations—including new vaccines, drugs, diagnostics, microbicides, and other tools—to combat global health diseases. The GHTC's members strongly believe that to meet the global health needs of tomorrow, it is critical to invest in research today so that the most effective health solutions are available when we need them, and that the U.S. Government has a historic and unique role in doing so. My testimony reflects the needs expressed by our member organizations[1] which include nonprofit advocacy organizations, policy think-tanks, implementing organizations, and many others. One-third of our members are also nonprofit product development partnerships, which work with partners in the private biotechnology and pharmaceutical and medical device sectors, as well as public research institutions, academia, and nongovernmental organizations to develop new and more effective life-saving technologies for the world's most pressing health issues. We strongly urge the Committee to continue its established support for global health research and development (R&D) by (1) sustaining and protecting the U.S. investment in global health research and product development, (2) instructing NIH and CDC, in collaboration with other agencies involved in global health, to continue their commitment to global health in their R&D programs, and (3) requiring leaders at U.S. agencies to put plans in place to ensure that global health R&D is efficient, coordinated and streamlined.

*Critical need for new global health tools*

Our Nation's investments have made historic strides in promoting better health around the world: nearly 6 million people living with HIV/AIDS now have access to life-saving medicines, new, cost-effective tools help us diagnose diseases quicker and more efficiently than ever before, and innovative new vaccines are making significant dents in childhood mortality. While we must increase access to these and other proven, existing health tools to tackle global health problems, it is just as critical that we continue to invest in developing the next generation of tools to stamp out disease and address current and emerging threats. For instance, newer, more robust, and easier to use antiretroviral drugs, particularly for infants and young children, are needed to treat (and prevent) HIV and even a 50 percent effective AIDS vaccine could prevent 1 million HIV infections every year. Drug-resistant tuberculosis is on the rise globally, including in the United States, however the only vaccine on the market is insufficient at 90 years old, and most therapies are more than 50 years old, extremely toxic, and exorbitantly expensive. New tools are also urgently needed for fatal neglected tropical diseases such as sleeping sickness for which diagnostic tools are inadequate, and the few drugs that are available are toxic and difficult to use. There are many very promising technology candidates in the R&D pipeline to address these and other health issues; however, these tools will never be available if the support needed to continue R&D is not protected and sustained.

*Research and US global health efforts*

The United States is at the forefront of innovation in global health technologies. For example, as recently as December, a new meningitis vaccine costing less than 50 cents per dose developed by the Meningitis Vaccine Project—a partnership be-

[1] GHTC member list: http://www.ghtcoalition.org/coalition-members.php.

tween the World Health Organization and the international nonprofit PATH—was distributed for the first time in Africa—the development and implementation of which was supported through strategic funding and scientific expertise from the CDC, NIH, U.S. Food and Drug Administration (FDA), and the U.S. Agency for International Development (USAID).

The NIH is the largest funder of global health research in the U.S. Government, and the agency has recently demonstrated a growing interest in global health issues. NIH Director Francis Collins made global health one of his top five priorities for the future of NIH, stating, ". . . the world has seen us as the soldier to the world. Might we not do better both in terms of our benevolence and our diplomacy by being more of a doctor to the world?[2] The NIH's Fogarty International Center recently began collaborating with the Department of Health and Human Services' Health Research Services Administration and the U.S. Department of State's Office of the U.S. Global AIDS Coordinator on the Medical Education Partnership Initiative to develop, expand, and enhance models of medical education. This includes enhancing the capacity of local individuals to conduct research on global health diseases. Also recently, the Therapeutics for Rare and Neglected Diseases (TRND) program at the NIH launched five pilot projects to spur drug development for diseases including schistosomiasis and hookwoom. Each of these efforts build on the historic work carried out by the agency which contributes to improved health around the world.

With operations in more than 54 countries, the CDC is engaged in many global health research efforts. The work of CDC scientists has led to major advances against devastating diseases, including the eradication of smallpox and early identification of the disease that became known as AIDS. Although CDC is known for its expertise and participation in HIV, TB, and malaria programs, it also operates several activities for neglected diseases in its National Center for Zoonotic, Vector-Borne, and Enteric Diseases.

*Leveraging the private sector for innovation*

NIH, CDC, USAID and other agencies involved in global health R&D regularly collaborate with the private sector in developing, manufacturing, and introducing important technologies such as those described above through public-private partnerships, including product-development partnerships. These partnerships leverage public-sector expertise in developing new tools, partnering with academia, large pharmaceutical companies, the biotechnology industry, and governments in developing countries to drive greater development of products for neglected diseases for which private industries have not historically invested. This unique model has generated twelve new global health products and has enormous potential for continued success if robustly supported.

In order to more fully engage the private sector in developing products for global health R&D, additional market-based incentives are needed. With little-to-no commercial drive to develop new drugs and vaccines for diseases that primarily affect the developing world, financial incentives and innovative financing must be pursued. No single incentive scheme or financing mechanism is capable of filling all the gaps and encouraging the full range of R&D activities across all of the diseases and products that the developing world urgently needs. A portfolio of incentives and financing mechanisms that can fill the multiple gaps in the product development pipeline for multiple diseases is needed. NIH should be applauded for its participation in the small business innovation research awards and a patent pool for HIV medicines, and additional efforts in this area are encouraged. The development of new incentive strategies is critical for long-term, meaningful private-sector engagement in global health.

*Innovation as a smart economic choice*

Global health R&D brings life-saving tools to those who need them most, however the benefits these efforts bring are much broader than preventing and treating disease. Global health R&D is also a smart economic investment in the United States, where it drives job creation, spurs business activity, and benefits academic institutions. Biomedical research, including global health, is a $100 billion enterprise in the United States. In a time of global financial uncertainty, it is important that the United States support industries, such as global health R&D, which build the economy at home and abroad.

History has shown that investing in global health research not only saves lives but is also a cost-effective approach to addressing health challenges. And an invest-

[2] NIH all-hands town meeting, 17 August 2009. http://videocast.nih.gov/Summary.asp?File=15247.

ment made today can help save significant money in the future. In the United States alone, for example, polio vaccinations during the last 50 years have resulted in a net savings of $180 billion, funds that would have otherwise been spent to treat those suffering from polio. In addition, new therapies to treat drug-resistant tuberculosis have the potential to reduce the price of tuberculosis treatment by 90 percent and cut health system costs significantly. The United States has made smart investments in research in the past that have resulted in lifesaving breakthroughs for global health diseases, as well as important advances in diseases endemic to the United States. We must now build on those investments to turn those discoveries into new vaccines, drugs, tests, and other tools.

*Recommendations*

In this time of fiscal constraint, support for global health research that improves the lives of people around the world—while at the same time creating jobs and spurring economic growth at home—should unquestionably be one of the Nation's highest priorities. In keeping with this value, the GHTC respectfully requests that the Committee do the following:

—Sustain and protect U.S. investments in global health research and product development within both the CDC and NIH budgets. We ask that this not come at the expense of robust funding for the entire set of global public health accounts, all of which complement each other and ultimately serve the common goal of building a healthier and more prosperous world.

—Instruct all U.S. agencies in its jurisdiction to continue their commitment to global health in their R&D programs by developing actions plans, including metrics to measure progress. The Committee shall request that leaders at NIH and CDC work with leaders at other U.S. agencies to ensure that efforts in global health R&D are coordinated, efficient, and streamlined by establishing transparency mechanisms designed to show what global health R&D efforts are taking place and how U.S. agencies are collaborating with each other to make efficient use of the U.S. investment.

—Request relevant agencies report on their progress to Congress and be made publicly available. Past accounting of the health R&D activities at individual agencies, such as Research, Condition, and Disease Categorization at NIH, have been very helpful in coordinating efforts between agencies and informing the public and such efforts should be expanded to include neglected disease categorization and extended to provide a comprehensive picture of this investment from all agencies involved in global health R&D.

We respectfully request that the Committee consider inclusion of the following language in the report on the fiscal year 2012 State and Foreign Operations appropriation legislation:

"The Committee recognizes the urgent need for new global health technologies in the fight against global health diseases, and the critical contribution that the NIH, CDC, and FDA make to this cause through their health research and training portfolios, operations research and regulatory capabilities. The Committee also acknowledges the urgent need to sustain and protect U.S. investment in this important research by fully funding these three agencies to carry out their work.

"New global health products such as drugs, vaccines, diagnostics, and devices are cost-effective public health interventions that play an important role in improving global health and are vital in stopping pandemics. The Committee understands the positive impact that global health research and development has on the U.S. economy through the creation of U.S. jobs and the development of foreign markets for U.S. products. NIH is widely recognized as the world leader in basic research, and has supplied invaluable breakthroughs that have led to new health tools, saving millions of lives globally. Through its Fogarty International Center, NIH harnesses its wealth of expertise to train the next generation of health scientists.

"The Committee directs the CDC, FDA, and NIH to each create metrics to measure progress and to develop concrete plans to prioritize and incorporate global health research, product development, and regulation into their U.S. global health and development strategies. The Committee directs CDC, FDA, and NIH to work with each other as well as the Department of State, the U.S. Agency for International Development, and the Office of the U.S. Global AIDS Coordinator to ensure that these efforts are coordinated, efficient, and streamlined across the agencies involved in implementing the President's Global Health Initiative. CDC, FDA, and NIH shall each make the documentation and results of these efforts available to Congress and the public."

As a leader in science and technology, the United States has the ability to capitalize upon our strengths to help reduce illness and death and ultimately eliminate

disabling and fatal diseases for people worldwide, contributing to a healthier world and a more stable global economy. Sustained investments in global health research to develop new drugs, vaccines, tests, and other health tools—combined with better access to existing methods to prevent and treat disease—present the United States with an opportunity to dramatically alter the course of global health while building political and economic security across the globe.

On behalf of the members of the GHTC, I would like to extend my gratitude to the Committee for the opportunity to submit written testimony for the record.

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PREPARED STATEMENT OF GOODWILL INDUSTRIES INTERNATIONAL

Mr. Chairman, Ranking Member, and Members of the Subcommittee, on behalf of Goodwill Industries International® (GII), I appreciate this opportunity to submit written testimony on Goodwill's priorities for fiscal year 2012 funding programs administered by the U.S. Departments of Labor, Health and Human Services, and Education.

Goodwill Industries International (GII) represents 158 local and autonomous Goodwill Industries agencies in the United States that help people with barriers to employment to participate in the workforce. One of Goodwill Industries' greatest strengths continues to be its entrepreneurial approach to sustaining its mission. In 2010, Goodwill raised more than $4 billion in its retail stores and other social enterprises and invested 84 percent of its privately raised revenues to supplement Federal investments in programs that give people the skills they need to reenter the workforce. Goodwill provided job training, employment services, and supportive services to nearly 2.5 million people, placing more than 170,000 people in jobs and employing 97,000. Nearly 160,000 people were referred to Goodwill from the workforce system or a State Vocational Rehabilitation Agency. In addition to our efforts to help people find jobs and advance in careers, Goodwill understands that many people need additional supportive services—child care, reliable transportation, stable housing, counseling and assistance in adjusting to the workplace, assistive technology—to ensure their success.

Now more than ever, with unemployment slowly declining from the highest levels experienced in a generation, local Goodwill agencies are on the front lines of the fragile recovery assisting people with employment barriers, including individuals with disabilities, older workers, and Temporary Assistance to Needy Families (TANF) recipients who are struggling to find and keep jobs during a stubbornly tight job market. In addition in 2010, Goodwill's collective investment in these services eclipsed the Department of Labor's combined investment in WIA's adult, youth, and dislocated workers.

While Goodwill is proud of these and other achievements, they are truly the result of a public-private partnership. As the fragile recovery from the worst recession since the Great Depression continues and unemployment rates slowly decline from near 10 percent, Goodwill understands the difficult challenge that appropriators face as they struggle to reduce the deficit while stretching limited resources to support an ever-increasing list of national priorities. Reducing the deficit is a serious issue that will require all to make sacrifices to address the Nation's spending problem while investing in integrated strategies that build upon and leverage existing resources that will address our Nation's revenue problem. Therefore, Goodwill was very concerned about the drastic cuts to the workforce system that were proposed in the fiscal year 2011 continuing resolution (H.R. 1) that was passed by the House of Representatives earlier this year, and thanks the Senate for its efforts to mitigate the cuts in the final fiscal year 2011 spending deal. As Congress works to develop its spending bills for fiscal year 2012, Goodwill is again concerned because the House budget allocation for Labor, Health and Human Services, and Education is $18 billion less than the amount agreed to in the final fiscal year 2011 budget deal.

Goodwill is aggressively moving to increase its capacity to do more to help people find jobs and advance in careers during and after these difficult times. Goodwill is working to open more stores and attended donation centers in order to create jobs and generate more privately raised revenues to invest in people who are facing employment challenges in the communities that local Goodwill agencies serve. In addition, Goodwill is more committed than ever to partnering with stakeholders at the Federal, State, and local levels by contributing the resources and expertise of local Goodwill agencies in support of public efforts and investments.

While our agencies care about a range of Federal funding sources, Goodwill urges Congress to provide funding for the Department of Labor's Senior Community Service Employment Program (SCSEP); the Workforce Investment Act's adult, dislocated

worker, and youth funding streams; summer jobs for youth; and the Department of Education's Vocational Rehabilitation programs.

*Senior Community Service Employment Program (SCSEP)*

Workers who are 55 and older have multiple barriers to employment and will be among the last rehired as the economy improves. Furthermore, according to the Bureau of Labor Statistics, the unemployment rate for older workers (over 55 years old) was 6.2 percent in April, 2011. While older workers are less likely to be unemployed than their younger counterparts, older workers who do lose their jobs face significant odds of finding another one. The average time spent looking for a job by someone between the ages of 55 and 64 is 44.6 weeks. Those over the age of 64 also spend nearly 1 year seeking work for an average of 43.9 weeks. Older workers are more likely to be laid off from industries that are in structural decline. This population may be less likely to go back to school as they have other financial burdens and are less mobile due to home ownership. Finally, these workers may face age discrimination when applying for a new job. Therefore, Goodwill is alarmed by the Administration's proposal to cut funding for the Community Services Employment for Older Americans program (also called the Senior Community Service Employment Program) by 45 percent which will result in the elimination of services to nearly 50,000 low income older workers who badly in need of assistance.

SCSEP helps provide low-income older workers with community services employment and private sector job placements. Preserving SCSEP funding is critical as it is the only program targeted to helping low income seniors regain employment, as this population is experiencing the toughest employment prospects in a generation. Goodwill is a national SCSEP grantee with providers around the country. While many individuals assume that SCSEP is for much older workers and question the type of training received, 42 percent of Goodwill's SCSEP participants are between the ages of 55 and 59. In 2010, SCSEP participants contributed nearly 1.4 million community service hours and our private sector placements averaged a starting wage of $9.75 per hour.

In recent years, Congress has demonstrated its commitment to older workers by providing an additional $120 million for SCSEP in the Recovery Act, and a $250 million increase in fiscal year 2010. These funds have allowed local Goodwill agencies to better address our waiting list of participants and help many older workers with part-time employment. Private sector placement wages also increased. Goodwill very much appreciates the monumental investment that the Congress has placed on helping older workers to survive the economic crisis. However, as SCSEP program providers prepare for a cut in funding, community service hours have been cut, new enrollees have not been accepted, and additional classroom training that has an added cost have been reduced or eliminated. Should SCSEP be cut further, it will result in a loss of professional staff and it will be more difficult to get out to non-urban areas since rural communities will have fewer slots.

Goodwill urges the Subcommittee to reject the Administration's proposed cuts to SCSEP. At a minimum Congress should fund SCSEP at no less than $600 million, which will allow a restoration of assistance to an additional 24,000 participants, nearly half of the participants cut from the program by funding reductions in the fiscal year 2011 Continuing Resolution.

*Workforce Investment Act*

Funding for the Workforce Investment Act's youth, adult, and dislocated worker formulas is one of Goodwill's top funding priorities for fiscal year 2012. Most Goodwill agencies have people referred to them through the workforce system. In addition, several agencies are one-stop lead operators or operators in association with other service providers, and are active on state and local workforce boards.

It should be noted that, in 2002, when the unemployment rate was 5.8 percent, combined funding for WIA's youth, adult, and dislocated worker funding streams was more that $3.67 billion. Since then, funding has steadily eroded; and nearly 10 years later, at a time when the unemployment rate remains much higher—around 9 percent—the Administration proposes just $2.96 billion for WIA's three main funding streams, nearly 20 percent less than the fiscal year 2002 level. Furthermore, the Administration proposes to divert 8 percent to contribute to the creation of a Workforce Innovation Fund to "support and test promising approaches to training, and breaking down program silos, building evidence about effective practices, and investing in what works."

Goodwill believes that a Workforce Innovation Fund is a promising idea, is very interested in the details, and is encouraged by the Administration's efforts to increase interagency collaborations and leverage resources provided by community-based organizations, however the proposed Workforce Innovation Funds should be

paid for with funds in addition to, rather than at the expense of, existing WIA formula funds—in fiscal year 2012 and beyond.

In 2010, the workforce system served more than 8 million people, placing more than half in jobs while helping others to access education and training aimed at improving their future employment prospects. As noted earlier, Goodwill is doing all it can to help people who have been affected by the recession. In fact in 2010, Goodwill's collective investment in job training and employment services eclipsed the Department of Labor's combined investment in WIA's adult, youth, and dislocated workers. Some agencies have, in fact, been doing more than they can by deliberately using their reserves in order to provide help to more people than their current revenues support. If not now, when? Therefore, Goodwill is very concerned the continued delay in reauthorizing WIA may put the whole system at risk, causing many Goodwill agencies to wonder how they would respond to the dramatic increase in requests for services if the workforce system were to be dismantled completely. Most agencies would be forced to turn away people in need or risk being overleveraged to the brink.

Goodwill understands that this Subcommittee faces a difficult challenge in stretching limited resources to cover a range of priorities; however the workforce system is vastly under-funded and preservation of WIA's formula funding streams should be a high priority. Therefore, Goodwill urges Congress to sustain WIA's adult, dislocated worker, and youth funding streams at current funding levels at a minimum. Before diverting funds from WIA's already underfunded programs, Congress should reauthorize WIA and include provisions that would establish the Workforce Innovation Fund without jeopardizing existing funds for WIA's three core funding streams.

*Vocational Rehabilitation (VR) Funding*

Goodwill Industries has a long history of helping people with disabilities to participate in the workforce despite the challenges their disabilities present. Years of inadequate funding for VR have left the system stretched much too thin to serve all who are eligible for assistance. As a result, most State VR agencies have Orders of Selection, a provision within the Rehabilitation Act that requires State VR agencies, when faced with a shortage of funds to meet the demand for services, to prioritize the provision of services to eligible people based on the severity of people's disabilities. In addition, reduced funding for WIA has placed an additional strain on mandatory partner programs, including VR, which are being asked to contribute more funding to pay for infrastructure and other costs associated with the operation of one-stop centers.

Goodwill supports the Administration's intent to increase multi-system collaboration and support for youth with disabilities who are transitioning from education to the workforce. The Administration's fiscal year 2012 budget proposes to increase funding for VR State agencies by $57 million, while diverting $30 million of VR's State grant funds to contribute to a new Workforce Innovation Fund. Funding for the Rehabilitation Services Administration's Migrant and Seasonal Farmworker program, Projects with Industry, and Supported Employment would be eliminated, thus offsetting the increase by $50 million.

For more than two decades, Goodwill has offered supported employment as a part of its service array. According to Goodwill Industries International's Annual Statistical Report, participation in local Goodwill agencies' supported employment programs has grown dramatically in recent years from providing 270,000 coaching sessions in 2007 to 630,000 sessions in 2009.

Goodwill is intrigued by the Administration's proposal to stimulate system collaboration by creating a Workforce Innovation Fund; however, Goodwill believes that funding for the Workforce Innovation Fund should not come at the expense of existing and already inadequate funds for the VR system.

Goodwill thanks the Subcommittee for considering these requests, and looks forward to working with the Subcommittee to help government meet the serious challenges our nation faces.

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## PREPARED STATEMENT OF THE HARLEM CHILDREN'S ZONE

Thank you for this opportunity to support comprehensive services for poor children and the U.S. Department of Education's (ED) Promise Neighborhoods program which we believe will break the cycle of generational poverty for hundreds of thousands of poor children.

Like the work at the Harlem Children's Zone® (HCZ®), the Promise Neighborhoods program has already begun to transform the odds for entire communities.

High-achieving schools are at the core of Promise Neighborhoods, but it is not only about creating a successful school. It is about programs for children from birth through college and career, supporting families and rebuilding community. Doing this changes the trajectory of an entire community.

In the mid-1990s it became clear to the HCZ team that despite heroic efforts at saving poor children, success stories remained the exception. Our piecemeal approach was of limited value against a perfect storm of problems and challenges. So the HCZ Project was created in Central Harlem to work with kids, their families and their community. Starting with one building, HCZ has grown to 97 blocks. Last year, the HCZ Project served 15,508 clients including 8,838 youth and 6,670 adults. HCZ, Inc., which includes the HCZ Project plus our Beacon Centers and Preventive Foster Care programs, served 23,556 clients including 10,541 youth and 13,015 adults.

Now, over a decade later, the Children's Zone® model is working. Parents are reading more to their children. Four year olds are ready for kindergarten. Students are closing the black-white achievement gap in several subjects. Teenagers are graduating from high school and this school year, over 600 of them who attended traditional public schools are in college. HCZ helps parents file for taxes including the Earned Income Tax Credit (EITC) and last tax season, families collectively received over $8 million.

HCZ's theory of change is embodied in the application of all of the following five principles:

—Serve an entire neighborhood comprehensively and at scale.

—Create a pipeline of high-quality programs that starts from birth and continues to serve children until they graduate from college. Provide parents with supports as well.

—Build community among residents, institutions, and stakeholders, who help to create the environment necessary for children's healthy development.

—Evaluate program outcomes; create a feedback loop that cycles data back to management for use in improving and refining program offerings; and hold people accountable.

—Cultivate a culture of success rooted in passion, accountability, leadership, and teamwork.

The HCZ® model is not cheap. On average, HCZ spends $5,000 per child each year to ensure children's success. For far less money than is already spent, just on incarceration, we can educate, graduate our children, and bring them back to our communities ready to be successful, productive citizens. We think the choice is obvious.

HCZ's achievements are not magic. They are a result of hard work and a comprehensive effort.

This same type of hard work and comprehensive effort is happening in countless communities across the country. To provide a sense of the level of interest in the Promise Neighborhoods program, when the Department of Education offered the first round of planning grants in fiscal year 2010's budget, over 339 communities competed for just 21 grants. Additionally, over 100 of these communities scored over 80, leading Secretary of Education Arne Duncan to note that there would have been more grants if resources were available. Just 7 months later, these communities are going strong. For example:

*Buffalo, New York*

The Buffalo Promise Initiative, which is led by M&T's Westminster Foundation, is collaborating with the John R. Oishei Foundation, Read to Succeed Buffalo, the City of Buffalo, Buffalo Public Schools, United Way of Buffalo and Erie County, Catholic Charities, Buffalo Urban League, and the University at Buffalo to serve 11,000 residents in a 1-square mile, low-income neighborhood. The Buffalo Promise Initiative is a vital counterpoint to the challenges brought about in Buffalo due to a shift away from industrially focused jobs, a shrinking population, and increasing poverty. A comprehensive approach is blooming, addressing the needs and hopes of children and their families in a changing Buffalo.

*Indianola, Mississippi*

The Indianola Promise Community (IPC) is located in Indianola, Mississippi, in the heart of the Mississippi Delta and the birthplace of musician B.B. King. The Delta Health Alliance is the lead agency for this unique public policy initiative. The Indianola Promise Community unites healthcare, education, community, and faith-based services to provide Indianola residents the chance to realize their promise as active members and leaders in their town and neighborhoods. The Delta Health Alliance has teamed up with a number of nonprofit organizations and government agen-

cies, including the local school district, the municipal government, Mississippi State University, the county hospital, and the Children's Defense Fund, to develop a comprehensive collaborative with the ability to take on a number of pressing challenges.

Although Indianola has a number of obstacles to overcome, leaders from all aspects of the community have joined together to make the IPC a success. The Delta Health Alliance is integrating more than a dozen of their preexisting services and adding new programs and new partners into a robust set of resources. The goal is to create a set of integrated services for children and their families. The IPC engages with all community service providers to prevent the duplication of resources and highlight service gaps. Community members also serve on the Steering Committee that oversees the work of the project.

*Northern Cheyenne Reservation*

The rich and deep history of the Northern Cheyenne community and their commitment to engage their members is apparent in their plans to develop a thriving Promise Neighborhood for their community. The Promise Neighborhood is located on the Northern Cheyenne Reservation and the surrounding communities of Colstrip and Ashland in southeast Montana. The land is sprawling, approximately 700 square miles, and approximately 7,300 people live within the Neighborhood.

The Boys and Girls Club of Northern Cheyenne Nation (BGCNCN), the Promise Neighborhood lead partner, believes in "systemic, collaborative, strengths-based and culturally appropriate approaches" to youth and community development that will comprehensively address the disadvantages that the community faces.

The Boys and Girls Club has established relationships with local communities, and thus is an excellent lead partner for this initiative. All of the primary institutions that serve young people in the area are involved in collaborating during this planning year. The Promise Neighborhood has the full support of the Northern Cheyenne government, local schools and agencies, Chief Dull Knife College, and a number of nonprofits. All are working together to specifically create and implement in- and out-of-school strategies and services that will support the academic achievement, healthy development, cultural awareness and connectedness, and college and career success of the Neighborhood's children. Some of the BGCNCN's programs for youth include a Native American Mentoring Program, a diabetes prevention program, leadership groups, and a computer lab. The planning phase has brought these groups together to begin a more concerted effort to assess and develop a pipeline of programs that will benefit the youth and community.

*San Antonio, Texas*

The Eastside Promise Neighborhood in San Antonio, Texas is led by the United Way and has a strong partnership with the City of San Antonio. San Antonio Mayor Julián Castro and other community leaders are major supporters of the initiative. The Promise Neighborhood initiative is part of the City's larger plan to support the struggling Eastside, including the development of affordable housing, education, environment, and other supports, and developing a strategic framework that speaks to the community's core problems.

The Promise Neighborhood initiative, with its set of partners like the San Antonio Independent School District, Family Service Association, Housing Authority, City Year, Trinity University, San Antonio for Growth on the Eastside (SAGE), and the Urban Land Institute, is working hard to coordinate the supports and resources in the neighborhood to activate their collective vision for community transformation. The planning and coordination of resources going into the community as a part of the Promise Neighborhood initiative fits into the City's broader Eastside Reinvestment Plan aiming to shift away from siloed and uncoordinated services on the Eastside.

Because parents are a key element to their children's success, Eastside Promise Neighborhood has a commitment to parental engagement and capacity-building through focus groups, community meetings during which the community shapes the agenda, and parentally focused career and empowerment groups through initiatives like the United Way's Family-School-Community Partnership.

This asset-based approach and vision ensures more efficient and effective use of neighborhood talent, resources, rich opportunities for young people through high quality neighborhood schools and engaged parents, and a solid physical infrastructure including high-quality housing in the neighborhood to support the community. The community looks to be on the right path toward stabilizing and empowering the Eastside to stay, grow, graduate and . . . stay.

To support all of the Promise Neighborhoods' efforts, HCZ, PolicyLink and the Center for the Study of Social Policy joined together to create the Promise Neighborhoods Institute at PolicyLink (PNI). Supported solely by private philanthropic dol-

lars, PNI provides communities with a system of support, resources, and information to help them in local Promise Neighborhoods efforts. PNI is already supporting 38 Promise Neighborhoods—including 21 funded by the U.S. Department of Education. PNI has three goals:

—Ensure the 21 Federal planning grantees are successful and transition to implementation.
—Support an additional 17 communities in their planning efforts and transition to implementation.
—Foster a national learning network that enable communities to learn from their peers and leverage resources in order to significantly improve the educational and developmental outcomes of children and youth in the Nation's most distressed communities.

To accomplish these goals, PNI offers:

—Site visits designed to assess community need and implement a comprehensive and personalized package of technical assistance services that help communities learn, make systemic, organizational and programmatic improvements and achieve measurable and sustainable results.
—Promise Neighborhood Network conferences to share best practices.
—Trainings on topics such as how to attract funding and talk to the media.
—Webinars and discussions moderated by experts in the field.
—A website—PromiseNeighborhoodsInstitute.org—featuring in-depth resources and tools.

Since its launch, PNI has:

—Developed a rich menu of technical assistance that is based on what works.
—Grown a robust community of practice that is being accessed by more than 2,000 people.
—Implemented a feedback loop to continually refine city, county, State, and Federal public policy and philanthropic approaches.
—Mobilized neighborhood leaders to advocate for integrated neighborhood revitalization investments to become the norm in solving some of the Nation's most intractable problems affecting poor children and families.

In the current planning phase, Promise Neighborhoods are getting ready to apply for full implementation. They are developing strategic business plans to estimate revenues and cover costs. Part of this includes the development of data systems for how they will track and evaluate data to make sure that they can document success, and catch and deal with challenges. In addition, they are developing powerful partnerships with schools and with organizations and agencies so they can provide children and families with the supports and services that are needed for success from cradle to college and career. We look forward to continuing to work with the Promise Neighborhoods grantees and others as they transition from planning to implementation. And, we look forward to seeing the results of their efforts.

We urge the Committee to support Promise Neighborhoods with resources for new sites to engage in planning, and for robust support for implementation in communities across the country. Thank you for your consideration. If you should need additional information about The Promise Neighborhoods program please contact Judith Bell from PolicyLink (Judith@policylink.org) or Katie Shoemaker at HCZ (kshoemaker@hcz.org).

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## PREPARED STATEMENT OF THE HEALTH PROFESSIONS AND NURSING EDUCATION COALITION

The members of the Health Professions and Nursing Education Coalition (HPNEC) are pleased to submit this statement for the record in support of the fiscal year 2012 budget request of $762.5 million for the health professions education programs authorized under Titles VII and VIII of the Public Health Service Act and administered through the Health Resources and Services Administration (HRSA). HPNEC is an informal alliance of more than 60 national organizations representing schools, programs, health professionals, and students dedicated to ensuring the healthcare workforce is trained to meet the needs of the country's growing, aging, and diverse population. For a complete list of HPNEC members, visit http://www.aamc.org/advocacy/hpnec/members.htm.

As you know, the Title VII and VIII health professions and nursing programs provide education and training opportunities to a wide variety of aspiring healthcare professionals, both preparing them for careers in the health professions and helping bring healthcare services to our rural and underserved communities. An essential component of the healthcare safety net, the Title VII and Title VIII programs are the only Federal programs designed to train healthcare providers in interdiscipli-

nary settings to meet the needs of the country's special and underserved populations, as well as increase minority representation in the healthcare workforce. Through loans, loan guarantees, and scholarships to students, and grants and contracts to academic institutions and nonprofit organizations, the Title VII and Title VIII programs fill the gaps in the supply of health professionals not met by traditional market forces.

Authorized since 1963, the Title VII and Title VIII education and training programs are designed to help the workforce adapt to the evolving healthcare needs of the ever-changing American population. In an effort to renew and update Titles VII and VIII to meet current workforce challenges, the programs were reauthorized in 2010—the first reauthorization in the past decade. Reauthorization not only improved the efficiency of the Title VII and Title VIII programs, but also laid the groundwork for innovative programs with an increased focus on recruiting and retaining professionals in underserved communities.

HPNEC is grateful for the Subcommittee's longstanding support of these important workforce programs. While we are keenly aware that the Subcommittee continues to face difficult decisions as it seeks to improve the Nation's fiscal health, a continued congressional commitment to programs supporting healthcare workforce development is essential to the physical health and prosperity of the American people. The country faces a critical disparity between the supply of practicing healthcare providers and the increasing demand for care, with HRSA estimating that over 33,000 additional health practitioners are needed to alleviate existing shortages. Destabilizing funding for the Title VII and Title VIII programs would reduce education and training support for primary care physicians, nurses, and other health professionals, exacerbating shortages and further straining the Nation's already fragile healthcare system. We recognize that relative to other Federal programs, HRSA's fiscal year 2011 operating plan imposes modest cuts to most Title VII and Title VIII programs, and we look forward to working with the subcommittee to prevent any further erosion to Federal support for health professions training.

Failure to fully fund the programs would jeopardize activities to train professionals across all disciplines to coordinate care for the Nation's expanding elderly population; limit training opportunities for providers to meet the unique needs of the Nation's sick and ailing children; severely impact the distribution of professionals practicing in rural and underserved communities; and hinder efforts to recruit and retain a diverse and culturally competent workforce. To ensure the healthcare workforce is equipped to address these issues, a strong commitment to the Title VII and Title VIII programs is essential.

The existing Title VII and Title VIII programs can be considered in seven general categories:

—The Primary Care Medicine and Oral Health Training programs, now authorized separately, provide for the education and training of primary care physicians, physician assistants, and dentists, to improve access and quality of healthcare in underserved areas. Two-thirds of all Americans interact with a primary care provider every year. Approximately one-half of primary care providers trained through these programs go on to work in underserved areas, compared to 10 percent of those not trained through these programs. The General Pediatrics, General Internal Medicine, and Family Medicine programs provide critical funding for primary care training in community-based settings and have been successful in directing more primary care physicians to work in underserved areas. They support a range of initiatives, including medical student training, residency training, faculty development and the development of academic administrative units. These programs also enhance the efforts of osteopathic medical schools to continue to emphasize primary care medicine, health promotion, and disease prevention, and the practice of ambulatory medicine in community-based settings. Recognizing that all primary care is not only provided by physicians, the primary care cluster also provides grants for Physician Assistant programs to encourage and prepare students for primary care practice in rural and urban Health Professional Shortage Areas. The General Dentistry, Pediatric Dentistry, and Public Health Dentistry programs provide grants to dental schools and hospitals to create or expand primary care and public health dental residency training programs.

—Because much of the Nation's healthcare is delivered in areas far removed from health professions schools, the Interdisciplinary, Community-Based Linkages cluster provides support for community-based training of various health professionals. These programs are designed to provide greater flexibility in training and to encourage collaboration between two or more disciplines. These training programs also serve to encourage health professionals to return to such settings after completing their training. The Area Health Education Centers (AHECs)

provide clinical training opportunities to health professions and nursing students in rural and other underserved communities by extending the resources of academic health centers to these areas. AHECs, which have substantial State and local matching funds, form networks of health-related institutions to provide education services to students, faculty and practitioners. Geriatric Health Professions programs support geriatric faculty fellowships, the Geriatric Academic Career Award, and Geriatric Education Centers, which are all designed to bolster the number and quality of healthcare providers caring for our older generations. Given America's burgeoning aging population, there is a need for specialized training in the diagnosis, treatment, and prevention of disease and other health concerns of older adults. The Mental and Behavioral Health Education and Training Programs help mitigate the growing shortages of mental and behavioral health providers by providing grants for training social workers, child and adolescent mental health professionals, and paraprofessionals working with children and adolescents. They also provide grants to doctoral, internship, and postdoctoral programs through the Graduate Psychology Education program, which supports interdisciplinary training of psychology students with other health professionals for the provision of mental and behavioral health services to underserved populations (i.e., older adults, children, chronically ill, and victims of abuse and trauma, including returning military personnel and their families), especially in rural and urban communities.

—The purpose of the Minority and Disadvantaged Health Professionals Training programs is to improve healthcare access in underserved areas and the representation of minority and disadvantaged healthcare providers in the health professions. Minority Centers of Excellence support programs that seek to increase the number of minority health professionals through increased research on minority health issues, establishment of an educational pipeline, and the provision of clinical opportunities in community-based health facilities. The Health Careers Opportunity Program seeks to improve the development of a competitive applicant pool through partnerships with local educational and community organizations. The Faculty Loan Repayment and Faculty Fellowship programs provide incentives for schools to recruit underrepresented minority faculty. The Scholarships for Disadvantaged Students make funds available to eligible students from disadvantaged backgrounds who are enrolled as full-time health professions students.

—The Health Professions Workforce Information and Analysis program provides grants to institutions to collect and analyze data on the health professions workforce to advise future decisionmaking on the direction of health professions and nursing programs. The Health Professions Research and Health Professions Data programs have developed a number of valuable, policy-relevant studies on the distribution and training of health professionals, including the Eighth National Sample Survey of Registered Nurses, the Nation's most extensive and comprehensive source of statistics on registered nurses. In conjunction with the reauthorization of the Title VII programs and in recognition of the need for better health workforce data to inform both public and private decisionmaking, the National Center for Workforce Analysis serves as a source of data and information on the health workforce for the Nation.

—The Public Health Workforce Development programs are designed to increase the number of individuals trained in public health, to identify the causes of health problems, and respond to such issues as managed care, new disease strains, food supply, and bioterrorism. The Public Health Traineeships and Public Health Training Centers seek to alleviate the critical shortage of public health professionals by providing up-to-date training for current and future public health workers, particularly in underserved areas. Preventive Medicine Residencies, which receive minimal funding through Medicare GME, provide training in the only medical specialty that teaches both clinical and population medicine to improve community health. The Title VII reauthorization reorganized this cluster to include a focus on loan repayment as an incentive for health professionals to practice in disciplines and settings experiencing shortages. The Pediatric Subspecialty Loan Repayment Program offers loan repayment for pediatric medical subspecialists, pediatric surgical specialists, and child and adolescent mental and behavioral health specialists, in exchange for services in areas where these types of professionals are in short supply. The Public Health Workforce Loan Repayment Program provides loan repayment for public health professionals accepting employment with Federal, State, local, and tribal public health agencies.

—The Nursing Workforce Development programs under Title VIII provide training for entry-level and advanced degree nurses to improve the access to, and

quality of, healthcare in underserved areas. These programs provide the largest source of Federal funding for nursing education, providing loans, scholarships, traineeships, and programmatic support that, between fiscal year 2006 and 2009, supported over 347,000 nurses and nursing students as well as numerous academic nursing institutions, and healthcare facilities. Healthcare entities across the Nation are experiencing a crisis in nurse staffing, caused in part by an aging workforce and capacity limitations within the educational system. Each year, nursing schools turn away tens of thousands of qualified applications at all degree levels due to an insufficient number of faculty, clinical sites, classroom space, clinical preceptors, and budget constraints. At the same time, the need for nursing services and licensed, registered nurses is expected to increase significantly over the next 20 years. The Advanced Education Nursing program awards grants to train a variety of advanced practice nurses, including nurse practitioners, certified nurse-midwives, nurse anesthetists, public health nurses, nurse educators, and nurse administrators. Workforce Diversity grants support opportunities for nursing education for students from disadvantaged backgrounds through scholarships, stipends, and retention activities. Nurse Education, Practice, and Retention grants are awarded to help schools of nursing, academic health centers, nurse-managed health centers, State and local governments, and other healthcare facilities to develop programs that provide nursing education, promote best practices, and enhance nurse retention. The Loan Repayment and Scholarship Program repays up to 85 percent of nursing student loans and offers full-time and part-time nursing students the opportunity to apply for scholarship funds. In return these students are required to work for at least 2 years of practice in a designated nursing shortage area. The Comprehensive Geriatric Education grants are used to train RNs who will provide direct care to older Americans, develop and disseminate geriatric curriculum, train faculty members, and provide continuing education. The Nurse Faculty Loan program provides a student loan fund administered by schools of nursing to increase the number of qualified nurse faculty.

—The loan programs under Student Financial Assistance support financially needy and disadvantaged medical and nursing school students in covering the costs of their education. The Nursing Student Loan (NSL) program provides loans to undergraduate and graduate nursing students with a preference for those with the greatest financial need. The Primary Care Loan (PCL) program provides loans covering the cost of attendance in return for dedicated service in primary care. The Health Professional Student Loan (HPSL) program provides loans covering the cost of attendance for financially needy health professions students based on institutional determination. The NSL, PCL, and HPSL programs are funded out of each institution's revolving fund and do not receive Federal appropriations. The Loans for Disadvantaged Students program provides grants to health professions institutions to make loans to health professions students from disadvantaged backgrounds.

By improving the supply, distribution, and diversity of the Nation's healthcare professionals, the Title VII and Title VIII programs not only prepare aspiring professionals to meet the country's workforce needs, but also help to improve access to care across all populations. The multi-year nature of health professions education and training, coupled with unprecedented existing and looming provider shortages across many disciplines and in many communities, necessitate a strong, continued, and reliable commitment to the Title VII and Title VIII programs.

While HPNEC members understand of the immense fiscal pressures facing the Subcommittee, we respectfully urge support for $762.5 million for the Title VII and VIII programs, a commitment essential not only to the development and training of tomorrow's healthcare professionals but also to our Nation's efforts to provide needed healthcare services to underserved communities. We forward to working with Senators to prioritize the health professions programs in fiscal year 2012 and into the future.

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## PREPARED STATEMENT OF THE HEPATITIS B FOUNDATION

Highlighting the urgent need to address the public health challenges of chronic hepatitis B by strengthening programs at the Centers for Disease Control and Prevention, and the National Institutes of Health.

Mr. Chairman, my name is Dr. Timothy Block, and I am the President and Co-Founder of the Hepatitis B Foundation and its research institute, the Institute for Hepatitis and Virus Research. I also serve as the President of the Pennsylvania Biotechnology Center and am a professor at Drexel University College of Medicine. My

wife Joan, and I, and another couple, Paul and Janine Witte, from Pennsylvania started the Hepatitis B Foundation 20 years ago to find a cure for this serious chronic liver disease and provide information and support to those affected.

Thank you for giving the Hepatitis B Foundation (HBF) the opportunity to provide testimony to the Subcommittee as you begin to consider funding priorities for fiscal year 2012. We are grateful to the Members of this Subcommittee for their interest and strong leadership for efforts to control and find cures for hepatitis B.

Today, the HBF is the only national nonprofit organization solely dedicated to finding a cure and improving the lives of those affected by hepatitis B worldwide through research, education and patient advocacy. Our scientists focus on drug discovery for hepatitis B and liver cancer, and early detection markers for liver cancer. HBF staff manages a comprehensive website which receives almost 1 million visitors each year, a national patient conference and outreach services. HBF public health professionals conduct research initiatives to advance our mission.

The hepatitis B virus (HBV) is the world's major cause of liver cancer—and while other cancers are declining, liver cancer is the fastest growing in incidence in the United States. Without intervention, as many as 100 million worldwide will die from a HBV-related liver disease, most notably liver cancer. In the United States, up to 2 million Americans have been chronically infected and more than 5,000 people die each year from complications due to HBV.

HBV is 100 times more infectious than the HIV/AIDS virus. Yet, hepatitis B can be prevented with a safe and effective vaccine. Unfortunately, for those who are chronically infected with HBV, the vaccine is too late. There are, however, promising new treatments for HBV. We are getting close to solutions but lack of sustained support for public health measures and scientific research is threatening progress. New research has confirmed that early detection and treatment significantly reduces healthcare costs, morbidity and mortality. The growing incidence of liver cancer, while most other cancer rates are on the decline, represents examples of serious shortcomings in our system. In the United States, 20,000 babies are born to mothers infected with HBV each year, and as many as 1,200 newborns will be chronically infected with the hepatitis B virus. More needs to be done to prevent new infections.

*HHS Interagency Working Group on Viral Hepatitis*

Last year, the Department of Health and Human Services put together an Interagency Working Group on Hepatitis to put together an Action Plan on Viral Hepatitis. This action plan will describe opportunities for HHS to respond to the 2010 Institute of Medicine (IOM) review of the viral hepatitis challenge in the United States and the IOM recommendations to prevent and build the capacity and collaborations essential for reducing the number of viral hepatitis infections and ameliorating the health and economic consequences of viral hepatitis among persons chronically infected. The Hepatitis B Foundation is very supportive of the efforts of the Working Group and is hopeful that its recommendations will result in actions to address the chronic underfunding of viral hepatitis prevention, research and outreach programs within the Department. We look forward to the release of the Hepatitis Action Plan in May of this year.

Mr. Chairman, as you know the two Federal agencies that are critical to the effort to help people concerned with hepatitis B are: the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH).

*The Centers for Disease Control*

CDC's Division of Viral Hepatitis (DVH), the centerpiece of the Federal response to controlling, reducing and preventing the suffering and deaths resulting from viral hepatitis, is chronically underfunded. DVH is included in the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention at the CDC, and is responsible for the prevention and control of viral hepatitis. DVH is currently (prior to finalization of the fiscal year 2011 continuing resolution) funded at $19.8 million, approximately $6 million less than its funding level in fiscal year 2003. In the President's fiscal year 2012 budget proposal, DVH is funded at $25 million, an increase of $5.2 million. The HBF is very supportive of this increase and joins the hepatitis community in urging the Committee to fund the President's request for the Division of Viral Hepatitis.

The responsibility for addressing the problem of hepatitis should not lie solely with the Division. In view of the preventable nature of these diseases, the Hepatitis B Foundation feels that the National Center for Chronic Disease Prevention should also include a targeted effort focused on the prevention of chronic viral hepatitis which adversely impacts 5 million Americans. Specifically, we ask that the Committee include language urging the Center to help insure that the Prevention and

Public Health Funds, particularly the Community Transformations Grants, are available to support viral hepatitis prevention projects.

Furthermore, there are 400 million people chronically infected with hepatitis B worldwide, with more than 120 million of these individuals in China. While hepatitis B transmission requires direct exposure to infected blood, worldwide misinformation about the disease has fueled inappropriate discrimination against individuals with this vaccine-preventable and treatable bloodborne disease. HBF urges the Committee to instruct the CDC to initiate global programs to increase the rate of vaccination, reduce mother-child transmission and promote educational programs to prevent the disease and to reduce discrimination targeted against individuals with the disease.

*The National Institutes of Health*

We depend upon the NIH to fund research that will lead to new and more effective interventions to treat people with hepatitis B and liver cancer. The Hepatitis B Foundation joins with the Ad Hoc Group for Biomedical Research and requests a funding level of $35 billion for the National Institutes of Health in fiscal year 2012.

We thank the Committee for their continued investment in the NIH. Sustaining progress in medical research is essential to the twin national priorities of smarter healthcare and economic revitalization. With additional investment, the Nation can seize the unique opportunity to build on the tremendous momentum emerging from the strategic investment in NIH made through the 2009 American Recovery and Reinvestment Act (ARRA). NIH invested those funds in a range of potentially revolutionary new avenues of research that will lead to new early screenings and new treatments for disease.

In fiscal year 2010, NIH spent approximately $70 million on hepatitis B funding overall including $4 million of onetime funding from the American Recovery and Reinvestment Act. It is estimated that in fiscal year 2011 hepatitis B funding will return to the base level of $66 million. Additional funding could make transformational advances in research leading to better treatments for HBV. The Hepatitis B Foundation recommends that at a minimum, funding allocated for HBV research in fiscal year 2012 be increased at the same rate recommended for NIH overall and, therefore, funded at $75.7 million.

The current leadership of the NIH has performed admirably with the limited resources they are provided; however, more is needed. While a number of cancers have achieved 5-year survival rates of over 80 percent and the average 5-year survival rate for all cancers has increased from 50 percent in 1971 to 66 percent, significant challenges still remain for other types of cancers, particularly the most deadly forms of cancer. In fact, nearly half of the 562,340 cancer deaths in 2009 were caused by eight forms of cancer with 5-year relative survival rates of less than 50 percent: ovary (45.5 percent), brain (35.0 percent), myeloma (34.9 percent), stomach (24.7 percent), esophagus (15.8 percent), lung (15.2 percent), liver (11.7 percent), and pancreas (5.1 percent). It is no coincidence that cancers with significantly better 5 year survival rates, such as breast, prostate, colon, testicular, and chronic myelogenous leukemia, also have early detection tools, and in many cases, several effective treatment options thanks to research programs championed and supported by Congress. By contrast, research into the cancers with the lowest 5-year survival rates has been relatively under-funded, and as a result, these cancers have no early detection or treatment tools.

The Hepatitis B Foundation requests the establishment of a targeted cancers program at the National Cancer Institute (NCI) for the high mortality cancers. It should include a strategic plan for progress, an annual report from NCI to Congress, and a new grant program specifically focused on the deadly cancers. Additionally, the Hepatitis B Foundation urges a stronger focus on liver cancer and urges the funding of a series of Specialized Programs of Research Excellence (SPOREs) focused on liver cancer. While SPOREs currently exist for every other major cancer, none currently exist that are focused on liver cancer.

*Prevention Fund*

The Patient Protection and Affordable Care Act included the creation of a Prevention and Public Health Fund, to be used to reduce chronic disease rates and to address health disparities. To further clarify the intended use of these funds, earlier this year, the National Prevention, Health Promotion and Public Health Council that was established to advice on the use of these funds, released a report with recommendations. Included in the report were recommendations that "opportunities be expanded within communities and populations at greatest risk for diseases such as Viral Hepatitis B and C" and that there be an increased use of the "the most effec-

tive and highest impact evidence-based clinical preventive services and medications, such as screening and treatment for chronic viral hepatitis." Therefore, it is our view that insuring the Prevention Funds resources can be used for viral hepatitis prevention projects would help address this urgent need to help close the gap between diagnosis and access to care for hepatitis patients. We urge the Committee to include language in both the Office of the Secretary and the CDC's National Center for Chronic Disease Prevention to insure that Prevention Funds, specifically Community Transformation Grants, be eligible to viral hepatitis initiatives.

SUMMARY AND CONCLUSION

While the HBF recognizes the demands on our Nation's resources, we believe the ever-increasing health threats and expanding scientific opportunities continue to justify higher funding levels for the CDC's Division of Viral Hepatitis and the National Institutes of Health.

Significant progress has been made in developing better treatments and cures for the diseases that affect humankind due to your leadership and the leadership of your colleagues on this Subcommittee. Significant progress has also similarly been made in the fight against hepatitis B.

In conclusion, we specifically request the following for fiscal year 2012:

—Fund the CDC's Division of Viral Hepatitis at $25 million;

—Language urging the HHS and the National Center for Chronic Disease Prevention to help insure that the Prevention and Public Health Funds, particularly the Community Transformations Grants, are available to support viral hepatitis prevention projects.

—Initiate global programs at the CDC to increase the rate of vaccination, reduce mother-child transmission and promote educational programs to prevent the disease and to reduce discrimination targeted against individuals with the disease;

—Provide $35 billion for the National Institutes of Health, including a $9.7 million increase per year for hepatitis B research;

—Establish a targeted cancers program at the NCI; and

—Fund a series of Specialized Programs of Research Excellence (SPOREs) focused on liver cancer at the NCI.

The Hepatitis B Foundation appreciates the opportunity to provide testimony to you on behalf of our constituents and yours.

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PREPARED STATEMENT OF THE HIV MEDICINE ASSOCIATION

The HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA) represents more than 4,500 physicians, scientists and other healthcare professionals who practice on the frontline of the HIV/AIDS pandemic. Our members provide medical care and treatment to people with HIV/AIDS throughout the United States, lead HIV prevention programs and conduct research to develop effective HIV prevention and treatment options. We work in communities across the country and around the globe as medical providers and researchers dedicated to the field of HIV medicine.

We appreciate the importance of addressing the fiscal challenges facing our Nation, but the continued fragile state of the economy makes it imperative to set priorities to ensure that our Nation has a strong healthcare safety-net, effective programs for preventing infectious diseases like HIV and a robust scientific research agenda.

The U.S. investment in HIV/AIDS programs has revolutionized HIV care globally, making HIV treatment one of the most effective medical interventions available. A vibrant research agenda and rapid public health implementation of scientific findings have transformed the HIV epidemic, reducing morbidity and mortality due to HIV disease by nearly 80 percent in the United States.

Implementation of healthcare reform and the administration's plans for a National HIV/AIDS Strategy offer promise for making significant progress in reducing the impact of the domestic HIV epidemic. However, their success will depend on maintaining adequate investments in the healthcare safety net, and in prevention, public health and research programs. The funding requests in our testimony largely reflect the consensus of the Federal AIDS Policy Partnership (FAPP), a coalition of HIV organizations from across the country, and are estimated to be the amounts necessary to sustain and strengthen our investment in combatting HIV disease.

*Health Care Reform*

We urge full funding of the President's fiscal year 2012 request level for healthcare reform programs supported with discretionary funding under the Patient Protection and Affordable Care Act (ACA), in particular: health workforce education and training programs under Titles VII and VIII of the Public Health Service Act (PHSA); healthcare quality improvement programs, and the Community Health Centers program.

*HIV/AIDS Bureau of the Health Resources and Services Administration*

We urge you to increase funding for the Ryan White program by $371 million in fiscal year 2011 with at least an increase of $65.8 million over the fiscal year 2010 level for Part C. At minimum, we strongly urge you to support the President's proposed fiscal year 2012 increase of $88.3 million for the Ryan White program, including a $5.1 million increase for Part C. Part C of the Ryan White Program funds comprehensive HIV care and treatment—services that are directly responsible for the dramatic decreases in AIDS-related mortality and morbidity over the last decade. On average it costs $3,501 per person per year to provide the comprehensive outpatient care and treatment available at Part C funded programs, including lab work, STD/TB/Hepatitis screening, ob/gyn care, dental care, mental health and substance abuse treatment, and case management. Part C funding covers a small percentage of the total cost of providing comprehensive care with some programs receiving $450 or lower per patient per year to cover care.

The Ryan White Program generally is underfunded and Part C of the program is disproportionately and severely underfunded. The Centers for Disease Control and Prevention estimate that there are more than 1.1 million persons living with HIV/AIDS and approximately 240,000, or almost 1 in 4, of these individuals receive services from Part C medical providers. Of the 240,000 patients, approximately 1 out of 3 is uninsured, and 2 out of 3 are underinsured.

While the patient caseload in Part C programs has been rising, funding for Part C has effectively decreased due to flat funding and funding cuts at the clinic level. Part C programs expect a continued increase in patients due to higher diagnosis rates and economic-related declines in insurance coverage. During this economic downturn people with HIV across the country are relying on Part C comprehensive services more than ever. As a result of consistently increasing caseloads and limited funding, Part C clinics are taking dramatic steps that adversely impact their ability to serve patients, including: Limiting primary care services; discontinuing critical services such as laboratory monitoring; suffering eviction from institutional-based clinic sites; laying off staff; and operating only 4 days/week.

The HIV medical clinics funded through Part C have been in dire need of increased funding for years, but new pressures are creating a crisis in communities across the country. An increase in funding is critical to prevent additional staffing and service cuts and ensure the public health of our communities.

*National Institutes of Health (NIH)—Office of AIDS Research*

HIVMA supports the medical research community's requested increase of $4 billion over the fiscal year 2010 level for all research programs at the NIH, including at least a $400 million increase for the NIH Office of AIDS. This level of funding is vital to sustain the pace of research that will improve the health and quality of life for millions of Americans. At minimum, we urge you to support the President's proposed fiscal year 2012 increase of $1 billion for the NIH.

A continued robust AIDS research portfolio is essential to sustain and to accelerate our progress in offering more effective prevention technologies; developing new and less toxic therapy; and supporting the basic research necessary to continue our work developing a vaccine that may end the deadliest pandemic in human history.

We appreciate the many difficult decisions that Congress faces this year, but urge you to recognize the importance of investing in HIV prevention, treatment and research now to avoid the much higher cost that individuals, communities and broader society will incur if we fail to support these programs. We must seize the opportunity to limit the toll of this deadly infectious disease on our planet and to save the lives of millions who are infected or at risk of infection here in the United States and around the globe.

*Center for Disease Control and Prevention's (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)*

HIVMA strongly urges total fiscal year 2012 funding of $1.953 billion for the CDC's NCHHSTP, an increase of $834.1 million over the fiscal year 2010 level, including increases of: $515.3 million for HIV prevention and surveillance, $20.2 million for viral hepatitis and $85.9 million for tuberculosis prevention.

Every 9½ minutes a new HIV infection happens in the United States with more than 60 percent of new cases occurring among African Americans and Hispanic/Latinos. Despite the known benefit of effective treatment, 21 percent of people living with HIV in the United States are still not aware of their status and as many as 36 percent of people newly diagnosed with HIV progress to AIDS within 1 year of diagnosis. A sustained commitment to HIV prevention funding is critical to enhance HIV/AIDS surveillance and expand HIV testing and linkage to care, in order to lower HIV incidence and prevalence in the United States. We appreciate that the President proposed a $68.8 million increase for HIV prevention at the CDC, and at a bare minimum we strongly urge the Committee to at least meet this request.

Finally, we strongly support adequate funding for science-based, comprehensive sex education programs. We are pleased that the fiscal year 2011 continuing resolution provides $109 million for the Teen Pregnancy Prevention Program, which focuses on reducing the risks of pregnancy and sexually transmitted diseases through proven and successful models. We urge the Committee to adopt report language supporting true, comprehensive sex education that promotes healthy behaviors and relationships for all young people, including lesbian, gay, bisexual, and transgender youth, including an explicit focus on prevention of HIV and other STDs.

*CDC—Tuberculosis*

Tuberculosis is the major cause of AIDS-related mortality worldwide and the second leading infectious disease killer. Congress passed landmark legislation in the Comprehensive Tuberculosis Elimination Act of 2008 to shore up State TB control programs, to enhance U.S. capacity to address drug-resistant tuberculosis; and to develop new drugs, diagnostics and vaccines.

State budget cuts have hit local TB control programs hard, and the CDC Division of TB Elimination has seen some budget reductions in the last 2 fiscal years. Our ability to respond to TB within our own borders is being compromised as a result. We must do better. Finally, we are beginning to see exciting new tools to combat tuberculosis after decades of little or no productive research and development in this area. We have an exciting new diagnostic test that can identify drug-susceptible and drug-resistant TB very quickly. There are a number of new drugs in clinical trials for both drug resistant and drug-susceptible TB. There are promising new TB vaccine candidates being tested. Now, resources are needed more urgently than ever to follow through on the research and development in progress and to ensure that these new tools reach the public health officials on the ground who need them. We respectfully request fiscal year 2012 funding for the CDC Division of TB Elimination at a level of $231 million. At minimum, we urge full funding of the President's fiscal year 2012 budget request of $143.6 million for this program.

*CDC—Viral Hepatitis*

A much more substantial commitment to Hepatitis co-infection is urgently needed, in addition to funding for core public health services and tracking of chronic cases of hepatitis. Co-infection is a serious health threat for nearly one-third of our HIV patients, and has an enormous impact on morbidity and mortality. Furthermore, with the advent of the recently approved protease inhibitors, providing funding to enable this population to receive treatment and/or access clinical trials becomes absolutely critical. We strongly urge you to boost funding for viral hepatitis at the CDC by $20.2 million over the fiscal year 2010 level million for a total funding of $40 million. At the very least, we urge you to support the President's proposed fiscal year 2012 increase of $5.2 million to respond to the viral Hepatitis epidemic.

*Agency for Health Care Quality and Research (AHRQ)*

HIVMA urges the Committee to provide $2.2 million, a $200,000 increase over the fiscal year 2010 level for the HIV Research Network (HIVRN), the only significant HIV work being done at AHRQ. The HIVRN is a consortium of 18 HIV primary care sites co-funded by AHRQ and HRSA to evaluate healthcare utilization and clinical outcomes in HIV infected children, adolescents and adults in the United States. The Network analyzes and disseminates information on the delivery and outcomes of healthcare services to people with HIV infection. These data help to improve delivery and outcomes of HIV care in the United States and to identify and address disparities in HIV care that exist by race, gender, and HIV risk factor. The HIVRN is a unique source of information on the cost and cost-effectiveness of HIV care in the United States at a time when data on comparative cost and effectiveness of healthcare is particularly needed to inform health systems reform and the development and implementation of a National HIV/AIDS Strategy.

PREPARED STATEMENT OF HOWARD UNIVERSITY

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. Eve Higginbotham, Senior Vice-President and Executive Dean for Howard University Health Sciences. I am the senior health official at Howard, with responsibilities for our College of Medicine, College of Dentistry, College of Pharmacy, Nursing, and Allied Health, Louis Stokes Health Sciences Library, and the Howard University Hospital. Howard University is the only Historically Black College or University (HBCU) with so many aspects of the health sciences housed at one institution. For that reason, we are poised to continue to impact the education of minorities and others dedicated to improving the health of all Americans.

Mr. Chairman, Howard University Health Sciences has made historic contributions to the reduction of health disparities, and it is because of programmatic activity like the Title VII Health Professionals Training programs that we are able to address a critical national need. Persistent and severe staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Furthermore, even after the landmark passage of health reform, it is important to note that our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example while blacks represent approximately 15 percent of the U.S. population, only 2–3 percent of the Nation's health professions workforce is black. Mr. Chairman, I would like to share with you how your committee can help HUHS continue our efforts to help provide quality health professionals and close our Nation's health disparity gap.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health professions institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need—even in austere financial times.

An October 2006 study by the Health Resources and Services Administration (HRSA), entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

In fiscal year 2012, funding for the Title VII Health Professions Training programs must at the very least be maintained, especially the funding for the Minority Centers of Excellence (COEs) and Health Careers Opportunity Program (HCOPs). In addition, the funding for the National Institutes of Health (NIH)'s National Institute on Minority Health and Health Disparities (NIMHD), as well as the Department of Health and Human Services (HHS)'s Office of Minority Health (OMH), should be preserved.

*Minority Centers of Excellence*.—COEs focus on improving student recruitment and performance, improving curricula in cultural competence, facilitating research on minority health issues and training students to provide health services to minority individuals. COEs were first established in recognition of the contribution made by four historically black health professions institutions to the training of minorities in the health professions. Congress later went on to authorize the establishment of "Hispanic", "Native American" and "Other" Historically black COEs. For fiscal year 2012, I recommend a funding level of $24.602 million for COEs.

*Health Careers Opportunity Program (HCOP)*.—HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary schools in order to identify and nurture promising students who demonstrate that they have the talent and potential to become a health professional. For fiscal year 2012, I recommend a funding level of $22.133 million for HCOPs.

*National Institutes of Health*

*Research Centers at Minority Institutions*.—The Research Centers at Minority Institutions program (RCMI), currently administered by the National Center for Research Resources, has a long and distinguished record of helping our institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2012.

*National Institute on Minority Health and Health Disparities*.—The National Institute on Minority Health and Health Disparities (NIMHD) is charged with addressing the longstanding health status gap between minority and nonminority populations. The NIMHD helps health professions institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, and other learning resources. The NIMHD also supports biomedical research focused on eliminating health disparities and develops a comprehensive plan for research on minority health at the NIH. Furthermore, the NIMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities through the Centers of Excellence program. For fiscal year 2012, I recommend funded increases proportional with the funding of the over NIH.

*Department of Health and Human Services*

*Department of Health and Human Services' Office of Minority Health*.—Specific programs at OMH include: assisting medically underserved communities with the greatest need in solving health disparities and attracting and retaining health professionals; assisting minority institutions in acquiring real property to expand their campuses and increase their capacity to train minorities for medical careers; supporting conferences for high school and undergraduate students to interest them in healthcareers, and supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions. The OMH has the potential to play a critical role in addressing health disparities. For fiscal year 2012, I recommend a funding level of $65 million for the OMH.

*Department of Education*

*Howard University Academic, Research, and Hospital Support*.—The Department of Education maintains support for Howard University's academic programs, research programs, construction activities, and the Howard University Hospital. Howard University has played a historic role in providing access to postsecondary educational opportunities for students from traditionally underrepresented backgrounds, especially African Americans. For this reason, and others, Howard is supported annually with a Federal appropriation. The direct Federal appropriation accounts for approximately 50 percent of the Howard University's operating costs, including nearly $29 million for the operation of the Howard Hospital—a staple of care for residents in Northwest Washington, DC. In fiscal year 2012, an appropriation of $235 million is suggested to continue the vital programs and services which we provide.

Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, Howard University's Health Sciences can help this country to overcome health disparities. Congress must be careful not to eliminate, paralyze or stifle programs that have been proven to work. HUHS seeks to close the ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work towards the goal of eliminating that disparity everyday.

Thank you, Mr. Chairman, and I welcome every opportunity to answer questions for your records.

PREPARED STATEMENT OF THE INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

Thank you for the opportunity to present the views of the International Foundation for Functional Gastrointestinal Disorders (IFFGD) regarding the importance of functional gastrointestinal (GI) and motility disorders research.

Established in 1991, IFFGD is a patient-driven nonprofit organization dedicated to assisting individuals affected by functional GI disorders, and providing education and support for patients, healthcare providers, and the public at large. The IFFGD also works to advance critical research on functional GI and motility disorders, in order to provide patients with better treatment options, and to eventually find a cure. IFFGD has worked closely with NIH on a number of priorities, including the NIH State-of-the-Science Conference on the Prevention of Fecal and Urinary Incontinence in Adults through NIDDK, the National Institute of Child Health and Human Development (NICHD), and the Office of Medical Applications of Research (OMAR). I have served on the National Commission on Digestive Diseases (NCDD), which released a long-range road map for digestive disease research in 2009, entitled Opportunities and Challenges in Digestive Diseases Research: Recommendations of the National Commission on Digestive Diseases.

The need for increased research, more effective and efficient treatments, and the hope for discovering a cure for functional GI and motility disorders are close to my heart. My own personal experiences of suffering from functional GI and motility disorders motivated me to establish IFFGD 20 years ago. I was shocked to discover that despite the high prevalence of these conditions among all demographic groups worldwide, such an appalling lack of dedicated research existed. This lack of research translates into a dearth of diagnostic tools, treatments, and patient supports. Even more shocking is the lack of awareness among both the medical community and the general public, leading to significant delays in diagnosis, frequent misdiagnosis, and inappropriate treatments including unnecessary medication and surgery. It is unacceptable for patients to suffer unnecessarily from the severe, painful, life-altering symptoms of functional GI and motility disorders due to a lack of awareness and education.

The majority of functional GI disorders have no cure and treatment options are limited. Although progress has been made, the medical community still does not completely understand the mechanisms of the underlying conditions. Without a known cause or cure, patients suffering from functional GI disorders face a lifetime of chronic disease management, learning to adapt to intolerable, disruptive symptoms. The medical and indirect costs associated with these diseases are enormous; estimates range from $25–$30 billion annually. Economic costs spill over into the workplace, and are reflected in work absenteeism and lost productivity. Furthermore, the emotional toll of these conditions affects not only the individual but also the family. Functional GI disorders do not discriminate, effecting all ages, races and ethnicities, and genders.

*Irritable Bowel Syndrome (IBS)*

IBS, one of the most common functional GI disorders, strikes all demographic groups. It affects 30 to 45 million Americans, conservatively at least 1 out of every 10 people. Between 9 to 23 percent of the worldwide population suffers from IBS, resulting in significant human suffering and disability. IBS as a chronic disease is characterized by a group of symptoms that may vary from person to person, but typically include abdominal pain and discomfort associated with a change in bowel pattern, such as diarrhea and/or constipation. As a "functional disorder", IBS affects the way the muscles and nerves work, but the bowel does not appear to be damaged on medical tests. Without a definitive diagnostic test, many cases of IBS go undiagnosed or misdiagnosed for years. It is not uncommon for IBS suffers to have unnecessary surgery, medication, and medical devices before receiving a proper diagnosis. Even after IBS is identified, treatment options are sorely lacking and vary widely from patient to patient. What is known is that IBS requires a multidisciplinary approach to research and treatment.

IBS can be emotionally and physically debilitating. Due to persistent pain and bowel unpredictability, individuals who suffer from this disorder may distance themselves from social events, work, and even may fear leaving their home. Stigma surrounding bowel habits may act as barrier to treatment, as patients are not comfortable discussing their symptoms with doctors. Because IBS symptoms are relatively common and not life-threatening, many people dismiss their symptoms or attempt to self-medicate using over-the-counter medications. In order to overcome these barriers to treatment, ensure more timely and accurate diagnosis, and reduce

costly unnecessary procedures, educational outreach to physicians and the general public remain critical.

*Fecal Incontinence*

At least 12 million Americans suffer from fecal incontinence. Incontinence is neither part of the aging process nor is it something that affects only the elderly. Incontinence crosses all age groups from children to older adults, but is more common among women and the elderly of both sexes. Often it is a symptom associated with various neurological diseases and many cancer treatments. Yet, as a society, we rarely hear or talk about the bowel disorders associated with spinal cord injuries, multiple sclerosis, diabetes, prostate cancer, colon cancer, uterine cancer, and a host of other diseases.

Courses of fecal incontinence include: damage to the anal sphincter muscles; damage to the nerves of the anal sphincter muscles or the rectum; loss of storage capacity in the rectum; diarrhea; or pelvic floor dysfunction. People who have fecal incontinence may feel ashamed, embarrassed, or humiliated. Some don't want to leave the house out of fear they might have an accident in public. Most attempt to hide the problem for as long as possible. They withdraw from friends and family, and often limit work or education efforts. Incontinence in the elderly burdens families and is the primary reason for nursing home admissions, an already huge social and economic burden in our aging population.

In November 2002, IFFGD sponsored a consensus conference entitled, Advancing the Treatment of Fecal and Urinary Incontinence Through Research: Trial Design, Outcome Measures, and Research Priorities. Among other outcomes, the conference resulted in six key research recommendations including more comprehensive identification of quality of life issues; improved diagnostic tests for affecting management strategies and treatment outcomes; development of new drug treatment compounds; development of strategies for primary prevention of fecal incontinence associated with childbirth; and attention to the stigmas that apply to individuals with fecal incontinence.

In December 2007, IFFGD collaborated with NIDDK, NICHD, and OMAR on the NIH State-of-the-Science Conference on the Prevention of Fecal and Urinary Incontinence in Adults. The goal of this conference was to assess the state of the science and outline future priorities for research on both fecal and urinary incontinence; including, the prevalence and incidence of fecal and urinary incontinence, risk factors and potential prevention, pathophysiology, economic and quality of life impact, current tools available to measure symptom severity and burden, and the effectiveness of both short and long term treatment. For fiscal year 2012, IFFGD urges Congress to review the Conference's Report and provide NIH with the resources necessary to effectively implement the report's recommendations.

*Gastroesophageal Reflux Disease (GERD)*

Gastroesophageal reflux disease, or GERD, is a common disorder affecting both adults and children, which results from the back-flow of acidic stomach contents into the esophagus. GERD is often accompanied by persistent symptoms, such as chronic heartburn and regurgitation of acid. Sometimes there are no apparent symptoms, and the presence of GERD is revealed when complications become evident. One uncommon but serious complication is Barrett's esophagus, a potentially precancerous condition associated with esophageal cancer. Symptoms of GERD vary from person to person. The majority of people with GERD have mild symptoms, with no visible evidence of tissue damage and little risk of developing complications. There are several treatment options available for individuals suffering from GERD. Nonetheless, treatment response varies from person to person, is not always effective, and long-term medication use and surgery expose individuals to risks of side-effects or complications.

Gastroesophageal reflux (GER) affects as many as one-third of all full term infants born in America each year. GER results from an immature upper gastrointestinal motor development. The prevalence of GER is increased in premature infants. Many infants require medical therapy in order for their symptoms to be controlled. Up to 25 percent of older children and adolescents will have GER or GERD due to lower esophageal sphincter dysfunction. In this population, the natural history of GER is similar to that of adult patients, in whom GER tends to be persistent and may require long-term treatment.

*Gastroparesis*

Gastroparesis, or delayed gastric emptying, refers to a stomach that empties slowly. Gastroparesis is characterized by symptoms from the delayed emptying of food, namely: bloating, nausea, vomiting, or feeling full after eating only a small amount of food. Gastroparesis can occur as a result of several conditions, including being

present in 30 percent to 50 percent of patients with diabetes mellitus. A person with diabetic gastroparesis may have episodes of high and low blood sugar levels due to the unpredictable emptying of food from the stomach, leading to diabetic complications. Other causes of gastroparesis include Parkinson's disease and some medications, especially narcotic pain medications. In many patients the cause of the gastroparesis cannot be found and the disorder is termed idiopathic gastroparesis. Over the last several years, as more is being found out about gastroparesis, it has become clear this condition affects many people and the condition can cause a wide range of symptom severity.

*Cyclic Vomiting Syndrome*

Cyclic vomiting syndrome (CVS) is a disorder with recurrent episodes of severe nausea and vomiting interspersed with symptom free periods. The periods of intense, persistent nausea, vomiting, and other symptoms (abdominal pain, prostration, and lethargy) lasts hours to days. Previously thought to occur primarily in pediatric populations, it is increasingly understood that this crippling syndrome can occur in a variety of age groups including adults. Patients with these symptoms often go for years without correct diagnosis. The condition leads to significant time lost from school and from work, as well as substantial medical morbidity. The cause of CVS is not known. Better understanding, through research, of mechanisms that underlie upper gastrointestinal function and motility involved in sensations of nausea, vomiting and abdominal pain is needed to help identify at risk individuals and develop more effective treatment strategies.

*Support for Critical Research*

IFFGD urges Congress to fund the NIH at level of $35 billion for fiscal year 2012, an increase of 13 percent over fiscal year 2011. This funding level will help preserve the initial investment in healthcare innovation established by the American Recovery and Reinvestment Act of 2009. Strengthening and preserving our Nation's biomedical research enterprise fosters economic growth, and supports innovations that enhance the health and well-being of the Nation.

Concurrent with overall NIH funding, the IFFGD supports growth of research activities on functional GI and motility disorders, particularly through NIDDK and the Office of Research on Women's Health (ORWH). Increased support for NIDDK and ORWH will facilitate necessary expansion of the research portfolio on functional GI and motility disorders necessary to grow the medical knowledge base and improve treatment. Such support would also expedite the implementation of recommendations from the National Commission on Digestive Diseases. It is also vitally important for NIDDK to work to expand its research on the impact these disorders have on pediatric populations, in addition the adult population.

Following years of near level-funding at NIH, research opportunities have been negatively impacted across all NIH Institutes and Centers, including NIDDK. With the expiration of funding from the American Recovery and Reinvestment Act of 2009, medical researchers run the risk of "falling off a cliff", stalling, if not losing promising research from that 2 year period. For this reason, IFFGD encouraged support for initiatives such as the Cures Acceleration Network (CAN), authorized in the Patient Protection and Affordable Coverage Act. IFFGD urges the Subcommittee to show strong leadership in pursuing a substantial funding increase for CAN through the fiscal year 2012 appropriations process.

Thank you for the opportunity to present the views of the functional GI disorders community.

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## PREPARED STATEMENT OF THE INTERNATIONAL MYELOMA FOUNDATION

The International Myeloma Foundation (IMF) appreciates the opportunity to submit written comments for the record regarding fiscal year 2012 funding for myeloma cancer programs. The IMF is the oldest and largest myeloma foundation dedicated to improving the quality of life of myeloma patients while working toward prevention and a cure.

To ensure that myeloma patients have access to the comprehensive, quality care that they need and deserve, the IMF advocates ongoing and significant Federal funding for myeloma research and its application. The IMF stands ready to work with policymakers to advance policies and programs that work toward prevention and a cure for myeloma and for all other forms of cancer.

*Myeloma Background*

The second most common blood cancer worldwide, multiple myeloma (or myeloma) is a cancer of plasma cells in the bone marrow. It is called "multiple" myeloma be-

cause the cancer can occur at multiple sites in multiple bones. Each year approximately 20,000 Americans are diagnosed with myeloma and 10,000 lose their battle with this disease.

Although the incidence of many cancers is decreasing, the number of myeloma cases is on the rise. Once a disease of the elderly, it is now being found in increasing numbers in people under the age of 65. The 2009 President's Cancer Panel Report suggests that much of the increase in cancer incidence is being caused by environmental toxins. To give just one example supporting this hypothesis, a recently published study in The Journal of Occupational and Environmental Medicine, suggests a link between blood cancers like myeloma and exposure to the toxic dust at Ground Zero.

In recent years significant gains have been made, extending myeloma patients' lives and improving their quality of life. Furthermore, progress begun in myeloma is already helping patients with other blood cancers and even solid tumors. It is important to maintain that momentum.

—There is no cure for myeloma.

—Remissions are not always permanent.

—Additional treatment options are essential.

Living with the disease, myeloma patients can suffer debilitating fractures and other bone disorders, severe side effects of certain treatments, and other problems that profoundly affect their quality of life, and significantly impact the cost of their healthcare.

*Sustain and Seize Cancer Research Opportunities*

Myeloma research is producing extraordinary breakthroughs—leading to new therapies that translate into longer survival and improved quality of life for myeloma patients and potentially those with other forms of cancer as well. Myeloma was once considered a death sentence with limited options for treatment, but today myeloma is an example of the progress that can be made and the work that still lies ahead in the war on cancer. Many myeloma patients are living proof of what innovative drug development and clinical research can achieve—sequential remissions, long-term survival, and good quality of life. Our Nation has benefited immensely from past Federal investment in biomedical research at the National Institutes of Health (NIH) and the IMF advocates $35 billion for NIH in fiscal year 2012.

A study in the Journal of Clinical Oncology projects that the number of new cancer cases diagnosed each year will jump 45 percent over the next 20 years. In multiple myeloma an even greater increase (57 percent) is projected, and we are already seeing increasing diagnoses in patients under age 65, including patients in their 30s, in what was once a rare disease of the elderly.

While a number of cancers have achieved 5-year survival rates of over 80 percent since passage of the National Cancer Act of 1971, significant challenges still remain for other cancers. In fact, nearly half of the 562,490 cancer deaths in 2010 were caused by just eight forms of cancer with 5-year survival rates of 45 percent or less—one of which is myeloma. Yet, myeloma and these other cancers have historically also received the least amount of Federal funding. As we have seen mortality rates of diseases such as breast cancer, prostate cancer, AIDS, and childhood leukemia greatly reduced through targeted, comprehensive, and well-funded programs that have led to earlier detection and superior forms of treatment, so too must we shine a brighter light on myeloma and the other seven deadly cancers to achieve this same goal for them. The IMF urges Congress to allocate $5.740 billion to the National Cancer Institute (NCI) in fiscal year 2012 to continue our battle against myeloma.

*Boost Our Nation's Investment in Myeloma Prevention, Early Detection, and Awareness*

As the Nation's leading prevention agency, the Centers for Disease Control and Prevention (CDC) plays an important role in translating and delivering at the community level what is learned from research. Therefore, the IMF advocates $6 million for the Geraldine Ferraro Blood Cancer Program. Authorized under the Hematological Cancer Research Investment and Education Act of 2002, this program was created to provide public and patient education about blood cancers, including myeloma.

With grants from the Geraldine Ferraro Blood Cancer Program, the IMF has successfully promoted awareness of myeloma, particularly in the African-American community and other underserved communities. IMF accomplishments include the production and distribution of more than 4,500 copies of an informative video which addresses the importance of myeloma awareness and education in the African-American community to churches, community centers, inner-city hospitals, and

Urban League offices around the country, increased African-American attendance at IMF Patient and Family Seminars (these seminars provide invaluable treatment information to newly diagnosed myeloma patients), increased calls by African-American myeloma patients, family members, and caregivers to the IMF's myeloma Hotline, and the establishment of additional support groups in inner city locations in the United States to assist underserved areas with myeloma education and awareness campaigns. Furthermore, the more than 90 IMF-affiliated patient support groups in the United States also made this effort their main goal during Myeloma Awareness Week in October 2005.

An allocation of $6 million in fiscal year 2012 will allow this important program to continue to provide patients—including those populations at highest risk of developing myeloma—with educational, disease management and survivorship resources to enhance treatment and prognosis.

Additionally, the IMF is concerned about the consolidation plan for chronic disease programs at the CDC outlined in the President's fiscal year 2012 budget. This would be a substantial change in the chronic disease program where the Geraldine Ferraro Blood Cancer Program is currently housed. While we agree that there are health issue areas that share risk factors such as healthy eating and maintaining an active lifestyle that make sense to consolidate, unfortunately those are not risk factors for myeloma. We urge the CDC to maintain the programs like the Geraldine Ferraro Blood Cancer Program as a stand-alone program which would cease to exist under the proposed consolidation plan.

*Conclusion*

The IMF stands ready to work with policymakers to advance policies and support programs that work toward prevention and a cure for myeloma. Thank you for this opportunity to discuss the fiscal year 2012 funding levels necessary to ensure that our Nation continues to make gains in the fight against myeloma.

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PREPARED STATEMENT OF THE INTERSTATE MINING COMPACT COMMISSION

We are writing in support of the fiscal year 2012 budget request for the Mine Safety and Health Administration (MSHA), which is part of the U.S. Department of Labor. In particular, we urge the Subcommittee to support a full appropriation for grants to States for safety and health training of our Nation's miners pursuant to section 503(a) of the Mine Safety and Health Act of 1977. MSHA's budget request for State grants is $8.941 million. This is the same amount that has been appropriated for State training grants by Congress over the past 2 fiscal years and, as such, does not fully consider inflationary and programmatic increases being experienced by the States. We therefore urge the subcommittee to restore funding to the statutorily authorized level of $10 million for State grants so that States are able to meet the training needs of miners and to fully and effectively carry out State responsibilities under section 503(a) of the Act.

The Interstate Mining Compact Commission is a multi-state governmental organization that represents the natural resource, environmental protection and mine safety and health interests of its 24 member States. The States are represented by their Governors who serve as Commissioners.

IMCC's member States are concerned that without full funding of the State grants program, the federally required training for miners employed throughout the United States will suffer. States are struggling to maintain efficient and effective miner training and certification programs in spite of increased numbers of trainees and the incremental costs associated therewith. State grants have flattened out over the past several years and are not keeping place with inflationary impacts or increased demands for training. The situation is of particular concern given the enhanced, additional training requirements growing out of the recently enacted MINER Act and MSHA's implementing regulations.

As you consider our request to increase MSHA's budget for State training grants, please keep in mind that the States play a particularly critical role in providing special assistance to small mine operators (those coal mine operators who employ 50 or fewer miners or 20 or fewer miners in the metal/nonmetal area) in meeting their required training needs.

We appreciate the opportunity to submit our views on the MSHA budget request as part of the overall Department of Labor budget. Please feel free to contact us for additional information or to answer any questions you may have.

PREPARED STATEMENT OF THE INTERSTITIAL CYSTITIS ASSOCIATION

Thank you for the opportunity to present the views of the Interstitial Cystitis Association (ICA) regarding the importance of public awareness activities and the importance of interstitial cystitis (IC) research.

ICA was founded in 1984 and remains the only nonprofit organization dedicated to improving the lives of those living with IC. The Association provides an important avenue for advocacy, research, and education in matters relating to IC. Since its founding, ICA has acted as a voice for those living with IC, including support groups and empowering patients. ICA advocates for the expansion of the IC knowledge-base and the development of new treatments, including investigator initiated research. Finally, ICA works doggedly to educate patients, healthcare providers, and the public at large about IC, including educational forums and information on how to live with this terrible condition.

IC is a condition that consists of recurring pain, pressure, or discomfort in the bladder and pelvic region and is often associated with urinary frequency and urgency. An estimated 4–12 million Americans have IC, approximately two-thirds of whom are women. The cause of IC is unknown and treatment options are limited. Diagnosis is made only after excluding other urinary/bladder conditions, possibly causing 1 or more years delay between onset of the symptoms and treatment. When healthcare providers are not properly educated about IC, patients may suffer for years before receiving an accurate diagnosis and appropriate treatment.

The effects of IC are pervasive and insidious, damaging work life, psychological well-being, personal relationships, and general health. The impact of IC on quality of life is equally as severe as rheumatoid arthritis and end-stage renal disease. Health-related quality of life in women with IC is worse than in women with endometriosis, vulvodynia, and overactive bladder. IC patients have significantly more sleep dysfunction, higher rates of depression, increased catastrophizing, anxiety, and sexual dysfunction.

*Public Awareness and Education*

As IC is a condition that often takes long periods to diagnosis, and this late diagnosis has such a major impact on the lives of patients, it is vitally important to continue to educate both the public and healthcare providers. The IC Education and Awareness Program at the Centers for Disease Control and Prevention (CDC) has played a major role in increasing the public's awareness of the devastating disease and is the only program in the Nation which promotes public awareness of IC. The public outreach of the CDC program includes public service announcements on major television networks and the Internet. Further, the CDC program has provided resources to make information on IC available to patients and the public though videos, booklets, publications, presentations, educational kits, websites, blogs, Facebook pages, and a YouTube channel. For providers, this program has included the development of an IC newsletter with information on IC treatments, research, news, and events; targeted mailings to providers; and exhibits at national medical conferences.

In order to continue these vitally important initiatives, which have reached thousands of Americans, it is critical that the CDC IC Education and Awareness Program be continued and receive a specific appropriation of $660,000 for fiscal year 2012.

*Research Through the National Institutes of Health*

The National Institutes of Health (NIH), mainly through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), maintains a robust research portfolio on IC, including five recent major studies yielding significant new information. The RAND IC Epidemiology (RICE) study found that nearly 2.7–6.7 percent of adult women have symptoms consistent with IC and will prove important to the future development of clinical trials and epidemiological studies. The IC Genetic Twin study found environmental factors, rather than genetic factors, to be substantial risk factors of developing IC. The Events Preceding Interstitial Cystitis (EPIC) study has yielded significant information linking non-bladder conditions and infectious agents to the development of IC in many newly diagnosed IC patients. The findings of the EPIC study have been reinforced in a Northwestern University study which found that an unusual form of toxic bacterial molecule (LPS) has an impact the development of IC as a result of an infectious agent. Finally, the Urologic Pelvic Pain Collaborative Research Network (UPPCRN) has indicated promising results for a new therapy for IC patients.

Research currently underway and expected to begin in the near future also holds great promise to increase our understanding of IC, and thus find new treatments and cure. The Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Syndrome Research Network holds great potential to understanding the un-

derlying issues related to IC, other conditions possibly associated with IC, and new information related to flares of the condition. Additionally, the investigator-initiated research portfolio will continue to support research relating to fundamental issues relating to IC and pelvic pain, including new avenues for interdisciplinary research and new treatment options. Finally, NIH will continue to focus on developing new treatment and therapies to relieve this condition.

In order for this positive research to reach its full potential, it is essential NIH continue to receive funding which will allow it to continue and expand on past and current research. For this reason we recommend a funding level of $35 billion for fiscal year 2012. We also recommend the continuation of the MAPP study and collaboration between NIDDK and the Office of Women's Health on issues related to IC.

Thank you for the opportunity to present the views of the interstitial cystitis community.

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PREPARED STATEMENT OF THE IOWA STATEWIDE INDEPENDENT LIVING COUNCIL

I am contacting you regarding the proposed restructuring of the Independent Living funding that is outlined in President Obama's 2012 budget.

The seven Iowa Centers for Independent Living, along with all the other Centers for Independent Living across the country, need your help.

As you may know, Centers for Independent Living (CILs) are nonprofit organizations run by people with disabilities for people with disabilities. They are authorized by the Federal Rehabilitation Act. CILs help people with disabilities to remain independent in their own homes and communities, being productive and contributing members of society. CILs work to help people remain independent so they are not forced to live in institutions such as nursing homes. As I am sure you are aware, in the vast majority of cases it is much less costly for a person with a disability to remain in their own home and community rather than pay for them to be institutionalized, and even more importantly people with disabilities have the same right to live independently as do people who do not have a disability.

The Independent Living movement, CILs, and SILCs promote the philosophy of consumer control. Consumers, who are people with disabilities, control the operations of CILs and SILCs.

I would like to provide you with some education about the reality of what the President's proposed restructuring of Independent Living funding will do to many Centers for Independent Living (CILs). I am opposed to this restructuring because of the damage it will do to many CILs, including the very real possibility that many CILs will have to close their doors as they will not be able to fiscally operate under this new structure.

Currently, under the Federal Rehabilitation Act, CILs receive their Part C Federal Independent Living funding directly from the Federal Rehabilitation Services Administration (RSA). The Federal Part B funds are given to the States, in most cases to the State Vocational Rehabilitation Services (VR) agency, and the VR does contracts with the CILs and the Statewide Independent Living Council (SILC) for these Part B Federal funds. The Federal Part C funds do not require a State match as they come directly from RSA at the Federal level to the individual CILs. The Part B funding does require a State match as it comes directly to the state VR agency.

Combining the Federal Part B and the Federal Part C Independent Living funding, and making these funds into a new block grant to States for Independent Living funding, is not acceptable for a number of reasons, and I would like to outline those reasons.

Combining these funds into a block grant and giving them to States will significantly reduce, if not eliminate, consumer control of independent living programs. Prior to the Part C funds being given to RSA to distribute directly to CILs, the funds were given out in grants to States. There were numerous problems with the State administering these grant funds, which is why the funding structure was changed to Part C going directly from RSA to CILs. Here are some examples of what happened in the past, and these problems will also occur under the President's proposed block grant funding:

—Under the past IL grant process, if the State had a freeze on hiring or travel, they would also make the CILs have a freeze on travel and hiring. This meant the CILs could not hire staff when needed, nor could they travel when needed. So even though the consumer controlled CIL Board directed the CIL Executive Director to hire a new staff, or directed that staff was to travel to attend a national conference, the State would not allow the CIL to do these things and would not provide the money to do these things, even though these things were

an allowable use of the Federal grant funds. The State agency controlled the CIL, the Consumer Board did not have any control.

—In many States, the Vocational Rehabilitation Services agency has procedures for reimbursing funds to the CILs, and in many States CILs would submit documentation for reimbursement and it would take 3, 4 or 5 months for the VR agency to get the money back to the CIL, which caused a great hardship for CILs to be able to keep their doors open. Here is one true example. One CIL Director re-financed his own house to take out a loan to meet staff payroll until the CIL received the reimbursement funds for their expenses from the State VR agency. Currently, I know this is an issue with the Federal Part B funds that the VR agencies give to CILs. It can take up to 4 or 5 months for a CIL to get reimbursed for their Part B funds. Fortunately, many of those CILs also get Federal Part C funds directly from RSA so they have money to cover their expenses until they get the Part B reimbursement check from VR. If the President's proposal becomes reality, there are many CILs that will most likely have to close as they will not have the working capital to pay their bills and then wait 4–5 months to get reimbursed by the VR agency.

There are additional concerns to consider.

—VR agencies are already under stress from State budget cuts, and it takes VR staff time to be able to do contracts and reimbursements for CILs. If these contracts become bigger, VRs will have to hire additional staff to manage these funds and do the contracts with the CILs. Where will the money come from for the VR agency to do this? Will it be taken out of the combined Part B and Part C funds, which means less funds going to CILs for direct consumer partner services, and less money to SILCs to be able to operate?

—Currently only the Part B funds require a State match. If you combine B and C into one block grant, will State match be required for this total amount? If so, where are States going to get the State funds to match the additional Part C funds? Many States can barely find the match for the Part B funds, so it is possible that States will not have funds to match the Part C funds too. That means the State will not get the Part C funds, and Centers will not have enough funding to keep their doors open.

—Providing direct funding to CILs is required by the Federal Rehabilitation Act, and for the President's budget proposal to be enacted, the Rehabilitation Act would have be significantly altered and then reauthorized.

These are very real and disturbing concerns. I would like to know that President Obama, as well as the Federal legislators, are looking at these concerns and how to address them before going ahead with the President's proposed restructuring. There must be a better way to do this that will maintain consumer partner control of CIL operations, and that will allow CILs to fiscally operate without risk of having to close their doors, and/or reduce staff and services to consumer partners.

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PREPARED STATEMENT OF THE JOINT ADVOCACY COALITION OF THE: ASSOCIATION FOR CLINICAL RESEARCH TRAINING, ASSOCIATION FOR PATIENT-ORIENTED RESEARCH, AND CLINICAL RESEARCH FORUM

The Association for Clinical Research Training (ACRT), the Association for Patient-Oriented Research (APOR), the Clinical Research Forum (CR Forum), and the Society for Clinical and Translational Science (SCTS) represent a coalition of professional organizations dedicated to improving the health of the public through increased clinical and translational research, and clinical research training. United by the shared priorities of the clinical and translational research community, ACRT, APOR, CR Forum, and SCTS advocate for increased clinical and translational research at the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), and other Federal science agencies.

On behalf of ACRT, APOR, CR Forum, and SCTS, I would like to thank the Subcommittee for their continued support of clinical and translational research, and clinical research training. The creation of the Patient-Centered Outcomes Research Institute and National Center for the Advancement of Translational Science in healthcare reform will provide a much-needed and greatly appreciated boost to comparative effectiveness research (CER) at the Federal level, as well as the organization of the new National Center for Translational Science (NCATS). As outlined by NIH Director Dr. Francis Collins in his five priorities for NIH, the translation of basic science to clinical treatment is an integral component of modern biomedical research, and a necessity to developing the treatments and cures of tomorrow.

Today, I would like to address a number of issues that cut to the heart of the clinical and translational research community's priorities, including the Clinical and

Translational Science Awards program (CTSA) at NIH, career development for clinical researchers, and support for CER at the Federal level.

As our Nation's investment in biomedical research expands to provide more accurate and efficient treatments for patients, we must continue to focus on the translation of basic science to clinical research. The CTSA program at NIH is quickly becoming an invaluable resource in this area, but full funding is needed if we are to truly take advantage of the CTSA infrastructure.

*Fully Funding and Support for the CTSA Program at NIH*

With its establishment in 2006, the CTSA program at NIH began to address the need for increased focus on translational research, or research that bridges the gap between basic scientific discoveries and the bedside. Originally envisioned as a consortium of 60 academic institutions, the CTSA program currently funds 55 academic medical research institutions nationwide, and is set to expand to the full 60 by the end of 2011. The CTSAs have an explicit goal of improving healthcare in the United States by transforming the biomedical research enterprise to become more effectively translational. Specifically, the CTSA program hopes to (1) improve the way biomedical research is conducted across the country; (2) reduce the time it takes for laboratory discoveries to become treatments for patients; (3) engage communities in clinical research efforts; (4) increase training and development in the next generation of clinical and translational researchers; and (5) accelerate T1 translational science.

Although the promise of the CTSA program is recognized both nationally and internationally, it has suffered from a lack of proper funding along with NIH, and the National Center for Research Resources (NCRR). In 2006, 16 initial CTSAs were funded, followed by an additional 12 in 2007 and 14 in 2008, 4 in 2009, and 9 in 2010. Level-funding at NIH curtailed the growth of the CTSAs, preventing recipient institutions from fully implementing their programs and causing them to drastically alter their budgets after research had already begun. If budgets continue to decline, the CTSAs risk jeopardizing not only new research but also the research begun by first, second, and third generation CTSAs. Professional judgments have determined full funding to be at a level of $700 million.

We recognize the difficult economic situation our country is currently experiencing, and greatly appreciate the commitment to healthcare Congress has demonstrated through stimulus funding, the fiscal year 2011 appropriations process, and through healthcare reform. The CTSAs are currently funding 55 academic research institutions nationwide at a level of $464 million, with the goal of full implementation by late 2011. In order to reach full implementation of 60 CTSAs by late 2011, and to realize the promise of the CTSAs in transforming biomedical research to improve its impact on health, it is imperative that the CTSA program receive funding at the level of $700 million in fiscal year 2012. Without full funding, more CTSAs will be expected to operate with fewer resources, curtailing their transformative promise.

A major part of the CTSA program's promise lies in its synergy with all of NIH's Institutes and Centers (ICs), and the acceleration and facilitation of the ICs' impact. The translation of laboratory research to clinical treatment directly benefits patients suffering from complex diseases and all fields of medicine. The CTSA program has created improved translational research capacity and processes from which all NIH's ICs stand to benefit. The development of a formal NIH-wide plan to link all ICs to the CTSA program would efficiently capitalize on NIH investment and the new opportunities presented by the advent of NCATS for clinical and translational science.

It is our recommendation that the Subcommittee support full implementation of the CTSA program by providing $700 million in fiscal year 2011, and we ask that the Subcommittee support the development of a formal NIH-wide plan to integrate the CTSAs to all of NIH's Institues and Centers.

*Continuing Support for Research Training and Career Development Programs Through the K Awards*

The future of our Nation's biomedical research enterprise relies heavily on the maintenance and continued recruitment of promising young investigators. Clinical investigators have long been referred to as an "endangered species", as financial barriers push medical students away from research. This trend must be arrested if we are to continue our pursuits of better treatments and cures for patients.

The K Awards at NIH and AHRQ provide much-needed support for the career development of young investigators. As clinical and translational medicine takes on increasing importance, there is a great need to grow these programs, not reduce them. Career development grants are crucial to the recruitment of promising young investigators, as well as to the continuing education of established investigators. Reduced

commitment to the K–12, K–23, K–24, and K–30 awards would have a devastating impact on our pool of highly trained clinical researchers. Even with the full implementation of the CTSA program, it will be critical for institutions without CTSAs to retain their K–30 Clinical Research Curriculum Awards, as the K–30s remain a highly cost-effective method of ensuring quality clinical research training. ACRT, APOR, CRF, and SCTS strongly support the ongoing commitment to clinical research training through K Awards at NIH and AHRQ.

We ask the Subcommittee to continue their support for clinical research training and career development through the K Awards at NIH and AHRQ, in order to promote and encourage investigators working to transform biomedical science.

*Continuing Support for CER*

Comparative effectiveness research or "CER" emerged at the forefront of the healthcare reform debate, capturing the interest of lawmakers and the American people. CER is the evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients. This broad definition can include medications, behavioral therapies, and medical devices among other interventions, and is an important facet of evidence-based medicine. On behalf of ACRT, APOR, CR Forum, and SCTS, I would like to thank the Senate for the creation of the Patient-Centered Outcomes Research Institute in the Patient Protection and Affordable Care Act, as well as the $1.1 billion included for CER at NIH and AHRQ in the American Recovery and Reinvestment Act (ARRA). Both AHRQ and NIH have long histories of supporting CER, and the standards for research instituted by agencies like NIH and AHRQ serve as models for best practices worldwide. Not only are these agencies experienced in CER, they are universally recognized as impartial and honest brokers of information.

We are pleased that Congress recognizes the importance of these activities and believe that the peer review processes and infrastructure in place at NIH and AHRQ ensure the highest quality CER. We believe that collaboration between the Patient-Centered Outcomes Research Institute, NIH, and AHRQ will motivate all Federal CER efforts. In addition to support for the CTSA program at NIH, we encourage the Subcommittee to provide continued support for Patient-Centered Health Research at AHRQ.

Thank you for the opportunity to present the views and recommendations of the clinical research training community. On behalf of ACRT, APOR, CR Forum, and SCTS, I would be happy to be of assistance as the appropriations process moves forward.

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## PREPARED STATEMENT OF LIONS CLUBS INTERNATIONAL

Lions Clubs International (LCI) its official charity arm, Lions Clubs International Foundation (LCIF), have been world leaders in serving the vision, hearing, youth development, disability and humanitarian needs of millions of people in America and around the world, and we work closely with other NGOs. Since LCIF was founded in 1968, it has awarded more than 9,000 grants, totaling more than $700 million for service projects ranging from affordable hearing aids to diabetes-prevention. All Administrative costs are paid for through interest earned on investments, allowing LCIF to maximize out impact on the community and demonstrating the motto "We Serve."

Our current 1.35 million-member global membership, representing over 206 countries, serves communities through the following ways: protect and preserve sight; provide disaster relief; combat disability; promote health; and serve youth. The 12,000 individual clubs representing over 375,000 individual citizens in North America are constantly expanding to add new programs and its volunteers are working to bring health services to as many communities as possible.

LCI represents the largest and most effective NGO service organization presence in the world. Awarded and recognized as the #1 NGO organization for partnership globally by The Financial Times 2007, LCI also holds a four star (highest) rating from the CharityNavigator.com (an independent review organization).

Today, we face many complex challenges in the health and education sector, from preventable diseases that cause blindness in children to bullying, violence, and drug use among school-aged children. I will offer a brief summary of recommendations in programs under the general jurisdiction of the Labor-HHS-Education Subcommittee.

*Domestic Sight Services*

Through our network of foundations and programs across America, LCI remains the single largest provider of charitable vision care, eyeglasses and hearing care services to needy and indigent people. Some of our major sight initiatives include:

—The Sight for Kids Program in collaboration with Johnson and Johnson. The program has provided 6 million vision screenings and eye-health education programs for children.

—Core 4 Preschool Vision Screening program enables LCI to conduct screenings for children in preschools. The program strives to deliver early detection and treatment for the most common vision disorders that can lead to amblyopia or "lazy eye." LCIF has also provided grants and services to those affected by eye conditions that cannot be improved medically.

—LCI Clubs sponsored "United We Serve Health Week" events around the country. These Health Week efforts, in conjunction with the White House, were effective in bringing awareness to vision health issues.

*National Eye Institute—Vision Health Recommendations*

LCI believes that vision loss is a major public health problem that increases healthcare costs and reduces productivity and quality of life for millions of Americans. LCI played an important role in the creation of a free-standing eye institute separate from the then-National Institute for Neurological Diseases and Blindness. The National Eye Institute Act was signed into law by President Johnson in 1968 as the Nation's lead Institute within the NIH to prevent blindness and save and restore vision of all Americans. NEI-funded research is resulting in treatments and therapies that save vision and restore sight, resulting in reduced healthcare costs and higher productivity.

LCI is concerned that proposals to reduce NIH funding to fiscal year 2008 levels would result in NEI funding for fiscal year 2011 at $667 million, or a $30 million loss. This would result in 43 fewer investigator-initiated research grants to save or restore vision. According to the National Association Eye and Vision Research, this funding reflects little more than 1 percent of the $68 billion annual cost of eye disease and vision impairment in the United States.

LCI supports fiscal year 2012 NIH funding at $35 billion. This funding level would ensure that NIH can maintain the number of multi-year investigator-initiated research grants, and enables NEI to build upon its record of basic clinical/translational research. We also support an increase in NEI funding above the 1.8 percent proposed by the President.

*Vision 2020 USA Partnership*

VISION 2020 USA members, including Lions Clubs International, share a commitment to blindness prevention, preserving sight, and ensuring that all individuals receive the vision and eye healthcare they need and deserve. We are particularly interested in ensuring that Congress provides for fiscal year 2012 to support the following programs and initiatives:

—Sustainment of at least $3.23 million for vision and eye health initiatives at the Centers for Disease Control and Prevention (CDC)

—Support of the Maternal and Child Health Bureau's (MCHB) National Center for Children's Vision and Eye Health

Vision-related conditions affect people across the lifespan from childhood through elder years. Fortunately, in children, many serious ocular conditions—such as amblyopia, nearsightedness, farsightedness, and astigmatism—are treatable, if diagnosed at an early stage. Yet, too many children do not receive vision screenings or follow-up comprehensive eye examinations and treatment. More than 80 million Americans are at risk for a potentially blinding eye disease such as diabetic retinopathy, glaucoma, cataract, and age-related macular degeneration. If nothing is done, the number of blind Americans is expected to double by 2030.

With fiscal year 2012 appropriations that maintain current funding for vision and eye health efforts of the CDC and increased resources for the NIH and NEI, these Federal vision and eye health partners will have the resources they need to sustain and expand their respective efforts and programs to advance the prevention, diagnosis, and treatment of vision problems and eye disease.

*Lions Affordable Hearing Aid Project (AHAP)*

LCI is committed to fighting hearing loss as well as blindness. By listening to community health organizations across the country, Lions Clubs International and their volunteer members became aware of the lack of quality and affordable hearing care, especially for people with incomes below or at 200 percent of the poverty level.

Many people have been unable to access other personal and family resources to purchase hearing aids, and have been denied State and Federal assistance. Fourteen centers have been working to expand output in this area as demand continues to rise with a network of mobile health units and community based programs that screen more than 2 million people each year and provide hearing aids to 14,000 low income patients.

The statistics are unacceptable: 31 million persons in the United States experience some form of hearing loss, yet only 7.3 million opt to use hearing aids. According to audiology researchers, the market penetration for hearing aids is about 23.6 percent. For every four patients that enter a practice needing hearing aids, only one will purchase them. The median price tag is $1,900 (2005) for a digital hearing aid and prices go as high as $4,000. State Foundations, public health departments, and aging departments are in need of assistance in this area.

With the recent 25–30 percent increase in people seeking assistance for hearing aids, there is an immediate public imperative to address the problem. Federal dollars are stretched, but Federal support in this area would have significant public health dividends in difficult economic times.

"LIONS QUEST"/EDUCATION/HEALTH PROGRAMS

LCIF's youth development initiatives, known collectively as "Lions Quest," have been a prominent part of school-based K–12 programs since 1984. Fulfilling its mission to teach responsible decisionmaking, effective communications and drug prevention, Lions Quest has been involved in training more than 350,000 educators and other adults to provide services for over 11 million youth in programs covering 43 States. LCIF currently invests more than $2 million annually in supporting life skills training and service learning, and that funding is matched by local Lions, schools and other partners.

Lions Quest curricula incorporate parent and community involvement in the development of health and responsible young people in the areas of: life skills development (social and emotional learning), character education, drug prevention, service learning, and bullying prevention. There is even a physical fitness component to this program that can assist Federal goals of reducing obesity in school-aged children.

These Lions Quest programs provide strong evidence of decreased drug use, improved responsibility for students own behavior, as well as stronger decisionmaking skills and test scores in math and reading. In August 2002, Lions Quest received the highest "Select" ranking from the University of Illinois at Chicago-based Collaborative for Academic, Social and Emotional Learning (CASEL) for meeting standards in life skills education, evidence of effectiveness and exemplary professional development.

Lions Quest has extensive experience with Federal programs. Lions Quest Skills for Adolescence received a "Promising Program" rating from the U.S. Department of Education Safe and Drug Free Schools and a "Model" rating from the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA).

Lions Quest also has extensive experience of partnering with State service commissions to reach more schools and engage more young people in service learning. Successful partnerships have been active in Michigan, New York, Oklahoma, Tennessee and West Virginia with progress being made in Texas and Ohio.

*Social and Emotional Learning Programs*

In addition, Lions Clubs recommends Congressional support for social and emotional learning (SEL) programs that stimulate growth among schools nationwide through distribution of materials and teacher training, and to create opportunities for youth to participate in activities that increase their social and emotional skills. Not only do SEL curricula contribute to the social and emotional development of youth, but they also provide invaluable support to students' school success, health, well-being, peer and family relationships, and citizenship. While still conducting scientific research and reviewing the best available science evidence, over time Lions Clubs and its SEL partners have increasingly worked to provide SEL practitioners, trainers and school administrators with the guidelines, tools, informational resources, policies, training, and support they need to improve and expand SEL programming.

Overall, SEL training programs and curricula have outstanding benefits for school-aged children:

—SEL prevents a variety of problems such as alcohol and drug use, violence, truancy, and bullying. SEL programs for urban youth emphasize the importance of cooperation and teamwork.

—Positive outcomes increase in students who are involved in social and emotional learning programming by an average of 11 percentile points over other students.
—With greater social and emotional desire to learn and commit to schoolwork, participants benefit from improved attendance, graduation rates, grades, and test scores.

CONCLUSION

Lions Clubs remains committed to domestic activities such as major sight initiatives and positive youth development and youth service programs. Today we face great health and educational challenges, and Lions Clubs International understands the importance not only of community service but of instilling those among members of our next generation. The success of nonprofit entities such as Lions Clubs show what the service sector can do for economic and social development of communities that are especially hard hit by the recession, and we are committed to forming more effective alliances and partnerships to increase our domestic impact.

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PREPARED STATEMENT OF THE MARCH OF DIMES FOUNDATION

The 3 million volunteers and nearly 1,300 staff members of the March of Dimes Foundation appreciate the opportunity to submit Federal funding recommendations for fiscal year 2012.

The March of Dimes was founded in 1938 by President Franklin D. Roosevelt to support research to prevent polio. Today, the Foundation aims to improve the health of women, infants and children by preventing birth defects, premature birth, and infant mortality through scientific research, community services, education and advocacy.

The March of Dimes is a unique partnership of scientists, clinicians, parents, members of the business community and other volunteers affiliated with 51 chapters and 213 divisions in every State, the District of Columbia and Puerto Rico. Additionally, in 1992, the March of Dimes extended its mission globally and now operates through partnerships in 33 countries on four continents.

The March of Dimes is aware that the current fiscal environment necessitates restrictions on Federal funding increases and program expansions. However, it is our hope that these budgetary limitations will not put at risk our vital mission on which affected families rely. Therefore, the March of Dimes recommends the following funding levels for programs and initiatives that are essential investments in maternal and child health.

PRETERM BIRTH

In 2008, one in eight infants was born preterm (before 37 weeks). Preterm birth is the leading cause of newborn mortality (death within the first month) and the second leading cause of infant mortality (death within the first year). In 2009, the National Center for Health Statistics (NCHS) reported that the primary reason for the higher infant mortality rate in the United States compared to other high resource countries is the greater percentage of preterm births—12.4 percent in the United States compared to 5.5 percent in Ireland. But survival alone does not necessarily result in good health for these infants. Among those who survive, one in five faces health problems that persist for life. Prematurity-related conditions include cerebral palsy, intellectual disabilities, chronic lung disease, blindness and deafness. A comprehensive report published by the Institute of Medicine in 2007 estimated that preterm births cost the United States more than $26 billion in 2005 alone, with costs climbing each year.

As a result of legislation enacted in 2006 (Public Law 109–450), the U.S. Surgeon General sponsored a conference in 2008 of more than 200 of the country's foremost experts that convened for 2 days to develop a strategy to address the costly and serious problems of preterm birth. The meeting resulted in an action plan that included several overarching themes and recommendations. Among the most important were the enhancement of biomedical and epidemiological research and strengthening our Nation's data resources that document the health status of pregnant women and infants. The Foundation's funding requests regarding preterm birth are based on these recommendations.

*National Institutes of Health*

The March of Dimes commends members of the Subcommittee for their continuing support of the National Children's Study (NCS). For fiscal year 2012, the Foundation supports the President's funding recommendation of $193.9 million for the NCS

and we urge the Subcommittee to support this recommendation as well. The NCS is the largest and most comprehensive study of children's health and development ever planned in the United States. The 37 "vanguard centers" have recruited nearly 3,000 participants thus far and more than 650 children have been born into the study. When fully implemented, this study will follow a representative sample of 100,000 children in the United States from before birth until age 21. The data from this important study will help scientists at universities and research organizations across the country and around the world identify precursors of diseases and develop new strategies for treatment and prevention. Specifically, the first data generated by the NCS will provide information concerning disorders of birth and infancy, including preterm birth and its health consequences. The Foundation remains committed to supporting a well-designed NCS that promotes research of the highest quality and asks the Subcommittee to do the same.

*Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)*

For fiscal year 2012, the March of Dimes recommends at least $1.35 billion for the NICHD. This $30 million increase compared to the fiscal year 2011 enacted level will enable NICHD to expand its support for preterm birth-related research through the Maternal-Fetal Medicine Units, Neonatal Research Network, and Genomic and Proteomic Network for Preterm Birth Research. In addition, it will allow for planning grants to begin establishing a network of integrated trans-disciplinary research centers, as recommended by the Institute of Medicine report and the aforementioned 2008 Surgeon General's Conference. The causes of preterm birth are multi-faceted and necessitate a coordinated and collaborative approach integrating many disciplines. These trans-disciplinary centers would serve as a national resource for investigators to design and share new research approaches and strategies to comprehensively address preterm birth.

*Centers for Disease Control and Prevention—Preterm Birth*

The National Center for Chronic Disease Prevention and Health Promotion's Safe Motherhood Program works to promote optimal reproductive and infant health. In 2009, CDC created a robust research agenda to prevent preterm birth by improving derivation of accurate data to understand preterm birth; developing, implementing and evaluating prevention methods; and conducting targeted etiologic and epidemiologic studies. For fiscal year 2012, the March of Dimes recommends a $6 million increase in the CDC's preterm birth budget compared to the fiscal year 2011 enacted level (for a total of $8 million) to strengthen our national data systems and to expand preterm birth research as authorized by the PREEMIE Act (Public Law 109–450).

*Centers for Disease Control and Prevention—National Center for Health Statistics*

The National Center for Health Statistics' (NCHS) vital statistics program collects birth and death data that are used to monitor the Nation's health status, set research and intervention priorities, and evaluate the effectiveness of existing health programs. It is imperative that data collected by NCHS be comprehensive and timely. Unfortunately, one-quarter of the States and territories lack the capacity to use the most recent (2003) birth certificate format and only two-thirds have adopted the most recent (2003) death certificate format. The March of Dimes supports the President's recommendation to provide $162 million for the NCHS in fiscal year 2012 and urges the Subcommittee to support this recommendation in both the bill language and in the accompanying committee report as well.

*Health Resources and Services Administration—Healthy Start*

The Maternal and Child Health Bureau's Healthy Start Program is a collection of community-based projects focused on reducing infant mortality, low birth weight, and racial disparities in perinatal outcomes among high-risk populations by strengthening local health systems and resources. Communities with Healthy Start programs have seen significant improvements in perinatal health outcomes. The March of Dimes supports the President's recommendation to provide $105 million for Healthy Start in fiscal year 2012 and urges the Subcommittee to support this recommendation as well.

BIRTH DEFECTS

According to the Centers for Disease Control and Prevention, an estimated 120,000 infants in the United States are born with major structural birth defects each year. Genetic or environmental factors, or a combination of both, can cause various birth defects; yet the causes of more than 70 percent are unknown. Many

birth defects result in childhood and adult disability that require costly, lifelong treatments and special care. Additional Federal resources are sorely needed to support research to discover causes of all birth defects and for the development of effective interventions to prevent or at least reduce their prevalence.

*CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD)*

The NCBDDD conducts programs to protect and improve the health of children by preventing birth defects and developmental disabilities and by promoting optimal development and wellness among children with disabilities. For fiscal year 2012, the March of Dimes requests at least $144 million for NCBDDD. In addition, we encourage the Subcommittee to allocate an additional $5 million specifically to support birth defects research and surveillance and an additional $2 million specifically to support folic acid education. A source for this $7 million in additional funding could be the Prevention and Public Health Fund. Investing in the work of the NCBDDD will promote wellness and preventive strategies aimed at children, reduce health disparities, and enable CDC to more effectively support transition to adulthood for children with lifelong disabilities.

Allocating an additional $5 million to support genetic analysis of the research samples already obtained through the NCBDDD's National Birth Defects Prevention Study—the largest case-controlled study of birth defects ever conducted—would be a sound investment. This analysis would enable researchers to begin the work needed to translate their findings into effective birth defects intervention and treatment programs. The study has already yielded rich results. In 2009 alone, 29 articles regarding risk factors for birth defects—for example maternal diabetes, obesity, use of certain medications, and smoking—were published in medical and health journals. In addition, this investment would make possible the continuation of NCBDDD's State-based birth defects surveillance grant program. Surveillance is the backbone of the public health network and its support should be a Subcommittee priority. Because of the current fiscal situation facing many States, funding for State-based surveillance systems is in jeopardy and requires increased Federal support to ensure the survival of essential birth defects surveillance programs.

Allocating an additional $2 million to NCBDDD will allow the CDC to expand its effective national education campaign aimed at reducing the incidence of spina bifida and anencephaly by promoting consumption of folic acid. Since the institution of fortification of U.S. enriched grain products with folic acid, the rate of neural tube defects has decreased by 26 percent. However, CDC estimates that up to 70 percent of neural tube defects could be prevented if all women of childbearing age consumed 400 micrograms of folic acid daily. To raise awareness among women of childbearing age and thereby increase the use of folic acid, NCBDDD's national education campaign must be expanded.

The March of Dimes is very concerned about the Administration's recommendation that the NCBDDD's budget lines be consolidated into three categories: Child Health and Development, Health and Development for People with Disabilities, and Public Health Approach to Blood Disorders. As proposed, the Birth Defects and Developmental Disabilities budget line would be renamed Child Health and Development and existing sub-categories would be eliminated (e.g. Birth Defects, Fetal Alcohol Syndrome, Folic Acid). While the March of Dimes recognizes and supports program flexibility for CDC management, we are concerned that the title "Child Health and Development" fails to make clear the overall purpose of the programs covered, masking the urgency and importance of the need for ongoing support from Congress. We urge the Subcommittee to modify the Administration's proposal by retaining the term "Birth Defects" as a sub-line with the category "Child Health and Development." We believe this adjustment is needed to ensure that the content of these essential programs to reduce birth defects is clearly articulated.

NEWBORN SCREENING

Newborn screening is a vital public health activity used to identify genetic, metabolic, hormonal and functional disorders in newborns so that treatment can be provided. Screening detects conditions in newborns that, if left untreated, can cause disability, developmental delays, intellectual disabilities, serious illnesses or even death. If diagnosed early, many of these disorders can be successfully managed. Across the Nation, State and local governments are experiencing significant budget shortfalls. Because of this fiscal pressure, discontinuing screening for certain conditions or postponing the purchase of necessary technology is a serious threat that, if left unresolved, will put infants at risk of permanent disability or even death. For fiscal year 2012, an additional $5 million for HRSA's heritable disorders program, as authorized by the Newborn Screening Saves Lives Act (Public Law 110–204), is necessary to increase support for State efforts to improve screening, enhance coun-

seling, and increase capacity to reach and educate health professionals and parents about newborn screening programs and follow-up services.

OTHER

*Agency for Health Research and Quality (AHRQ)*

AHRQ supports research to improve healthcare quality, reduce costs and broaden access to essential health services. For fiscal year 2012, the March of Dimes recommends $405 million total for AHRQ to continue its important work, including the development and dissemination of maternal and pediatric quality measures and comparative effectiveness research. Moreover, with the historic enactment of health reform last year, AHRQ's research is needed more than ever to build the evidence-base that will be used to improve health and healthcare coverage.

*Health Resources and Services Administration—Maternal and Child Health Block Grant*

Title V of the Social Security Act, the Maternal and Child Health Block Grant, supports a growing number of community-based programs (e.g. home visiting, respite care for children with special healthcare needs, and supplementary services for pregnant women and children enrolled in Medicaid and the State Children's Health Insurance Program), but Federal support has not kept pace with increased enrollment and demand for these services. For fiscal year 2012, the March of Dimes recommends $700 million for the Maternal and Child Health Block Grant—$44 million more than the fiscal year 2011 enacted level.

*CDC National Immunization Program*

Infants are particularly vulnerable to infectious diseases, which is why it is critical to protect them through immunization. In 2008, the national estimated immunization coverage among children 19–35 months of age was 76 percent. The CDC's National Immunization Program supports States, communities and territorial public health agencies through grants to reduce the incidence of disability and death resulting from vaccine-preventable diseases. The March of Dimes is requesting $685 million in fiscal year 2012 for the National Immunization Program.

*CDC Polio Eradication*

Since its creation as an organization dedicated to research and services related to polio, the March of Dimes has been committed to the eradication of this disabling disease. We support the Administration's Global Polio Eradication Strategic Plan for the remaining endemic countries, and urge the Subcommittee to approve the President's request for $112 million in fiscal year 2012 to support CDC's Polio Eradication Program.

CLOSING

Thank you for the opportunity to testify on the federally supported programs of highest priority to the March of Dimes. The Foundation's volunteers and staff in every State, the District of Columbia and Puerto Rico look forward to working with Members of this Subcommittee to secure the resources needed to improve the health of the Nation's mothers, infants and children.

MARCH OF DIMES FISCAL YEAR 2012 FEDERAL FUNDING PRIORITIES

| Program | Fiscal year 2011 funding (w/prevention fund add-on where applicable) | March of Dimes fiscal year 2012 request |
|---|---|---|
| National Institutes of Health (Total) | $30.77 B | $35 B |
| National Children's Study | 191.05 M | 193.9 M |
| Common Fund | 543.02 M | 556.9 M |
| National Institute of Child Health and Human Development | 1.32 B | 1.35 B |
| National Human Genome Research Institute | 511.5 M | 524.8 M |
| National Center on Minority Health and Disparities | 209.71 M | 214.6 M |
| Centers for Disease Control and Prevention (Total) | 6.26 B | 7.7 B |
| Birth Defects Research & Surveillance | 20.3 M | 25.3 M |
| Folic Acid Campaign | 2.8 M | 4.8 M |
| Immunization | 525.57 M | 685 M |
| Polio Eradication | 101.6 M | 112 M |
| Preterm Birth (Safe Motherhood) | 1.97 M | 8 M |
| National Center for Health Statistics | 168.68 M | 162 M |

MARCH OF DIMES FISCAL YEAR 2012 FEDERAL FUNDING PRIORITIES—Continued

| Program | Fiscal year 2011 funding (w/prevention fund add-on where applicable) | March of Dimes fiscal year 2012 request |
|---|---|---|
| Health Resources and Services Administration (Total) | 6.29 B | 7.65 B |
| Maternal and Child Health Block Grant | 656.32 M | 700 M |
| Newborn Screening | 9.95 M | 15 M |
| Newborn Hearing Screening | 18.88 M | 19 M |
| Community Health Centers | 2.48 B | 2.56 B |
| Healthy Start | 104.36 M | 105 M |
| Agency for Healthcare Research and Quality (Total) | 392.05 M | 405 M |

## PREPARED STATEMENT OF THE MEALS ON WHEELS ASSOCIATION OF AMERICA

Thank you for the opportunity to present testimony to your subcommittee concerning fiscal year 2012 funding for Senior Nutrition Programs administered by the Administration on Aging (AoA) within the U.S. Department of Health and Human Services (HHS). I am Enid A. Borden, President and CEO of the Meals On Wheels Association of America (MOWAA), the oldest and largest national organization representing local, community-based Senior Nutrition Programs—both congregate and home-delivered (commonly referred to as Meals On Wheels)—and the only national organization and network dedicated solely to ending senior hunger in America. I speak on behalf not only of that national network of Senior Nutrition Programs but also for the hundreds of thousands of seniors in communities across this Nation who depend upon those programs for access to nutritious meals. I speak for them because many are behind closed doors, invisible and without a voice of their own. But it is not only for those particular seniors that I bring our concerns before you. I also speak for those other seniors who like their peers need meals, but who do not receive them, not because we lack the infrastructure and expertise to serve them but because our Senior Nutrition Programs lack the adequate financial resources to provide them. At MOWAA we call those individuals the hidden hungry, and we call the situation that lets them remain so a national tragedy and morally unacceptable circumstance in the richest Nation on earth. Those, I realize, are strong words. But they are also carefully chosen and in no way hyperbolic. Later I will attempt to put impartial numbers to those words, and then some humanity.

But before I do that, let me stop and offer MOWAA's sincere thanks to this Subcommittee, and in particular to you, Mr. Chairman, for your longstanding support of Senior Nutrition Programs as well as for your leadership in ensuring that these programs received increases in appropriations the past several fiscal years. We are quite mindful that the chairman's mark of the Senate version of the fiscal year 2011 bill, crafted by this Subcommittee and approved by the full Committee, contained increases of $38 million above the fiscal year 2010 level for these programs. We are grateful for those actions at the same time that we are extremely disheartened that the final fiscal year 2011 continuing resolution did not provide for any increases.

Today Senior Nutrition Programs are struggling to maintain services; many are unable to do so and therefore are forced to reduce services. That is today, and as prices of gasoline and food continue to climb, more and more programs will find themselves in that predicament. More starkly, homebound seniors who cannot shop and prepare meals for themselves, who have no other access to nutritious food, will be forced to go without meals. The consequences of that are something for which we will all pay. I use the word "pay" both literally and figuratively. If we leave frail seniors languishing in their homes without proper nutrition, their health will inevitably fail. If they survive, they will end up hospitalized or institutionalized at a cost to the Government that far exceeds the cost of providing adequate funds to Senior Nutrition Programs to enable them to furnish seniors meals in the homes and other settings. Senior Nutrition Programs can provide meals for nearly 1 year for roughly the cost of one Medicare day in the hospital. We can quantify the savings that can accrue when seniors receive nutritious meals immediately following a hospital stay for an acute condition.

Our evidence in this regard is based on 2006 data (in 2006 dollars) from a special project that MOWAA carried out in partnership with a major national insurance company. The findings were presented in December 2006 in Washington at a Leadership Summit sponsored by AoA. Through the special partnership, Medicare Advantage patients in select markets across the United States were offered without

cost to themselves 10 meals, delivered by local Meals On Wheels programs, immediately following hospital discharge. Participation was purely voluntary. Individuals who chose to receive the service were typically sicker than those who declined it. Despite this, the insurance data show that those seniors who received meals had first month post-discharge healthcare costs on average $1,061 lower than those who did not. The beneficial affects were also lasting. The third month after receiving those meals, the average per person savings were $316. Individuals who did not receive meals had both more inpatient hospital days and more inpatient admissions per 1,000 than those who did receive meals. I cannot calculate the savings had meals been provided to every senior who was discharged from the hospital, or even to half of them, but I know that it is significant. According to PricewaterhouseCoopers, preventable hospital readmissions cost the Nation approximately $25 billion each year. One out of every five Medicare patients discharged from a hospital is readmitted within 30 days at an annual cost to Medicare of $17 billion. Given these facts, providing adequate funds for Senior Nutrition Programs can only be regarded as a strong and demonstrable value proposition. Beyond that, from a human and humane perspective, and from the perspective of the value of individuals and their liberty—principals on which this Nation was founded and for which it still stands—it is the only acceptable and right thing to do.

As you are well aware, however, the President's fiscal year 2012 budget proposes continued funding for these programs for another fiscal year at the fiscal year 2010 level. If that occurs it will not only be costly on the other side of the Federal ledger but it will also be nothing less than disastrous for seniors who are already vulnerable. So we appeal to this Subcommittee to provide substantial increases above the President's request for Title III C1 (Congregate Meals), Title III C2 (Home-Delivered Meals) and Nutrition Services Incentive Program (NSIP). We ask knowing that the fiscal context in which you are working for this fiscal year 2012 appropriation bill is extraordinarily challenging, and we ask knowing that providing increases to our programs means reducing or eliminating others. But we also ask knowing that without such increases vulnerable seniors will go hungry.

One of the great strengths of community-based Senior Nutrition Programs is that they are strong public-private partnerships that rely on the community to contribute significant financial support to augment those Federal funds furnished through this Labor, Health and Human Services, Education and Related Agencies appropriation bill. A host of partners give generously, and without them Senior Nutrition Programs could not operate. But without a strong Federal commitment in the form of adequate appropriations most Senior Nutrition Programs could not leverage these other funds effectively. In fiscal year 2009, the last year for which AoA has data, only 28.4 percent of the expenditures for Title III C2 home-delivered meals were Title III dollars. The remainder was from other sources. For Title III C1 congregate meals the Title III share was 41 percent. Funds are not the only invaluable resources that communities contribute to Senior Nutrition Programs. The programs typically rely on volunteers to perform many of the critical functions of the operation, such as meal delivery. We are proud to claim what we believe to be the largest volunteer army in the world, numbering in the neighborhood of 1.7 million individuals each year. Despite all of these assets Senior Nutrition Programs will fail to reach the most vulnerable elderly in their communities without adequate Federal financial support.

Simply put, Senior Nutrition Programs are lifelines to those men and women they serve. Regrettably they are reaching only a small proportion of the population needing services. A February 2011 Government Accountability Office (GAO) report prepared for Senator Herb Kohl paints a grim picture. The GAO (GAO–11–237) found that ". . . approximately 9 percent of an estimated 17.6 million low-income older adults received meal services like those provided by Title III programs. However, many more older adults likely needed services, but did not receive them . . . For instance, an estimated 19 percent of low-income older adults *were food insecure and about 90 percent of these individuals did not receive any meal services* [emphasis added]. Similarly approximately 17 percent of those with low incomes had two or more types of difficulties with daily activities that could make it difficult to obtain or prepare food. *An estimated 83 percent of those individuals with such difficulties did not receive meal services* [emphasis added].

As dire as this report is, we wish to point out that it undercounts the percentage of the population needing services that fail to receive them. This is due to the fact that the GAO confined their investigation to low-income seniors. Title III and NSIP funded meal programs are explicitly prohibited by the Older Americans Act (OAA) from means-testing and many individuals with incomes above the Federal poverty line receive services based on their physical condition, homebound status, social or geographic isolation and other factors that create an inability to access nutritious

food from any other source. If you factor individuals meeting these criteria into the equation, the percentage of seniors needing meal services but who do not get them will certainly increase. Surely our Federal and national commitment to our most vulnerable elders should reach more than 10 percent of those needing meals.

Given the current economic situation and the exponential growth of the aging population, if funding remains static it is unavoidable that the percentage of people needing services to whom Senior Nutrition Programs will be able to provide services will erode substantially. Sky-rocketing food and fuel prices are having a deleterious impact on programs that are dependent upon these two items. MOWAA has determined that every 1 cent increase in the price of gasoline results in a $250,000 increase in the cost of providing services. Gasoline prices for the week of May 9, 2011 were $1.06 higher than for the same week of 2010. This means that costs nationally of delivering services based on this factor alone increased by $26,500,000. It is true that some, but not all, of these costs are borne by volunteers who donate the use of their vehicles, but as gas prices increase many of these individuals, a number of whom are older and on fixed incomes themselves, are either requesting reimbursement from programs or suspending their volunteer activities. When this happens, Senior Nutrition Programs often must bear the costs. The point is that factors far outside the control of Senior Nutrition Programs are increasing their costs; so flat funding will translate into a significant reduction or curtailment of nutrition services to our most vulnerable seniors.

Last year, MOWAA engaged an expert actuary to examine Federal funding for Senior Nutrition Programs for the past two decades. Looking at population data and appropriations, he determined a per capita commitment to seniors and Senior Nutrition Programs in fiscal year 1992. Then, taking into account the growth in the ages 60+ and the 85+ population and the changes in the CPI–U, he projected what the fiscal year 2012 total appropriation for Title III C1, Title III C2 and NSIP would be in fiscal year 2011 if that per capita commitment were maintained. The current year (fiscal year 2011) figure would be $1,275,571,000 based on the 60+ population and $1,743,182,000 based on the 85+ population. We are not asking for either of those funding levels, the latter of which be more than double the current year appropriation of $819,474,000 for the three line items combined. But we do believe that this provides a reasonable context in which to make decisions. Surely the senior citizens of today are as valuable and deserving of life sustaining meals as those seniors of two decades ago were. Meals are not dispensable. To live and live healthily people must eat. To ensure that frail seniors do, Congress must increase funding for Senior Nutrition Programs. We respectfully request that increases of no less than your Subcommittee originally approved for fiscal year 2011, that is of at least $38 million for Title III C combined with a commensurate increase for NSIP, should be the baseline.

In closing I would like to thank this Subcommittee again for its longstanding support, acknowledge that MOWAA understands the difficulty of your task and the boldness of our "ask" in this difficult budget year. We mean no disrespect. But part of our role, in addition to supporting our member Senior Nutrition Programs in providing meals, is to call attention to the need to afford those older adults, who contributed so much to this Nation, the respect that they are due. It is in that spirit that we make our request. As you consider it and as you make the difficult funding decisions that the Subcommittee must, we respectfully request that you think of Senior Nutrition Programs not simply as one of the hundreds of programs supported through the Labor, Health and Human Services, Education and Related Agencies appropriation bill, but instead as an essential service. For what is more essential to the sustaining of life than nutritious food and hydration? Those are the fundamental services Senior Nutrition Programs deliver.

Again, we thank you for the opportunity to present this testimony to you.

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## PREPARED STATEMENT OF THE MEDICAL LIBRARY ASSOCIATION AND ASSOCIATION OF ACADEMIC HEALTH SCIENCES LIBRARIES

### SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2011

Continue the commitment to the National Library of Medicine (NLM) by increasing funding levels to $402 million for fiscal year 2012.

Continue to support the medical library community's role in NLM's outreach, telemedicine, disaster preparedness and health information technology initiatives and the implementation of healthcare reform.

## INTRODUCTION

The Medical Library Association (MLA) and the Association of Academic Health Sciences Libraries (AAHSL) thank the Subcommittee for the opportunity to submit testimony regarding fiscal year 2012 appropriations for the National Library of Medicine (NLM), a division of the National Institutes of Health. Working in partnership with other parts of the NIH and other Federal agencies, NLM is the key link in the chain that translates biomedical research into practice, making the results of research readily available worldwide.

MLA is a nonprofit, educational organization with approximately 4,000 health sciences information professional members worldwide. Founded in 1898, MLA provides lifelong educational opportunities, supports a knowledge base of health information research, and works with a global network of partners to promote the importance of quality information for improved health to the healthcare community and the public. AAHSL is composed of the directors of 123 libraries of accredited U.S. and Canadian medical schools, and 26 associate members. AAHSL's goals are to promote excellence in academic health sciences libraries and to ensure that the next generation of health practitioners is trained in information seeking skills that enhance the quality of information delivery. Together, MLA and AAHSL address health information issues and legislative matters of importance to both our organizations.

## THE IMPORTANCE OF ANNUAL FUNDING INCREASES FOR NLM

We are pleased that the fiscal year 2010 appropriations package contained funding increases for NIH and NLM which

bolstered their baseline budgets, and that the proposed fiscal year 2011 budget included increases. In today's challenging budget environment, we recognize the difficult decisions Congress faces as it seeks to improve our Nation's fiscal stability. We appreciate and thank the Subcommittee for its commitment to strengthening the NIH and NLM budget.

MLA and AAHSL believe that increased funding for NLM is essential to maximize the return on the investment in research conducted by the NIH and other organizations. By collecting, organizing, and making the results of biomedical information more accessible to other researchers, clinicians, business innovators, and the public, NLM enables such information be used more efficiently and effectively to drive innovation and improve the national's health. This role has become more important as the volume of biomedical data produced each year expands exponentially driven by the influx of data from high-throughput genome sequencing systems and genome-wide association studies. NLM plays a critical role in accelerating nationwide deployment of health information technology, including electronic health records (EHRs) by leading the development, maintenance and dissemination of key standards for health data interchange that are now required of certified EHRs. NLM also contributes to Congressional priorities related to drug safety through its efforts to expand its clinical trial registry and results database in response to recent legislation requirements, and to the nation's ability to prepare for and respond to disasters.

We encourage the Subcommittee to continue to provide meaningful annual increases for NLM in the coming years and recommend an increase to $402 million for fiscal year 2012. Recovery funding and the fiscal year 2010 budget increases stimulated the economy and biomedical research. For NLM, Recovery Act funding allowed timely and much needed increases in support of leading edge research and training in biomedical informatics—the kinds of programs that will influence future health information technology developments. In fiscal year 2012 and beyond, it is critical to augment NLM's baseline budget to accommodate expansion of its information resources, services, and programs which must collect, organize, and make accessible rapidly expanding volumes of biomedical knowledge.

### *Growing Demand for NLM's Basic Services*

The National Library of Medicine is the world's largest biomedical library and the source of trusted health information. Every day, medical librarians across the Nation assist clinicians, students, researchers, and the public in accessing the information they need to save lives and improve health. NLM delivers more than a trillion bytes of data to millions of users every day to help researchers advance scientific discovery and accelerate its translation into new therapies; provides health practitioners with information that improves medical care and lowers its costs; and gives the public access to resources and tools that promote wellness and disease prevention. Without NLM, our Nation's medical libraries would be unable to provide the

quality information services that our Nation's health professionals, educators, researchers and patients have come to expect.

NLM's data repositories and online integrated services such as such as GenBank, PubMed, and PubMed Central are helping to revolutionize medicine and advance science to the next important era which includes individualized medicine based on an individual's unique genetic differences. GenBank, with its international partners, has become the definitive source of gene sequence information and organizing, along with NLM's other genetic databases, the volumes of data that are needed to detect associations between genes and disease and translate that knowledge into better diagnosis and treatments. PubMed, with more than 20 million citations to the biomedical literature, is the world's most heavily used source of information about published results of biomedical research. Approximately 700,000 new citations are added each year, and it is searched more than 2.2 million times each day. PubMed Central, NLM's freely accessible digital repository of biomedical journal articles, has become a valuable resource for researchers, clinicians, consumers and librarians. On a typical weekday more than 420,000 users download 740,000 full-text articles. We commend the Appropriations Committee for its support of the NIH public access policy which requires all NIH-funded researchers to deposit their final, peer-reviewed manuscripts in NLM's PubMed Central database within 12 months of publication. This highly beneficial policy is improving access to timely and relevant scientific information, stimulating discovery, informing clinical care, and improving public health literacy. We ask the Committee to remain a strong voice in support of the NIH policy and to support the extension of public access policies to other Federal science and education agencies because this would bring the benefits of public access to other research disciplines and because research in other fields is increasingly relevant to biomedicine.

As the world's largest and most comprehensive medical library, NLM's traditional print and electronic collections continue to steadily increase each year. These collections stand at more than 11.4 million items—books, journals, technical reports, manuscripts, microfilms, photographs and images. By selecting, organizing and ensuring permanent access to health science information in all formats, NLM is ensuring the availability of this information for future generations, making it accessible to all Americans, irrespective of geography or ability to pay, and ensuring that each citizen can make the best, most informed decisions about their healthcare.

Clearly, NLM is a national treasure which is making a difference in patients' lives and healthcare outcomes. For example, an MLA member shared that recently a surgeon came to the library 12 minutes before surgery to find an article on the complex procedure he was about to perform. By searching NLM's PubMed/Medline database, the librarian found illustrations that guided the surgeon during surgery enabling him to save the man's foot.

ENCOURAGE NLM PARTNERSHIPS WITH THE MEDICAL LIBRARY COMMUNITY

*Outreach and Education*

NLM's outreach programs are of interest to both MLA and AAHSL. These activities are designed to educate medical librarians, health professionals and the general public about NLM's services and to train them in the most effective use of these services. NLM has taken a leadership role in promoting educational outreach aimed at public libraries, secondary schools, senior centers and other consumer-based settings. Furthermore, NLM's emphasis on outreach to underserved populations assists the effort to reduce health disparities among large sections of the American public. One example of NLM's leadership is the "Partners in Information Access" program which is designed to improve the access of local public health officials to information needed to prevent, identify and respond to public health threats. With nearly 6,000 members in communities across the country, the National Network of Libraries of Medicine (NNLM) is well positioned to ensure that every public health worker has electronic health information services that can protect the public's health.

NLM is also at the forefront of efforts to provide consumers with trusted, reliable health information. Its MedlinePlus system provides consumer-friendly information on more than 80 topics in English and Spanish and has become a top destination for those seeking information on the Internet, attracting more than half-million visitors per day. Librarians at Louisiana State University's Health Sciences Center Medical Library in Shreveport provide in-person support for patients and the public seeking health information and have also established "healthelinks.org", a website with information on diseases and conditions, medicines, procedures and surgical operations, lab tests, and more from NLM's MedlinePlus system. With help from Congress, NLM, NIH and the Friends of NLM launched NIH MedlinePlus Magazine in September 2006. This quarterly publication is distributed in doctors' waiting rooms

and provides the public will access to high-quality, easily understood health information. Its readership is now estimated at 5 million people nationwide and is poised to grow thanks to the launch of a Spanish/English version, NIH MedlinePlus Salud, in January 2009. NLM also continues to work with medical librarians and health professionals to encourage doctors to provide MedlinePlus "information prescriptions" to their patients, directing them to relevant information on NLM's consumer-oriented MedlinePlus information system. This initiative also encourages genetics counselors to prescribe the use of NLM's Genetic Home Reference website. Using NLM's new MedlinePlus Connect utility, a growing number of clinical care organizations are implementing specific links from their electronic health record systems to relevant patient education materials in MedlinePlus, enabling them to achieve an emerging criterion for achieving meaningful use of health information technology. MedinePlus Connect was recently named a winner in the HHS Innovates competition.

NLM also provides access to information about clinical research for a wide range of diseases. Launched in February 2000, ClinicalTrials.gov contains registration information for some 105,000 trials. The database is a free and invaluable resource for patients and families who are interested in participating in cutting-edge treatments for serious illnesses. In recent years, it has become more valuable for patients, clinicians, researchers, and others, including librarians, who help patients identify relevant trials and provide clinicians and researchers with access to information about specific products such as new drugs under study. In response to the Food and Drug Administration Amendments Act of 2007, NLM has expanded ClinicalTrials.gov to accept summary results of clinical trials, including adverse events. Such information is not available systematically from other publicly accessible resources, and all too often is not published in the scientific literature. The system currently contains results for more than 3,200 trials, and the Library receives approximately 50 new results submission each week. More than 50,000 users visit the site ach day.

MLA and AAHSL applaud the success of NLM's outreach initiatives, particularly those initiatives that reach out to the medical libraries and health consumers. We ask the Committee to encourage NLM to continue to coordinate its outreach activities with the medical library community in fiscal year 2012.

*Emergency Preparedness and Response*

NLM has a long history of programs and resources that support disaster preparedness and response activities. Building on its experiences in responding to Hurricane Katrina, NLM established a Disaster Information Management Research Center to collect and organize disaster-related health information, ensure effective use of libraries and librarians in disaster planning and response, and develop information services to assist responders. MLA and NLM are developing a Disaster Information Specialization (DIS) program aimed at building the capacity of librarians and other interested professionals to provide disaster-related health information outreach. Earlier this year, NLM convened a Disaster Information Outreach Symposium for information professionals across the country. This highly successful program addressed strategies for assessing and meeting the information needs of disaster managers and responders; communications, social media and disasters; using library facilities to support disaster needs during response and recovery, workforce development; disaster resources for librarians; and tools for providing disaster health information. Working with libraries and American publishers, NLM has established an Emergency Access Initiative that makes available free full-text articles from hundreds of biomedical journals and reference books for use by medical teams responding to disasters. This initiative has been activated multiple times in the last 15 months to assist relief efforts in Japan, Pakistan, and Haiti. It organized and made available health information resources relevant to the Gulf Oil spill. MLA and AAHSL see a clear role for NLM and the Nation's health sciences libraries in disaster preparedness and response activities, and we ask the Subcommittee to support NLM's role in this initiative which has a major objective of ensuring continuous access to health information and effective use of libraries and librarians when disasters occur.

MLA and AAHSL see a clear role for NLM and the Nation's health sciences libraries in disaster preparedness and response activities, and we ask the Subcommittee to support NLM's role in this initiative which has a major objective of ensuring continuous access to health information and effective use of libraries and librarians when disasters occur.

*Health Information Technology and Bioinformatics*

NLM has played a pivotal role in creating and nurturing the field of medical informatics which is the intersection of information science, computer science and healthcare. Health informatics tools include computers, clinical guidelines, formal medical terminologies, and information and communication systems. For nearly 35 years, NLM has supported informatics research, training and the application of advanced computing and informatics to biomedical research and healthcare delivery including a variety of telemedicine projects. Many of today's informatics leaders are graduates of NLM-funded informatics research programs at universities across the country. Many of the country's exemplary electronic and personal health record systems benefits from NLM grant support.

The importance of NLM's work in health information technology continues to grow as the Nation moves toward more interoperable health information technology systems. A leader in supporting, licensing, developing and disseminating standard clinical terminologies for free United States-wide use (e.g., SNOWMED), NLM works closely with the Office of the National Coordinator for Health Information Technology (ONCHIT) to promote the adoption of interoperable electronic records, It has developed tools to make it easier for EHR developers and users to implement accepted health data standards in their systems.

MLA and AAHSL encourage the Subcommittee to continue their strong support for NLM's medical informatics and genomic science initiatives, at a point when the linking of clinical and genetic data holds increasing promise for enhancing the diagnosis and treatment of disease. MLA and AAHSL also support health information technology initiatives in ONCHIT that build upon initiatives housed at NLM.

*Building and Facility Needs*

The tremendous growth in NLM's basic functions related to the acquisition, organization and preservation of its ever-expanding collection of biomedical literature, combined with its growing contributions to healthcare reform, health information technology, drug safety, and exploitation of genomic information is straining the Library's physical resources. During times of economic hardship, NLM's role becomes increasingly important and it often serves as an archive of last resort for medical libraries looking for ways to cut back and trim their own collections.

NLM now houses 1,100 staff in a facility built to accommodate 650. This increase in the volume of biomedical information and in the number of personnel has led to a serious space shortage. Digital archiving—once thought to be a solution to the problem of housing physical collections—has only added to the challenge, as materials must often be stored in multiple formats and as new digital resources consume increasing amounts of data center storage space. As a result, the space needed for computing facilities has also grown, and a new facility is urgently needed. This need has been recognized by the NLM Board of Regents as well as the Subcommittee in Senate Report 108–345 that accompanied the fiscal year 2005 appropriations bill. However, the economic challenges of the last several years have hampered movement on this project.

While Congress continues to face tremendous funding challenges in fiscal year 2012, MLA and AAHSL encourage the Subcommittee to acknowledge the need for construction of the new building to take place when the Federal budget stabilizes so that information-handling capabilities and biomedical research are not jeopardized. At a time when medical and health science libraries across the Nation face growing financial and space constraints, ensuring that NLM continues to serve as the archive of last resort for biomedical collections is critical to the medical library community and the public we serve.

Thank you again for the opportunity to present the views of the medical library community.

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## PREPARED STATEMENT OF THE MEHARRY MEDICAL COLLEGE

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. Wayne J. Riley, President and CEO of Meharry Medical College in Nashville, Tennessee. I have previously served as vice-president and vice dean for health affairs and governmental relations and associate professor of medicine at Baylor College of Medicine in Houston, Texas and as assistant chief of medicine and a practicing general internist at Houston's Ben Taub General Hospital. In all of these roles, I have seen firsthand the importance of minority health professions institutions and the Title VII Health Professions Training programs.

Mr. Chairman, time and time again, you have encouraged your colleagues and the rest of us to take a look at our Nation and evaluate our needs over the next 10 years. I took you seriously and came here prepared to offer my best judgments. First, I want to say that it is clear that health disparities among various populations and across economic status are rampant and overwhelming. Over the next 10 years, we will need to be able to deliver more culturally relevant and culturally competent healthcare services. Bringing healthcare delivery up to this higher standard can serve as our Nation's own preventive healthcare agenda keeping us well positioned for the future.

Minority health professional institutions and the Title VII Health Professions Training programs address this critical national need. Persistent and severe staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example, African Americans represent approximately 15 percent of the U.S. population while only 2–3 percent of the Nation's healthcare workforce is African American.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health profession institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need.

An October 2006 study by the Health Resources and Services Administration (HRSA), entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

Institutions that cultivate minority health professionals have been particularly hard-hit as a result of the cuts to the Title VII Health Profession Training programs in fiscal year 2006 and fiscal year 2007 funding resolution passed earlier this Congress. Given their historic mission to provide academic opportunities for minority and financially disadvantaged students, and healthcare to minority and financially disadvantaged patients, minority health professions institutions operate on narrow margins. The cuts to the Title VII Health Professions Training programs amount to a loss of core funding at these institutions and have been financially devastating.

Mr. Chairman, I feel like I can speak authoritatively on this issue because I received my medical degree from Morehouse School of Medicine, a historically black medical school in Atlanta. I give credit to my career in academia, and my being here today, to Title VII Health Profession Training programs' Faculty Loan Repayment Program. Without that program, I would not be the president of my father's alma mater, Meharry Medical College, another historically black medical school dedicated to eliminating healthcare disparities through education, research and culturally relevant patient care.

*Minority Centers of Excellence*.—COEs focus on improving student recruitment and performance, improving curricula in cultural competence, facilitating research on minority health issues and training students to provide health services to minority individuals. COEs were first established in recognition of the contribution made by four historically black health professions institutions (the Medical and Dental Institutions at Meharry Medical College; The College of Pharmacy at Xavier University; and the School of Veterinary Medicine at Tuskegee University) to the training of minorities in the health professions. Congress later went on to authorize the es-

tablishment of "Hispanic", "Native American" and "Other" Historically black COEs. For fiscal year 2012, I recommend a funding level of $24.602 million for COEs.

*Health Careers Opportunity Program (HCOP)*.—HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary schools in order to identify and nurture promising students who demonstrate that they have the talent and potential to become a health professional. Over the last three decades, HCOPs have trained approximately 30,000 health professionals including 20,000 doctors, 5,000 dentists and 3,000 public health workers. For fiscal year 12, I recommend a funding level of $22.133 million for HCOPs.

*National Institutes of Health (NIH)*

*Research Centers at Minority Institutions*.—The Research Centers at Minority Institutions program (RCMI) at the National Center for Research Resources has a long and distinguished record of helping our institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2012.

*National Institute on Minority Health and Health Disparities*.—The National Institute on Minority Health and Health Disparities (NIMHD) is charged with addressing the longstanding health status gap between minority and nonminority populations. The NIMHD helps health professional institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, and other learning resources. The NIMHD also supports biomedical research focused on eliminating health disparities and develops a comprehensive plan for research on minority health at the NIH. Furthermore, the NIMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities. For fiscal year 2012, I recommend that this Institute's funding grow proportionally with the funding of the NIH.

*Department of Health and Human Services*

Office of Minority Health: Specific programs at OMH include:

— Assisting medically underserved communities with the greatest need in solving health disparities and attracting and retaining health professionals,

—Assisting minority institutions in acquiring real property to expand their campuses and increase their capacity to train minorities for medical careers,

—Supporting conferences for high school and undergraduate students to interest them in healthcareers, and

—Supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions.

The OMH has the potential to play a critical role in addressing health disparities. For fiscal year 2012, I recommend a funding level of $65 million for the OMH.

*Department of Education*

*Strengthening Historically Black Graduate Institutions Program*.—The Department of Education's Strengthening Historically Black Graduate Institutions program (Title III, Part B, Section 326) is extremely important to MMC and other minority serving health professions institutions. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2012, an appropriation of $65 million is suggested to continue the vital support that this program provides to historically black graduate institutions.

Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, Meharry Medical College along with other minority health professions institutions and the Title VII Health Professions Training programs can help this country to overcome health and healthcare disparities. Congress must be careful not to eliminate, paralyze or stifle the institutions and programs that have been proven to work. Meharry and other minority health professions schools seek to close the ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work towards the goal of eliminating that disparity as we have done for 1876.

Thank you, Mr. Chairman, for this opportunity.

PREPARED STATEMENT OF THE MOREHOUSE SCHOOL OF MEDICINE

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. John E. Maupin, President of Morehouse School of Medicine (MSM) in Atlanta, Georgia. I have previously served as President of Meharry Medical College, executive vice-president at Morehouse School of Medicine, director of a community health center in Atlanta, and deputy director of health in Baltimore, Maryland. In all of these roles, I have seen firsthand the importance of minority health professions institutions and the Title VII Health Professions Training programs.

I want to say that minority health professional institutions and the Title VII Health Professionals Training programs address a critical national need. Persistent and sever staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Furthermore, our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example while blacks represent approximately 15 percent of the U.S. population, only 2–3 percent of the Nation's health professions workforce is black. Morehouse is a private school with a very public mission of educating students from traditionally underserved communities so that they will care for the underserved. Mr. Chairman, I would like to share with you how your committee can help us continue our efforts to help provide quality health professionals and close our Nation's health disparity gap.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health profession institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need.

An October 2006 study by the Health Resources and Services Administration (HRSA), entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

Given the historic mission, of institutions like MSM, to provide academic opportunities for minority and financially disadvantaged students, and healthcare to minority and financially disadvantaged patients, minority health professions institutions operate on narrow margins. The slow reinvestment in the Title VII Health Professions Training programs amounts to a loss of core funding at these institutions and have been financially devastating.

Mr. Chairman, I feel like I can speak authoritatively on this issue because I received my dental degree from Meharry Medical College, a historically black medical and dental school in Nashville, Tennessee. I have seen first hand what Title VII funds have done to minority serving institutions like Morehouse and Meharry. I compare my days as a student to my days as president, without that Title VII, our institutions would not be here today. However, Mr. Chairman, since those funds have been slowly replenished, we are standing at a cross roads. This committee has the power to decide if our institutions will go forward and thrive, or if we will continue to try to just survive. We want to work with you to eliminate health disparities and produce world class professionals, but we need your assistance.

Minority Centers of Excellence: COEs focus on improving student recruitment and performance, improving curricula in cultural competence, facilitating research on minority health issues and training students to provide health services to minority

individuals. COEs were first established in recognition of the contribution made by four historically black health professions institutions (the Medical and Dental Institutions at Meharry Medical College; The College of Pharmacy at Xavier University; and the School of Veterinary Medicine at Tuskegee University) to the training of minorities in the health professions. Congress later went on to authorize the establishment of "Hispanic", "Native American" and "Other" Historically black COEs. For fiscal year 2012, I recommend a funding level of $24.602 million for COEs.

Health Careers Opportunity Program (HCOP): HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary schools in order to identify and nurture promising students who demonstrate that they have the talent and potential to become a health professional. Over the last three decades, HCOPs have trained approximately 30,000 health professionals including 20,000 doctors, 5,000 dentists and 3,000 public health workers. For fiscal year 2012, I recommend a funding level of $22.133 million for HCOPs.

*National Institutes of Health (NIH)*

*National Institute on Minority Health and Health Disparities*.—The National Institute on Minority Health and Health Disparities (NIMHD) is charged with addressing the longstanding health status gap between minority and nonminority populations. The NIMHD helps health professional institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, and other learning resources. The NIMHD also supports biomedical research focused on eliminating health disparities and develops a comprehensive plan for research on minority health at the NIH. Furthermore, the NIMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities through the Minority Centers of Excellence program. For fiscal year 2012, I recommend a funding increase proportional to any increase given to the NIH for the NIMHD.

*Research Centers at Minority Institutions*.—The Research Centers at Minority Institutions program (RCMI), currently administered at the National Center for Research Resources, has a long and distinguished record of helping our institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2012.

*Department of Health and Human Services*

*Office of Minority Health*.—Specific programs at OMH include: (1) Assisting medically underserved communities with the greatest need in solving health disparities and attracting and retaining health professionals; (2) Assisting minority institutions in acquiring real property to expand their campuses and increase their capacity to train minorities for medical careers; (3) Supporting conferences for high school and undergraduate students to interest them in healthcareers, and (4) Supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions. The OMH has the potential to play a critical role in addressing health disparities, and with the proper funding this role can be enhanced. For fiscal year 2012, I recommend a funding level of $65 million for the OMH.

*Department of Education*

*Strengthening Historically Black Graduate Institutions*.—The Department of Education's Strengthening Historically Black Graduate Institutions program (Title III, Part B, Section 326) is extremely important to MSM and other minority serving health professions institutions. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2012, an appropriation of $65 million is suggested to continue the vital support that this program provides to historically black graduate institutions.

Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, Morehouse School of Medicine along with other minority health professions institutions and the Title VII Health Professions Training programs can help this country to overcome health and healthcare disparities. Congress must be careful not to eliminate, paralyze or stifle the institutions and programs that have been proven to work. MSM and other

minority health professions schools seek to close the ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work towards the goal of eliminating that disparity as we have since our founding day.

Thank you, Mr. Chairman, and I welcome every opportunity to answer questions for your records.

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## PREPARED STATEMENT OF THE NATIONAL AHEC ORGANIZATION

The National AHEC Organization (NAO) is the professional organization representing Area Health Education Centers (AHECs). Our message is simple:

—The Area Health Education Center program is effective and provides vital services and national infrastructure.

—Area Health Education Centers are the workforce development, training and education machine for the Nation's healthcare safety-net programs.

AHEC is one of the Title VII Health Professions Training programs, originally authorized at the same time as the National Health Service Corps (NHSC) to create a complete mechanism to provide primary care providers for Community Health Centers (CHCs) and other direct providers of healthcare services for underserved areas and populations. The plan envisioned by creators of the legislation was that the CHCs would provide direct service. The NHSC would be the mechanism to fund the education of providers and supply providers for underserved areas through scholarship and loan repayment commitments. The AHEC program would be the mechanism to recruit providers into primary health careers, diversify the workforce, and develop a passion for service to the underserved in these future providers, i.e. Area Health Education Centers are the workforce development, training and education machine for the Nation's healthcare safety-net programs. The AHEC program is focused on improving the quality, geographic distribution and diversity of the primary care healthcare workforce and eliminating the disparities in our Nation's healthcare system.

AHECs develop and support the community based training of health professions students, particularly in rural and underserved areas. They recruit a diverse and broad range of students into health careers, and provide continuing education, library and other learning resources that improve the quality of community-based healthcare for underserved populations and areas.

The Area Health Education Center program is effective and provides vital services and national infrastructure. Nationwide, over 379,000 students have been introduced to health career opportunities, and over 33,000 mostly minority and disadvantaged high school students received more than 20 hours each of health career exposure. Over 44,000 health professions students received training at 17,530 community-based sites, and furthermore; over 482,000 health professionals received continuing education through AHECs. AHECs perform these education and training services through collaborative partnerships with Community Health Centers (CHCs) and the National Health Service Corps (NHSC), in addition to Rural Health Clinics (RHCs), Critical Access Hospitals, (CAHs), Tribal clinics and Public Health Departments.

*Justification for Recommendations*

Imbalances in our healthcare system result in marked inequities in access to and quality of healthcare services. This perpetuates disparities in health status and the under-representation of minority and disadvantaged individuals in the healthcare workforce. AHEC programs play a key role in correcting these inequities and strengthening the Nation's healthcare safety net.

In order to continue the progress that the Title VII Health Professions Training programs, especially AHECs, have already made toward their goal, an additional Federal investment is required. NAO recommends that the AHEC program is funded at $75 million. Investment at this level and at this time will be the first step toward full investment at the authorized level of $125 million.

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## PREPARED STATEMENT OF THE NATIONAL ALLIANCE FOR EYE AND VISION RESEARCH

### EXECUTIVE SUMMARY

NAEVR requests fiscal year 2012 NIH funding at $35 billion, which reflects a $3 billion increase over President Obama's proposed funding level of $32 billion. Funding at $35 billion, which reflects NIH net funding levels in both fiscal year 2009 and fiscal year 2010, ensures it can maintain the number of multi-year investigator-

initiated research grants, the cornerstone of our Nation's biomedical research enterprise.

The vision community commends Congress for $10.4 billion in NIH funding in the American Recovery and Reinvestment Act (ARRA), as well as fiscal year 2009 and fiscal year 2010 funding increases that enabled NIH to keep pace with biomedical inflation after 6 previous years of flat funding that resulted in a 14 percent loss of purchasing power. Fiscal year 2012 NIH funding at $35 billion enables it to meet the expanded capacity for research—as demonstrated by the significant number of high-quality grant applications submitted in response to ARRA opportunities—and to adequately address unmet need, especially for programs of special promise that could reap substantial downstream benefits, as identified by NIH Director Francis Collins, M.D., Ph.D. in his top five priorities. As President Obama has stated repeatedly, most recently during the 2011 State of the Union Address, biomedical research has the potential to reduce healthcare costs, increase productivity, and ensure the global competitiveness of the United States.

NAEVR requests that Congress increase NEI funding above the 1.8 percent proposed by the President—even if it does not fund NIH at $35 billion—since the proposed increase does not match biomedical inflation.

In 2009, Congress spoke volumes in passing S. Res. 209 and H. Res. 366, which designated 2010–2020 as The Decade of Vision, in which the majority of 78 million Baby Boomers will turn 65 years of age and face greatest risk of aging eye disease. This is not the time for a less-than-inflationary increase that nets a loss in the NEI's purchasing power, which eroded by 18 percent in the fiscal year 2003–fiscal year 2008 timeframe. NEI-funded research is resulting in treatments and therapies that save vision and restore sight, which can reduce healthcare costs, maintain productivity, ensure independence, and enhance quality of life.

THE BIPARTISAN NIH SUPPORT DISPLAYED AT THE SUBCOMMITTEE'S MARCH 30 HEARING WITH SECRETARY SEBELIUS DEMONSTRATES THE VALUE OF INCREASED AND TIMELY APPROPRIATIONS

NAEVR was pleased to hear the level of bipartisan support expressed for NIH at the March 30 Senate L–HHS Appropriations Subcommittee hearings with Department of Health and Human Services (DHHS) Secretary Kathleen Sebelius and was especially impressed by two sets of comments:

—Senate Ranking Member Richard Shelby (R-AL) cautioned against across-the-board cuts and urged Congress to sustain programs that are effective—where he cited NIH as "one of the most results-driven aspects of our entire Federal budget." He added that "research conducted at NIH reduces disabilities, prolongs life, and is an essential component to the health of all Americans. NIH programs consistently meet their performance and outcomes measures, as well as achieve their overall mission." These comments are stated so well that NAEVR will not expand upon them, other than to cite vision examples in the next sections.

—Senator Barbara Mikulski (D-MD) noted that a government shutdown, NIH cuts, or delayed appropriations, individually or in combination, will have far-reaching consequences, especially for academic Institutions across the country which receive funding.

To demonstrate that point, in late January 2011, NAEVR hosted 11 domestic and 6 international members of the Association for Research in Vision and Ophthalmology (ARVO) in Capitol Hill visits. They educated staff that a cutback to the fiscal year 2008 level would reduce NEI funding by $30 plus million and reduce the number of grants by 43—any one of which could hold the key to saving or restoring vision. The advocates also described the impact of delayed appropriations, in terms of continuity of research and retention of trained staff. If a department does not have bridge or philanthropic funding to retain staff while awaiting full funding of awards, it will need to let staff go, and that usually means a highly trained person is lost to another area of research or an institution in another State, or even another country.

FISCAL YEAR 2012 NIH FUNDING AT $35 BILLION ENABLES THE NEI TO BUILD UPON THE IMPRESSIVE RECORD OF BASIC AND CLINICAL/TRANSLATIONAL RESEARCH THAT MEETS NIH'S TOP FIVE PRIORITIES AND WAS FUNDED THROUGH FISCAL YEAR 2009/2010 ARRA AND INCREASED "REGULAR" APPROPRIATIONS

NEI's research addresses the preemption, prediction, and prevention of eye disease through basic, translational, epidemiological, and comparative effectiveness research which also address the top five NIH priorities, as identified by Dr. Collins:

genomics, translational research; comparative effectiveness; global health, and empowering the biomedical enterprise.

With respect to translational research, in June 2010, NEI hosted a Translational Research and Vision conference as the last of a series of NIH-campus based educational events recognizing its 40th anniversary (previous events addressed genetics/genomics, optical imaging, stem cell therapies, and the latest glaucoma research). In keynote comments, Dr. Collins recognized NEI as a leader in translational research. He specifically cited NEI's leadership in ocular genetics, noting that NEI has worked collaboratively with other NIH Institutes, especially the National Human Genome Research Institute (NHGRI) to elucidate the basis of eye disease and to develop treatments. As NEI Director Paul Sieving, M.D., Ph.D. has stated, one-quarter of all genes identified to date are associated with eye disease/visual impairment.

Dr. Collins also lauded the NEI's use of Genome-Wide Association Studies (GWAS) to determine the increased risk of developing age-related macular degeneration (AMD) from gene variants in the Complement Factor H (CFH) immune pathway, noting that "this was the first demonstration that GWAS is a useful tool to make the connection between gene variants and disease conditions." He added that, "Twenty years ago we could do little to prevent or treat AMD. Today, because of new treatments and procedures based on NIH/NEI research, 1.3 million Americans at risk for severe vision loss from AMD over the next 5 years can receive potentially sight-saving therapies."

With increased "regular" fiscal year 2009/2010 appropriations and ARRA funding, NEI has been able to build upon past research in two important areas:

*Genetic Basis of AMD*.—In 2010, NEI initiated the International AMD Genetics Consortium, reflecting researchers on five continents who will be sharing and analyzing GWAS results to further elucidate the genetic basis of AMD. This may lead to new diagnostics and treatments for this leading blinding eye disease, growing in incidence with the aging of the population and with potential significant costs to the Medicare program.

*Treatment of Diabetic Macular Edema*.—In May 2010, the NEI's Diabetic Retinopathy Clinical Research (DRCR) Network—a multi-center network dedicated to facilitating clinical research into diabetic retinopathy, diabetic macular edema, and associated conditions—reported results of a comparative effectiveness trial. The study confirmed that laser treatment for diabetic macular edema, when combined with injections of the Food and Drug Administration (FDA)-approved anti-angiogenic drug Lucentis, is more effective than laser treatment alone, the latter of which has been the standard of care for the past 25 years. With NIH's recent announcement of a new strategic plan to combat diabetes, led by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), this research is more important than ever within the larger context of NIH priorities. The current DRCR Network is a successor to several previous networks, all of which involved NEI–NIDDK collaboration. NEI's emphasis on diabetic retinopathy reflects the fact that it is the leading cause of vision loss in the working-age population and occurs with disproportionately greater incidence in the Hispanic population.

### IF CONGRESS DOES NOT INCREASE FISCAL YEAR 2012 NIH FUNDING ABOVE THE PRESIDENT'S REQUEST, IT IS EVEN MORE VITAL TO IMPROVE UPON THE PROPOSED 1.8 PERCENT INCREASE FOR NEI

The NIH budget proposed by the administration and finalized by Congress during the second year of the congressionally designated Decade of Vision should not contain a less-than-inflationary increase for the NEI due to the enormous challenges it faces in terms of the aging population, the disproportionate incidence of eye disease in fast-growing minority populations, and the visual impact of chronic disease (e.g., diabetes). If Congress is unable to fund NIH at $35 billion in fiscal year 2012 (NEI level of $794.5 million) and adopts the President's proposal, the 1.8 percent increase in funding must be increased to at least an inflationary level of 2.4 percent to prevent any further erosion in NEI's purchasing power. NEI funding is an especially vital investment in the overall health, as well as the vision health, of our Nation. It can ultimately delay, save, and prevent health expenditures, especially those associated with the Medicare and Medicaid programs, and is, therefore, a cost-effective investment.

### VISION LOSS IS A MAJOR PUBLIC HEALTH PROBLEM: INCREASING HEALTHCARE COSTS, REDUCING PRODUCTIVITY, DIMINISHING LIFE QUALITY

The NEI estimates that more than 38 million Americans age 40 and older experience blindness, low vision, or an age-related eye disease such as AMD, glaucoma, diabetic retinopathy, or cataracts. This is expected to grow to more than 50 million

Americans by year 2020. The economic and societal impact of eye disease is increasing not only due to the aging population, but to its disproportionate incidence in minority populations and as a co-morbid condition of chronic disease, such as diabetes.

Although the NEI estimates that the current annual cost of vision impairment and eye disease to the United States is $68 billion, this number does not fully quantify the impact of indirect healthcare costs, lost productivity, reduced independence, diminished quality of life, increased depression, and accelerated mortality. NEI's fiscal year 2010 baseline funding of $707 million reflects just a little more than 1 percent of this annual costs of eye disease. The continuum of vision loss presents a major public health problem, as well as a significant financial challenge to the public and private sectors.

NAEVR URGES CONGRESS TO FUND THE NIH AT $35 BILLION IN FISCAL YEAR 2012 WHICH WILL ENSURE THE MOMENTUM OF BREAKTHROUGH NEI-FUNDED VISION RESEARCH AND THE RETENTION OF TRAINED PERSONNEL

ABOUT NAEVR

The National Alliance for Eye and Vision Research (NAEVR) is a 501(c)4 nonprofit advocacy coalition comprised of 55 professional (ophthalmology and optometry), patient and consumer, and industry organizations involved in eye and vision research. Visit NAEVR's Web site at www.eyeresearch.org.

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## PREPARED STATEMENT OF THE NATIONAL ALLIANCE OF STATE & TERRITORIAL AIDS DIRECTORS

The National Alliance of State & Territorial AIDS Directors (NASTAD) represents the Nation's chief State health agency staff who have programmatic responsibility for administering HIV/AIDS and viral hepatitis healthcare, prevention, education, and supportive service programs funded by State and Federal governments. On behalf of NASTAD, we urge your support for increased funding for Federal HIV/AIDS and viral hepatitis programs in the fiscal year 2012 Labor-HHS-Education Appropriations bill, and thank you for your consideration of the following critical funding needs for HIV/AIDS, viral hepatitis and STD programs in fiscal year 2012. These funding needs support activities aligned with the goals set forth in the National HIV/AIDS Strategy (NHAS)—a game-changing blueprint for tackling the Nation's HIV/AIDS epidemic.

As we approach 30 years into the HIV/AIDS epidemic, we must be mindful that HIV/AIDS is still a crisis in the United States, not just a global issue. HIV/AIDS is an emergency and while there are life-saving medications that did not exist 20 years ago, there is still no cure, and we still see new infections—about 56,000 annually. The Nation's prevention efforts must match our commitment to the care and treatment of infected individuals. First and foremost we must address the devastating impact on racial and ethnic minority communities, particularly African Americans and Latinos, as well as gay men and other men who have sex with men (MSM) of all races and ethnicities, substance users, women and youth. To be successful, we must expand outreach, scale-up and consider new and innovative approaches to arrest the epidemic here at home.

The President's fiscal year 2012 budget proposal provides increases to HIV/AIDS prevention, care and the Ryan White Program in support of the National HIV/AIDS Strategy for a total investment of $3.5 billion. The Budget prioritizes HIV/AIDS resources within high burden communities and among high-risk groups, including MSM, African Americans and Hispanics, and realigns resources within CDC, HRSA, SAMHSA, and the Office of the Secretary to support the National HIV/AIDS Federal Implementation Plan. Additionally, the budget allows CDC and States to transfer up to 5 percent across HIV/AIDS, tuberculosis, STD and viral hepatitis programs to improve coordination and integration.

*HIV/AIDS Care and Treatment Programs*

The Health Resources and Services Administration (HRSA) administers the $2.2 billion Ryan White Program that provides health and support services to more than 500,000 persons living with HIV/AIDS (PLWHA). The President's budget includes an increase of $63 million for a total of $2.4 billion for the entire Ryan White Program. The Budget also includes $940 million for AIDS Drug Assistance Programs (ADAPs), an increase of $55 million.

NASTAD requests a minimum increase of $183 million in fiscal year 2012 for State Ryan White Part B grants compared to the President's budget of flat funding Part B at its fiscal year 2010 level of $418.8 million and requesting a $55 million

increase or a total of $940 million for ADAPs. We are requesting an increase of $77 million for the Part B Base and $106 million or a total of $991 million for ADAPs. ADAPs truly need an increase of $360 million in fiscal year 2012 to maintain their programs and fill the structural deficits that have built up during the last several years. With these funds States and territories provide care, treatment and support services to PLWHA, who need access to HIV clinicians, life-saving and life-extending therapies, and a full range of support services to ensure adherence to complex treatment regimens. All States have reported to NASTAD a significant increase in the number of individuals seeking Part B Base and ADAP services.

State ADAPs provide medications to low-income uninsured or underinsured PLWHA. In fiscal year 2009, over 213,000 clients were enrolled in ADAPs nationwide. Due to many factors such as unemployment, economic challenges, increased HIV testing and linkages to care, and new HIV treatment guidelines calling for earlier therapeutic treatments, program demand has increased dramatically, and thus ADAPs are ever more in crisis. As of May 19, 2011, there 8,310 individuals are on waiting lists in 13 States to receive their life-sustaining medications through ADAP:

—Alabama: 15 individuals
—Arkansas: 59 individuals
—Florida: 3,938 individuals
—Georgia: 1,520 individuals
—Idaho: 14 individuals
—Louisiana: 696 individuals
—Montana: 26 individuals
—North Carolina: 242 individuals
—Ohio: 413 individuals
—South Carolina: 693individuals
—Utah: 6 individuals
—Virginia: 684 individuals
—Wyoming: 4 individuals

Last year, as of April 2010, there were 10 States with less than 900 individuals on waiting lists. Thus, we have seen an over 900 percent increase in individuals on waiting lists in the last year.

*HIV/AIDS Prevention and Surveillance Programs*

One of the major goals of the NHAS is to lower the annual number of new infections from 56,300 to 42,225 by 2015. In order to meet this ambitious goal, NASTAD requests an increase of $90 million above fiscal year 2011 funding levels for a total of $555 million compared to the President's request of a $4 million increase for State and local health department HIV prevention and surveillance cooperative agreements in order to provide comprehensive prevention programs. By providing adequate resources to State and local health departments to scale up HIV prevention and surveillance programs, we will be closer to meeting the NHAS goal of reducing new HIV infections by 25 percent by 2015. In addition, NASTAD fully supports the President's request to allocate $30.4 million from the Prevention and Public Health Fund for HIV prevention activities consistent with the allocation of these resources in fiscal year 2010.

Of the total increase requested, NASTAD supports an increase of $60 million above fiscal year 2011 levels compared to the President's request of a $6.4 million increase for the HIV prevention cooperative agreements with health departments in order to scale up effective prevention programs and enable CDC to implement a new funding formula that would provide equitable funding to all jurisdictions based on disease burden without dismantling existing prevention efforts in some jurisdictions. Moreover, these additional resources will allow health departments to increase their efforts in a variety of areas such as: expanding the reach of activities targeting men who have sex with men (MSM). According to the September 2010 CDC Fact Sheet HIV/AIDS Among Gay and Bisexual Men, MSM account for nearly half (48 percent) of the more than 1 million people living with HIV/AIDS and account for 53 percent of new infections. Young men from racial and ethnic minority communities bear a disproportionate burden of the disease and there are more new HIV infections among young Black MSM (aged 13–29) than among any other age and racial group of MSM. Additional funding will allow heath departments to continue developing and implementing innovative, cost effective and evidence-based prevention programming. Increased funding will also allow health departments to expand services to other disproportionately impacted populations including Black women, persons who inject drugs and youth. With additional funding, health departments will expand outreach, targeted and routine HIV testing, partner services and linkage to care and other evidence-based prevention interventions. Increased funding will also allow for the expansion of additional core prevention services such as partner services (the

identification, notification and counseling of partners of persons whom have tested HIV positive), capacity building and technical assistance to implement routine HIV testing and highly targeted behavior change interventions to community-based organizations and healthcare providers as well as public education campaigns to reinforce accurate, evidence-based information and begin to reduce the stigma associated with the disease.

In addition, NASTAD believes increased funding should be directed toward critical HIV surveillance efforts and requests an increase of $30 million above fiscal year 2011 levels compared to the President's request of a decrease of nearly $2 million. Additional resources will allow improvements in core surveillance and expand surveillance for HIV incidence, behavioral risk, and receipt of care information including CD4 and viral load reporting. HIV surveillance data are the mechanism through which the success at achieving the goals of the NHAS will be measured. The completeness of national HIV surveillance activities is critical to monitor the HIV/AIDS epidemic and to provide data for targeting with greater precision the delivery of HIV prevention, care, and treatment services.

The funding increase will also allow for the continuation of the Expanded Testing Program, Enhanced Comprehensive HIV Prevention Planning (ECHPP) and Program Collaboration and Service Integration (PCSI) activities. NASTAD supports maintaining funding at $70 million to health departments to continue the highly successful Expanded Testing Program (ETP), which targets African Americans, Latinos, gay and bisexual men of all races and ethnicities, and persons who inject drugs. For the 30 jurisdictions currently funded for ETP, the program has been an effective way to implement routine HIV testing in clinical settings—increasing the number of people who know their HIV status and linking those with HIV to care and treatment. During the first 3 years of the program approximately 2.6 million tests were conducted with an estimated 28,000 being confirmed HIV positive. Reducing new HIV infections relies heavily on "knowing your status." This program should be preserved with adequate funding to ensure that more individuals learn their HIV status and are linked to care.

The first step in the NHAS is to "intensify HIV prevention efforts in communities where HIV is most heavily concentrated." In response, in August 2010, the CDC funded ECHPP. Eligible jurisdictions were awarded on September 30, 2010 with an average award of $960,000. Through ECHPP, these highly impacted urban areas were awarded resources to test and evaluate new approaches to integrate planning, monitoring and delivering HIV prevention and care services in their specific localities. NASTAD supports continuing ECHPP funding at $12 million in order to fund the next round of State health departments for this important activity.

NASTAD also requests continued support for Program Collaboration and Service Integration (PCSI) to enable health departments to integrate prevention services for HIV, STD, viral hepatitis, and TB at the client level. Currently six jurisdictions are funded by CDC for PCSI activities.

*HIV School-based Prevention for Youth*

NASTAD also supports an increase for evidence-based programs for youth funded through the CDC. An increase of $10 million above the President's fiscal year 2012 level of $40 million should be supported for HIV school health for a total of $50 million. CDC currently funds HIV school health programs through the Division of Adolescent and School Health (DASH). The President's budget proposal moves HIV-specific DASH funding to the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention to ensure closer coordination with other HIV prevention programs, which NASTAD supports. One-third of all new infections are among young people under the age of 29, the largest share of any age group of new infections.

*Viral Hepatitis Prevention Programs*

NASTAD requests an increase of $40 million for a total of $59.8 million in fiscal year 2012 compared to the President's request of $5.2 million for a total of $25 million. Funding increases would go to the CDC's Division of Viral Hepatitis (DVH) to support the HHS Action Plan on Viral Hepatitis for a national testing, education and surveillance initiative as outlined in the Division's professional judgment budget submitted to Congress last year. While we are hopeful about the first-ever HHS Viral Hepatitis Action Plan, funding is needed to support increased capacity at the HHS Office of the Assistant Secretary for Health (ASH) for supporting the implementation of this plan.

We believe that testing to identify over 3 million people or 65–75 percent of chronic hepatitis B and C patients who do not know they are infected is the highest priority for reducing illness and death related to viral hepatitis. Testing must accompany education efforts to reach those already infected and at high risk of death and

of spreading the disease. Surveillance is needed to monitor disease trends and evaluate evidence-based interventions. Unlike other infectious diseases, viral hepatitis lacks a national surveillance system. Further this funding would enhance the role of Adult Viral Hepatitis Prevention Coordinators (AVHPCs) based in State health departments to implement and integrate testing, education and surveillance into the existing public health infrastructure. States and cities receive an average funding award from DVH of $90,000, which supports a single staff position and is not sufficient for the provision of core prevention services. Therefore, NASTAD requests funding to State adult viral hepatitis prevention coordinators be increased from $5 to $10 million.

In addition, we encourage Congress to work with CDC to provide adequate hepatitis B vaccination through the Section 317 program as proposed in CDC's fiscal year 2012 budget. In years past, cost-savings from the Section 317 program supported an at-risk adult hepatitis B vaccine initiative with a funding high of $20 million. While this funding went to vaccine-purchase only and not staff capacity or infrastructure, it was a highly successful initiative at administering nearly 1 million doses of vaccine. Unfortunately cost-savings for the program were expended in fiscal year 2011.

Further we encourage the utilization of health reform's Prevention and Public Health Fund to support a broad testing and screening initiative that would include neglected diseases such as viral hepatitis in order to capture patients before they progress in their liver disease and increase costs to public healthcare systems.

*STD Prevention Programs*

NASTAD supports an increase of $212.7 million for a total of $367.4 million in fiscal year 2012 compared to the President's request of a $7 million increase for STD prevention, treatment and surveillance activities undertaken by State and local health departments. CDC's Division of STD Prevention has prioritized four disease prevention goals—Prevention of STD-related infertility, STD-related adverse pregnancy outcomes, STD-related cancers and STD-related HIV transmission. CDC estimates that 19 million new infections occur each year, almost half of them among young people ages 15 to 24. In one year, the United States may spend over $8 billion to treat the symptoms and consequences of STDs. Untreated STDs contribute to infant mortality, infertility, and cervical cancer. Additional Federal resources are needed to reverse these alarming trends and reduce the Nation's health spending. The teen pregnancy prevention initiative should be expanded to include prevention of HIV and STDs and funded at $20 million above the President's 2012 request of $114.5 million. Such an increase would allow providers to serve an additional 100,000 youth.

As you contemplate the fiscal year 2012 Labor, HHS and Education Appropriations bill, we ask that you consider all of these critical funding needs. We thank the Chairman, Ranking Member and members of the Subcommittee, for their thoughtful consideration of our recommendations. Our response to the HIV, viral hepatitis and STD epidemics in the United States defines us as a society, as public health agencies, and as individuals living in this country. There is no time to waste in our Nation's fight against these infectious and often chronic diseases. The Nation's prevention efforts must match our commitment to the care and treatment of infected individuals.

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## PREPARED STATEMENT OF THE NATIONAL ASSOCIATION FOR PUBLIC HEALTH STATISTICS AND INFORMATION SYSTEMS

The National Association for Public Health Statistics and Information Systems (NAPHSIS) welcomes the opportunity to provide this written statement for the public record as the Labor, Health and Human Services (HHS), Education and Related Agencies Appropriations Subcommittee prepares its fiscal year 2012 appropriations legislation. NAPHSIS represents the 57 vital records jurisdictions that collect, process, and issue birth and death records in the United States and its territories, including the 50 States, New York City, the District of Columbia and the five territories. NAPHSIS coordinates and enhances the activities of the vital records jurisdictions by developing standards, promoting consistent policies, working with Federal partners, and providing technical assistance.

NAPHSIS respectfully requests that the Subcommittee provide the National Center for Health Statistics (NCHS) $162 million, consistent with the President's budget request. This funding will enable the National Vital Statistics System to support States and territories as they implement the 2003 Standard Certificates of Birth, Death, and Fetal Deaths and move toward electronic collection of vital events data.

This infrastructure investment will address the Healthy People 2020 goal of increasing the number of States that record vital events using the latest U.S. standard certificates (PHI–10.1–10.3). Ultimately, this investment will lead to timelier, richer data that will facilitate public health planning, surveillance, service delivery, and evaluation. Specifically, such data will facilitate tracking of other Healthy People 2020 objectives in maternal, infant, and child health, cancer, diabetes, heart disease, respiratory disease, injury and prevention, and substance abuse, among others.

Collection of birth and death data through vital records is a State function and thus governed under State laws. NCHS purchases birth and death data from the States to compile national data on vital events—births, deaths, marriages, divorces, and fetal deaths. These data are used to monitor disease prevalence and our Nation's overall health status, develop programs to improve public health, and evaluate the effectiveness of those interventions. For example, birth data have been used to:

—Establish the relationship of smoking and adverse pregnancy outcomes;
—Link the incidence of major birth defects to environmental factors;
—Establish trends in teenage births;
—Determine the risks of low birth weight; and
—Measure racial disparities in pregnancy outcomes.

Just as fundamentally, death data are used to:

—Monitor the infant mortality rate as a leading international indicator of the Nation's health status;
—Track progress and regress in reducing mortality from the leading causes of death, such as heart disease, cancer, stroke, and diabetes;
—Document racial disparities; and
—Otherwise provide sound information for programmatic interventions.

Years of chronic underfunding at NCHS have threatened the collection of these important data on the national level, to the extent that in fiscal year 2007 NCHS would have been unable to collect a full 12 months of vital statistics data from States. Had the Subcommittee not intervened with a small but critical budget increase to continue vital statistics collection, the United States would have been the first nation in the industrialized world to be without a complete year's worth of vital data. Countless national programs and businesses that depend on vital events information would have been immeasurably affected.

Since that time, the Subcommittee has continually supported NCHS's vital statistics cooperative with the States. NAPHSIS and the broader public health community deeply appreciate these efforts. We are pleased that the President has once again followed the Subcommittee's lead in seeking to build a 21st century national statistical agency, requesting a $23 million increase for NCHS in fiscal year 2012, and directing NCHS to support the modernization of the National Vital Statistics System. This funding increase will support States as they upgrade their outdated and vulnerable paper-based vital statistics systems, addressing critical needs for activities that have been on hold or curtailed because of budget constraints.

As we make significant strides in implementing and meaningfully using health information technology, it is imperative that we similarly invest in building a modern vital statistics system that monitors our citizens' health, from birth until death. The requested funding will move us toward a timelier and more comprehensive vital statistics infrastructure where all States collect the same data and all States collect these data electronically. Two forms of birth and death certificates are in use by States—the older 1989 standard certificate and the newer 2003 standard certificate This more recent birth certificate revision includes data on insurance and access to prenatal care, labor and delivery complications, delivery methods, congenital anomalies of the newborn, maternal morbidity, mother's weight and height, breast feeding status, maternal infections, and smoking during pregnancy, among other factors. The 2003 death certificate includes data on smoking-related, pregnancy-related, and job-related deaths.

Currently, only 75 percent of the States and territories use the 2003 standard birth certificate and 65 percent have adopted the 2003 standard death certificate (see Table 1). Many States continue to rely on paper-based records, a practice which compromises the timeliness and interoperability of these data. Jurisdictions that had planned and budgeted to upgrade their certificates and systems have seen funding for these projects erode as States face severe budget shortfalls. These jurisdictions need the Federal Government's help to complete building a 21st century vital statistics system. The President's requested down payment will help in this regard, allowing all jurisdictions to implement the 2003 birth certificate and electronic birth record systems. Approximately $30 million is needed to modernize the death statistics system; but the President's budget request is nonetheless an important first step.

TABLE 1.—JURISDICTIONS REQUIRING SUPPORT TO MODERNIZE VITAL STATISTICS SYSTEM

| No 2003 Birth Certificate | No Electronic Birth Records | Incomplete Electronic Birth Records[1] | No 2003 Death Certificate | No Electronic Death Records | Incomplete Electronic Death Records[2] |
|---|---|---|---|---|---|
| Total = 20 | Total = 17 | Total = 4 | Total = 19 | Total = 24 | Total = 27 |
| Alabama | Alaska | Alabama | Alabama | Alaska | Alabama |
| Alaska | American Samoa | Hawaii | Alaska | American Samoa | Arizona |
| American Samoa | Arizona | Mississippi | American Samoa | Arkansas | Delaware |
| Arizona | Arkansas | Rhode Island | Colorado | Colorado | Washington, DC |
| Arkansas | Connecticut | | Guam | Connecticut | Georgia |
| Connecticut | Guam | | Iowa | Florida | Hawaii |
| Guam | Louisiana | | Louisiana | Iowa | Idaho |
| Louisiana | Maine | | Maryland | Kentucky | Illinois |
| Maine | Massachusetts | | Massachusetts | Louisiana | Indiana |
| Massachusetts | Minnesota | | Mississippi | Maine | Michigan |
| Minnesota | New Jersey | | North Carolina | Maryland | Minnesota |
| Mississippi | Northern Mariana | | Northern Mariana | Massachusetts | Montana |
| New Jersey | North Carolina | | Pennsylvania | Mississippi | Nebraska |
| Northern Mariana | Puerto Rico | | Puerto Rico | Missouri | Nevada |
| North Carolina | Virgin Islands | | Tennessee | New York | New Hampshire |
| Rhode Island | West Virginia | | Virgin Islands | North Carolina | New Jersey |
| Virgin Islands | Wisconsin | | Virginia | Oklahoma | New Mexico |
| Virginia | | | West Virginia | Pennsylvania | New York City |
| West Virginia | | | Wisconsin | Rhode Island | North Dakota |
| Wisconsin | | | | Tennessee | Ohio |
| | | | | Virginia | Oregon |
| | | | | Washington | South Carolina |
| | | | | West Virginia | South Dakota |
| | | | | Wisconsin | Texas |
| | | | | | Utah |
| | | | | | Vermont |
| | | | | | Wyoming |

[1] Has an electronic birth record but does not collect all 2003 data items; requires funding to modify the electronic birth record to collect the 2003 data items.
[2] Has an electronic death record but requires funding to finish enrolling physicians and funeral directors in the system.

Source: NAPHSIS Survey of Vital Statistics Jurisdictions.

The data NCHS collects are needed to track Americans' health and evaluate our progress improving it. The President's requested increase of $23 million for NCHS and the National Vital Statistics System will move us toward a timelier and more comprehensive system where all States collect the same data and all States collect these data electronically, enabling us to better compare critical information on a local, State, regional, and national basis. Without additional funding, a potential erosion of State data infrastructure and lack of standardized data will undeniably create enormous gaps in critical public health information and may have severe and lasting consequences on our ability to appropriately assess and address critical health needs.

NAPHSIS appreciates the opportunity to submit this statement for the record and looks forward to working with the Subcommittee. If you have questions about this statement, please do not hesitate to contact NAPHSIS Executive Director, Patricia W. Potrzebowski, Ph.D., at ppotrzebowski@naphsis.org or (301) 563–6001. You may also contact our Washington representative, Emily Holubowich, at eholubowich@dc-crd.com or (202) 484–1100.

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## PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS

*Introduction*

Chairman Harkin, Ranking Member Shelby, and Distinguished Members of the Subcommittee: My name is Dan Hawkins, and I am the Senior Vice President for Public Policy and Research at the National Association of Community Health Centers. On behalf of the 23 million patients served nationwide by health centers; 150,000 full-time health center staff; and countless volunteer board members; I would like to express my heartfelt appreciation to the Subcommittee for your support of America's healthcare safety net, and specifically of our mission to deliver affordable and accessible care to all Americans. I am pleased to have an opportunity to submit testimony for your consideration as you prepare the fiscal year 2012 Labor-Health and Human Services-Education and Related Agencies Appropriations bill.

*About Community Health Centers*

Health centers offer cost-effective, high-quality, and patient-directed primary and preventive care in 8,000 rural and urban underserved communities across the United States. In Iowa and Alabama, respectively, health centers deliver care to 154,020 patients in 108 communities and 315,670 patients in 140 communities.[1] By statute, health centers must be located in a medically underserved area (MUA) or serve a medically underserved population (MUP) and provide comprehensive primary care services to all community residents regardless of insurance status—offering care on a sliding fee scale. Because of this, health centers serve as the "healthcare home" for America's most vulnerable populations, including one-third of individuals living below poverty, one in seven Medicaid beneficiaries, and one in seven of America's uninsured. And nearly half of health center organizations are located in our Nation's rural areas.

Presidents of both parties and Senators on both sides of the aisle—including many members of this Subcommittee—have long-recognized the value of health centers. As a result and with bipartisan support, health centers have been on an expansion path for over a decade. Within the past 2 years, and as a result of investments this Subcommittee made through the American Recovery and Reinvestment Act, 127 new health centers opened and over 4.3 million new patients received access to care at virtually every health center in the country. I'd like to elaborate on why the Health Centers program is such a worthwhile investment that produces documented savings to the entire health system—a primary reason this program has been able to count on the Subcommittee's support for several decades.

Health centers save the country money by keeping patients out of costlier healthcare settings (like emergency departments and hospitals), coordinating care amongst providers of many health disciplines, and effectively managing chronic conditions. Medicaid beneficiaries who rely on health centers for routine care are 19 percent less likely to use the emergency department (ED) and 11 percent less likely to be hospitalized for ambulatory care-sensitive (ACS) conditions when compared to

[1] See http://www.nachc.com/state-healthcare-data-list.cfm for State Fact Sheets on Health Centers.

beneficiaries who see other providers.[2] Additionally, counties with at least one health center have 25 percent fewer ED visits for ACS conditions than counties without a health center presence.[3] By providing timely and appropriate care, health centers save over $1,200 per person per year, lowering costs across the healthcare system—from ambulatory care settings to hospital stays.[4] All told, health centers currently generate $24 billion in savings each year. This is all possible through an investment of just $1.67 per patient per day.[5]

Health centers meet or exceed national practice standards for chronic condition treatment and ensure that their patients receive more recommended screening and health promotion services than patients of other providers—despite serving underserved and traditionally at-risk populations.[6] The Institute of Medicine (IOM) and the U.S. Government Accountability Office (GAO) have recognized health centers as models for screening, diagnosing, and managing a wide array of relatively common and costly chronic conditions such as diabetes, cardiovascular disease, asthma, depression, cancer, and HIV.[7] Specifically related to diabetes, a leading cause of death and disability, health centers significantly reduce the expected lifetime incidence of diabetes complications, including blindness, kidney failure, and certain forms of heart disease.[8] America's health centers also play an important role in improving access to prenatal care and improving birth outcomes. Health centers have demonstrated their ability to reduce the disparity of low birth weight by at least 50 percent compared to the national average.[9]

A key driver of the success of the health center model is that each non-profit entity is locally-owned and directed by a patient majority board that ensures the health center is accountable and responsive to the needs of the community it serves. Research has demonstrated that this type of consumer participation on governing boards ensures higher quality care, lower costs of services, and better results.[10] In addition to tailoring their services to make healthcare delivery individualized to unique local circumstances, health centers also have a substantial and positive economic impact on their communities. In 2009 alone, health centers generated $20 billion in total economic benefit and created 189,158 jobs.[11]

*Funding Background*

The Health Resources and Services Administration (HRSA) fiscal year 2011 spending or operating plan, pursuant to Section 1863 of Public Law 112–10, provides $1.581 billion in discretionary funding for the Health Centers program—a reduction of $604.4 million relative to the fiscal year 2010-enacted level of $2.185 billion. Together with the $1.0 billion in fiscal year 2011 funding available for health centers through the Affordable Care Act (ACA), health centers have a net increase of $395.6 million in total programmatic funding for fiscal year 2011.

While we await word from HRSA about how available fiscal year 2011 programmatic funding will be allocated between existing and new health center efforts, we are heartened that there should be no interruption of existing health center ac-

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[3] Rust G, et al. "Presence of a Community Health Center and Uninsured Emergency Department Visit Rates in Rural Counties." Winter 2009 Journal of Rural Health 25(1):8–16.

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[5] Bureau of Primary Health Care, Health Resources and Services Administration, DHHS. 2009 Uniform Data System.

[6] Shi L, Tsai J, Higgins PC, Lebrun La. (2009). Racial/ethnic and socioeconomic disparities in access to care and quality of care for U.S. health center patients compared with non-health center patients. Journal of Ambulatory Care Management 32(4): 342–50. Hing E, Hooker RS, Ashman JJ. (2010). Primary Health Care in Community Health Centers and Comparison with Office-Based Practice. Journal of Community Health. 2010 Nov 3 epublished.

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[8] Huang E, et al. "The Cost-effectiveness of Improving Diabetes Care in U.S. Federally Qualified Community Health Centers." 2007 Health Services Research, 42(6): 2174–93.

[9] Politzer R, Yoon J, Shi L, Hughes R, Regan J, and Gaston M. "Inequality in America: The Contribution of Health Centers in Reducing and Eliminating Disparities in Access to Care." 2001 Medical Care Research and Review 58(2):234–248.

[10] Crampton P, et al. "Does Community-Governed Nonprofit Primary Care Improve Access to Services?" 2005 International Journal of Health Services 35(3): 465–78.

[11] NACHC, Capital Link. Community Health Centers as Leaders in the Primary Care Revolution. August 2010. www.nachc.com/research-data.cfm.

tivities, including the new centers and patients added in the past 2 years. We strongly support prioritizing fiscal year 2011 funding to maintain existing health center activities. It is worth noting, however, that most of the nearly $400 million programmatic increase in the fiscal year 2011 CR is needed to continue ongoing operations—leaving very limited funding to support expansion efforts that would otherwise have been possible if the $1.0 billion in new ACA resources were not being redirected to continue existing operations.

Currently, 60 million Americans lack access to a routine source of care.[12] And even with implementation of ACA, it is imperative that as more Americans become insured, they have access to care through a healthcare home in their community. Prior to the completion of fiscal year 2011 appropriations, health centers were on track to double their capacity and serve 40 million patients over the next 5 years, reaching a sizeable portion of the medically underserved individuals who would otherwise be forced to seek care in EDs, or delay care until hospitalization is the only option.

HRSA previously announced several fiscal year 2011 funding opportunities, including grants for new health centers and support for expanded capacity at virtually every existing health center nationwide. These opportunities produced: (1) over 800 applications submitted for 350 New Access Point (new health center) awards in communities not currently served by existing health centers, demonstrating the great need across the country for new centers to serve patients who most need access to primary care; and (2) nearly 1,100 health center grantee applications submitted to expand health center services to reach additional individuals in need in their current communities, adding new medical, oral, behavioral, pharmacy, and vision capacity. The reduction to the Health Center program's fiscal year 2011 discretionary funding leaves HRSA far short of the funding needed to make their previously-announced awards at this time.

*Fiscal Year 2012 Funding Request*

Health centers stand ready to continue working to ensure that everyone has access to primary and preventive healthcare services. In fiscal year 2012, we respectfully ask that the Subcommittee provide a discretionary funding level of no less than $1.79 billion for the Health Centers program. This funding level, together with ACA funding available in fiscal year 2012, will allow health centers to extend cost-effective primary care over 3 million Americans this year alone. It will also allow HRSA to fund remaining and worthwhile applications that will go unfunded in fiscal year 2011, including over 200 new health center applications and funding for expanded medical, oral, behavioral, pharmacy, and vision health services at existing health centers.

*Conclusion*

As the Congress works to tackle our Nation's deficit, I understand Members of this Subcommittee are faced with incredibly difficult decisions about funding levels for the programs within the fiscal year 2012 Labor-Health and Human Services-Education and Related Agencies Appropriations bill. However, health centers have proven time and time again that the Federal investment in the Health Centers program is prudent—translating to improved health outcomes for our most vulnerable Americans and reduced healthcare expenditures for this Nation. I'd ask for this Subcommittee's support in continuing the bipartisan expansion of health centers in fiscal year 2012 to ensure that our shared goal of improved access to high-quality and cost-effective care is realized.

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## PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS

*Summary*

The National Association of County and City Health Officials (NACCHO) represents the Nation's 2,800 local health departments (LHDs). These governmental agencies work every day in their communities to protect people, prevent disease, and promote wellness. Local health departments have a unique and distinctive role and set of responsibilities in the larger health system and within every community. The Nation depends upon the capacity of local health departments to play this role well.

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[12] NACHC, the Robert Graham Center, and Capital Link. Access Granted: The Primary Care Payoff. August 2007. www.nachc.com/accessreports.cfm.

The Nation's current financial challenges are compounded by those in State and local government further diminishing the ability of local health departments to measure population-wide illness, take steps to prevent disease and prolong quality of life, and to serve the public in ways others don't. Repeated rounds of budget cuts and lay-offs continue to erode local health department capacity. NACCHO surveys have found that from 2008 to 2010, local health departments have lost 29,000 jobs due to budget reductions. This represents a nearly 20 percent reduction in local public workforce. These are jobs in local communities nationwide.

On a fraying shoestring, local health departments continue to respond to an ever changing set of challenges, including ongoing public health emergency threats like floods, hurricanes, oil spills, infectious and chronic disease epidemics. The protection offered by local health departments can't be taken for granted. To help maintain the stability of LHDs, the Federal Government should invest in the following programs in fiscal year 2012 appropriations: National Public Health Improvement Initiative, Public Health Emergency Preparedness cooperative agreements, Advanced Practice Centers, Public Health Workforce Development, Chronic Disease Prevention and Health Promotion Grants, and Community Transformation Grants.

*Public Health Recommendations*

*National Public Health Improvement Initiative*

NACCHO request: $50 million
Fiscal Year 2012 President's Budget: $40.2 million
Fiscal Year 2010: $50 million

The National Public Health Improvement Initiative (NPHII) increases local health departments' capability to meet national public health standards and conduct effective performance management. This initiative promotes the effective and efficient use of resources in local health departments across the country while strengthening our public health infrastructure. In addition, these funds improve public health policies and decisionmaking crucial to protecting our communities from public health threats. NPHII boosts the ability of local health departments to reengineer their systems to meet 21st century challenges including implementation of the full range of science-based approaches to improving community health. As local health departments prepare to meet newly established national accreditation standards, NACCHO recommends $50 million in funding for fiscal year 2012 to continue to improve efficiency and effectiveness at local health departments.

*Public Health Workforce Development*

NACCHO request: $73 million
Fiscal Year 2012 President's Budget: $73 million
Fiscal Year 2010: $38 million

The Nation suffers an acute shortage of trained public health professionals, including epidemiologists, laboratorians, public health nurses, and public health informaticians. This investment in public health education and training is essential to maintain a prepared and sustainable public health workforce. With the increasing variety and magnitude of public health threats, it is vital to train new public health staff and provide continuous education for existing staff in order to maintain and upgrade the skills needed to protect our communities. This funding also supports the Centers for Disease Control and Prevention (CDC) Prevention Corps, a workforce program to recruit and train new talent for assignments in State and local health departments. This new program will also address retention by requiring professionals to commit to a designated timeframe in State and local health departments as a condition of the fellowship. NACCHO recommends $73 million in funding for fiscal year 2012 to bolster the public health workforce.

*Emergency Preparedness Recommendations*

*Public Health Emergency Preparedness Cooperative Agreements*

NACCHO request: $730 million
Fiscal Year 2012 President's Budget: $643 million
Fiscal Year 2010: $715 million

Constant readiness for both new and emerging public health threats requires an established local public health team that can plan, train, and practice on a regular basis. Emergency response capabilities and tasks, such as distributing medical countermeasures, addressing the needs of at-risk individuals, conducting drills, and organizing collaboration among staff in public health departments, schools, businesses and with volunteers, requires continuous attention and ongoing preparation. These are not supplies purchased once and stored until needed. If a community is not prepared to respond to multiple hazards, capacity to respond will not be immediately available when disasters happen. Valuable time will be lost and people will suffer,

particularly the elderly, disabled and disenfranchised, low-income residents, vulnerable populations. The only way to ensure that local health departments and their community partners are ready to respond to emergencies is to maintain consistent funding. With this funding, local health departments can sustain their level of readiness to meet benchmarks that align with the Pandemic and All Hazards Preparedness Act.

With recent progress in nationwide preparedness, now is not the time to reduce Federal funding that helps health departments continue their progress and address new, emerging threats. Especially when local health departments are under great stress from the loss of over 29,000 jobs in the last few years, the Nation cannot afford to lose the gains made by recent Federal investment in public health. Continuous training and exercising of all health department staff so that they are all ready for the next emergency must continue. A loss of readiness is inevitable if the level of Federal investment is reduced.

The safety and well-being of America's communities is dependent on the capacity of their health departments to respond in any emergency that threatens human health, including bioterrorism, infectious disease outbreaks, nuclear emergencies and natural disasters. The CDC has explicitly adopted an "all-hazards" approach to preparedness, recognizing that the capabilities necessary to respond to differing public health threats have many common elements. Through the Public Health Emergency Preparedness cooperative agreements CDC supports State and local health departments so that they can adequately prepare for and respond to such emergencies. NACCHO recommends $730 million in funding for fiscal year 2012 to continue to support emergency preparedness in our communities.

*Advanced Practice Centers*

NACCHO request: $5.4 million
Fiscal Year 2012 President's Budget: 0
Fiscal Year 2010: $5.4 million

The Advanced Practice Center program started as a CDC pilot project in 1999, and has since expanded to a national program. The APC program funds exemplary local health departments to be innovative leaders in public health preparedness to develop, evaluate, and promote products and resources that other local health department practitioners can use to meet the preparedness requirements expected for their organization or community. Since its inception, the APC program has created over 150 products and hosted numerous workshops, webinars, and other presentations to local health departments. NACCHO recommends level funding in fiscal year 2012 of $5.4 million for the Advanced Practice Center program administered by CDC's Office of Public Health Preparedness and Response.

*Disease Prevention Recommendations*

*Chronic Disease Prevention and Health Promotion Grants*

NACCHO request: $705 million
Fiscal Year 2012 President's Budget: $705 million

Chronic diseases such as heart disease, cancer, stroke and diabetes are responsible for 7 of 10 deaths among Americans each year and account for 75 percent of healthcare spending. The President's budget consolidates several previously existing grants for disease prevention and health promotion to provide State and local health departments with greater flexibility to target funds to those diseases that most burden their jurisdictions, using the most effective strategies for the populations they serve. The program recognizes that many chronic diseases have common risk factors such as obesity and physical inactivity.

Supporting effective approaches to reducing contributing factors and therefore rates of chronic disease will not only make our communities healthier, but save money for taxpayers and the Government in the long run. NACCHO recommends $705 million in funding for fiscal year 2012 to reduce chronic disease in our communities and looks forward to working with Congress on the array of details that will ensure successful, efficient, accountable implementation of a consolidated grant program that enables communities to address their chronic disease burden.

*Community Transformation Grants*

NACCHO request: $221 million
Fiscal Year 2012 President's Budget: $221 million

This program builds on the success of its predecessors: Healthy Communities, Racial and Ethnic Approaches to Community Health, and Communities Putting Prevention to Work. These funds are awarded on a competitive basis to State or local government agencies, territories, national networks of community based organizations, State or local nonprofit organizations and Indian tribes or tribal organizations

to reduce health disparities and leading causes of death. Communities will use these resources to invest in evidence-based approaches to creating a healthy population by promoting smoking cessation, active living, healthy eating, and prevention of injuries. NACCHO recommends an allocation process which makes these funds available to communities of all sizes. NACCHO recommends $221 million in funding for fiscal year 2012 to continue proven approaches to protecting public health in our communities.

As the Subcommittee drafts the fiscal year 2012 Labor-Health and Human Services-Education Appropriations bill, we ask for consideration of NACCHO's recommendations for these programs that are critical to protecting people and improving the public's health. We are fully aware of the budgetary challenges facing Congress and the need to reduce deficit spending. Budgetary cuts must be made carefully to cause the least disruption to critical public health functions and protect the health of the U.S. population.

NACCHO thanks the Subcommittee members for their previous support of public health initiatives that support work in local communities and welcomes the opportunity to discuss these requests further.

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## PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF NUTRITION AND AGING SERVICES PROGRAMS

On behalf of NANASP, the National Association of Nutrition and Aging Services Programs, I thank you for providing an opportunity to submit testimony as you consider an fiscal year 2012 Labor-HHS and Education Appropriations bill. NANASP is a national membership organization for persons across the country working to provide older adults healthful food and nutrition through community-based services. NANASP has 14 members in Iowa and 17 members in Alabama.

I am writing today to urge you to provide a much needed increase to President Obama's fiscal year 2012 funding proposal for two major programs in the Older Americans Act: the senior nutrition programs and Community Service Employment for Older Adults.

The congregate and home-delivered (Meals on Wheels) nutrition programs and the Nutrition Services Incentive Program (NSIP) are the largest and most visible component of the Older Americans Act. Next year, the senior nutrition program celebrates its 40th anniversary of helping to keep millions of the vulnerable elderly healthy and independent in their homes and communities. This is a much more fiscally sound solution than having our seniors institutionalized because of the detrimental effects of hunger and malnutrition.

The President's budget proposes no increase for the senior nutrition programs in fiscal year 2012. This is extremely alarming as these same programs were deemed worthy of increases for the past 5 fiscal years. The need for an increase in funding for meals for our seniors remains today. According to the Administration on Aging (AoA), flat funding for the nutrition programs means that 36 million fewer home-delivered and congregate meals will be served in fiscal year 2012 compared to fiscal year 2010. These meals are especially critical for the health of the 58 percent of congregate and 60 percent of home-delivered meal participants who report that they receive the majority of their daily food intake from the nutrition program.

The second major program we ask you to consider for increased funding is the Community Service Employment for Older Adults, also known as the Senior Community Service Employment Program or SCSEP. Administered by the Labor Department, SCSEP provides part-time jobs to thousands of low-income seniors, about one-fourth of them working in senior nutrition and other programs serving the elderly. These disadvantaged and previously unemployed seniors earn the minimum wage as they re-enter the job market.

In fiscal year 2012, the President's budget proposes to reduce the number of SCSEP participants by 25 percent below the fiscal year 2008 level. SCSEP is the only Federal job training program targeted for older workers, who continue to suffer in today's economy. While the current unemployment rate among older adults is lower than among younger workers, older workers are less likely to find new employment, and when they do find new jobs, their job search has taken longer. For example, nearly 30 percent of unemployed people aged 55+ were jobless for an entire year or more, a rate that exceeds that of all other age groups. Such a drastic cut in funding would not only eliminate over 22,000 job opportunities for older workers, but also take away 12 million hours of staffing for senior nutrition and other programs serving the community.

At NANASP we always say, "It is more than just a meal." Our programs provide much needed socialization for older adults and the link between nutrition and

health is irrefutable. The senior nutrition and community service employment programs play a key role in health promotion and disease prevention. Our programs keep the very vulnerable elderly healthy, engaged, and independent and out of expensive long-term care institutions that are very costly to the Medicaid program. We hope you will strongly consider an increase in funding for the nutrition and community service employment programs in your Labor-HHS, Education Appropriations bill for fiscal year 2012.

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## PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE COMPREHENSIVE HEALTH INSURANCE PLANS

The National Association of State Comprehensive Health Insurance Plans (NASCHIP) appreciates the opportunity to submit testimony as you consider an fiscal year 2012 Labor-HHS and Education Appropriations bill. NASCHIP represents the State high risk pools which were established by statute initially passed 10 years before the Federal high risk pool program (PCIP) was created by the ACA, the Affordable Care Act. Our programs operate in 35 States including your States, Mr. Chairman and Mr. Shelby. We serve more than 200,000 people providing them with insurance notwithstanding their preexisting conditions. This number reflects a 7 percent increase from 2009 levels which we consider a significant indicator of the value and necessity of our programs.

We are here to urge that you support a level of $75 million for the Federal grant program for State high risk pool programs for fiscal year 2012. This was the authorization level contained in our statute the State High-Risk Pool Funding Extension Act of 2006. This funding allows many States to provide means based premium subsidies to their citizens who might otherwise not be able to afford coverage.

We consider this level of funding the essential minimum for us to continue to do our work of providing a vital safety net to individuals who might otherwise be uninsured. For the current fiscal year, the Federal grant program for State high risk pool programs has $55 million in available funding which represents only a fraction of the total costs of care for State high risk pools. In fact, total State pool expenses in 2009 were approximately $2.2 billion.

We were disappointed that the President only requested $44 million in funding for the Federal grant program for State high risk pools in his fiscal year 2012 budget proposal. It was based in part on an incorrect premise that as enrollments grow in the PCIP program it would lessen enrollment in our programs. The request also ignores the reality of increased enrollment into our programs in 2010. Only by receiving $75 million in funding for fiscal year 2012 would we stand a chance of serving the individuals we need to serve.

The issues related to the PCIP program and either lower or higher than expected enrollments should have no bearing on the funding level we request. We have and will continue to work with administration officials to improve enrollments in PCIP as we want to see this program succeed. However, the State high risk pools serve a growing population and are in need of continued funding. We urge you to include $75 million in your Labor-HHS and Education appropriations bill for fiscal year 2012.

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## PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE HEAD INJURY ADMINISTRATORS

Thank you for this opportunity to submit testimony regarding the fiscal year 2012 budget as it pertains to funding for programs authorized by the Traumatic Brain Injury (TBI) Act of 1996, as amended in 2008. The TBI Act authorizes funding to the U.S. Department of Health and Human Services (HHS) to carry out the intent of the Act through the (1) Centers for Disease Control and Prevention (CDC) for purposes of brain injury surveillance, prevention and education; and the (2) Health Resources and Services Administration (HRSA) for grants to State governmental agencies and to Protection and Advocacy Systems to improve and increase access to rehabilitation services and community services and supports for individuals with TBI and their families.

NASHIA is a nonprofit organization representing State governmental officials who administer an array of short-term and long-term rehabilitation and community services and supports for individuals with TBI and their families. These services are generally financed through an array of Federal, State and dedicated funds (State trust funds) with the HRSA Federal TBI grants used to support and improve the necessary infrastructure to support these service systems. While NASHIA is well

aware that Federal funds are becoming increasingly difficult to obtain, NASHIA is recommending increased funding for the Federal TBI Act programs because:

—The number of Americans who sustain a TBI is increasing, especially among the elderly and young children, and among our men and women in uniform as a result of the wars in Iraq and Afghanistan, while at the same time,

—States are experiencing significant budget cuts impacting rehabilitation and community services and supports for individuals with TBI, yet

—The number of States receiving grants has been reduced from 49 to 21 due to recent changes in HRSA policy and the level of appropriations to support State grant activities.

These factors, as well as the overall economy, are creating a strain on State TBI systems. As the TBI Act program is the only Federal funding to help States to better serve individuals with TBI, NASHIA recommends:

—$10 million for the CDC programs to support TBI registries and surveillance; to develop Brain Injury Acute Care Guidelines, and to expand prevention and public education regarding injury prevention, including sports-related concussions (mild TBI);

—$ 8 million for the HRSA Federal TBI State Grant Program to increase the number of grants to States; and

—$ 4 million for the HRSA Federal TBI Protection & Advocacy (P&A) Systems Grant Program to increase the amount of grant awards.

### HRSA FEDERAL TBI STATE GRANT PROGRAM

Since 1997, HRSA has awarded grants to 48 States, District of Columbia and one Territory to develop and improve services and systems to address the short-term and long-term needs. These grants have been time limited and are relatively small. Two years ago, HRSA increased the amount of the award from approximately $100,000 to $250,000 to make it more feasible for States to carry out their grant goals and the legislative intent. While this increased amount is more attractive to States, this change reduced the number of grantees from 49 to 21—less than half of the States and Territories. As a result, States that do not have Federal funding are finding it increasingly more difficult to sustain their previous efforts, let alone expand and improve, due to other budget constraints in their States.

Over the course of the grant program, States, depending on individual State needs, have developed State plans for improving service delivery; information and referral systems; service coordination systems; outreach and screening among unidentified populations such as children, victims of domestic violence, and veterans; and training programs for direct care workers and other staff. States have also conducted public awareness and educational activities that have helped States to leverage and coordinate funding in order to maximize resources to the benefit of individuals with TBI.

In keeping with the HRSA Federal TBI State Grant Program most States have identified a lead State agency responsible for providing and coordinating services and an advisory board to plan and coordinate public policies to better serve individuals who frequently needs assistance from multiple agencies and funding streams in order to address the complexity of their needs.

### STATE COLLABORATIVE EFFORTS TO ADDRESS THE NEEDS OF VETERANS

The HRSA grant funding has been used to address the needs of returning service members and veterans with TBI and their families. Since service members and veterans first began to return from Iraq and Afghanistan, States have been contacted by families and returning servicemembers, especially those who served in the National Guard and Reserves, to obtain community resources in order to return to work, home and community.

NASHIA and some individual States have reached out to U.S. Department of Veterans Affairs (VA), particularly staff from individual Polytrauma Centers, to promote collaboration in order to better understand VA benefits for veterans that may be seeking State services, and for VA to understand what is available in the communities. In addition, some States have added representatives from VA, National Guard and Reserves, State Veterans Affairs, and/or veterans organizations to serve on their State advisory board in order to improve communications and policies across these programs.

### THE INCIDENCE AND PREVALENCE OF TBI IS ON THE RISE

CDC released new data last year showing that the incidence and prevalence of TBI in the United States is on the rise. CDC reported that each year, an estimated 1.7 million people sustain a TBI. Of that amount: 52,000 die; 275,000 are hospital-

ized; and 1.365 million (nearly 80 percent) are treated and released from an emergency department. TBI is a contributing factor to a third (30.5 percent) of all injury-related deaths in the United States. About 75 percent of TBIs that occur each year are concussions or other forms of mild TBI. The number of people with TBI who are not seen in an emergency department or who receive no care is unknown." (www.cdc.gov/TraumaticBrainInjury/statistics.hml)

The data collected by CDC relies heavily on State data, gathered through State registries and hospital discharge data. These numbers do not include the veterans who sustained TBIs in Iraq or Afghanistan and now use private or State funded resources for care, or undiagnosed TBIs.

ABOUT STATE RESOURCES AND SERVICES

Since the 1980s, States have developed services and supports largely in response to families who often seek help in crisis situations, such as loss of job due to TBI; or out of control behaviors or substance abuse that may result in family violence or dangerous situations to self and others; and the need for overall help in providing care to their family members who have extensive medical, behavioral and cognitive problems. A critical service that States provide is service coordination to help coordinate and maximize resources and supports for individuals with TBI and their families.

Over the past 25 years, States have developed service delivery systems that generally offer information and referral, service coordination, rehabilitation, in-home support, personal care, counseling, transportation, housing, vocational and other support services for persons with TBI and their families. These services are funded by State appropriations, designated funding (trust funds), Medicaid and Rehabilitation Act programs and are administered by programs located in the State public health, Vocational Rehabilitation, mental health, Medicaid, developmental disabilities, education or social services agencies.

Approximately half of all States have a dedicated funding mechanism, mainly through traffic related fines, and about half of all States also administer a Medicaid Home and Community-Based Services (HCBS) Waiver for individuals with brain injury who are Medicaid eligible. Individuals with TBI are also served in other State waiver programs designed for physical disabilities, developmental disabilities, elderly and other populations. Some States have the advantage of both waiver and trust fund programs, in addition to other State and Federal resources.

As private insurance generally does not provide for extended rehabilitation and long-term care, supports and services, most long-term services and supports for persons with TBI are administered by the States. These programs are funded mainly through the shared Federal/State Medicaid Home and Community-based Services Waivers (HCBS) program and Medicaid State Plan services, such as personal assistance, nursing homes and in-home care.

Medicaid HCBS Waivers for Individuals with TBI have grown significantly in recent years, doubling from 5,400 individuals served in 2002 to 11,214 in 2006, at a cost of $155 million in 2002 to $327 million in 2006 (Kaiser Commission on Medicaid and the Uninsured (2007, December); Medicaid Home and Community-Based Service Programs: Data Update, The Henry J. Kaiser Family Foundation, Washington, DC).

Without appropriate services and supports, individuals with TBI may become homeless, or inappropriately placed in institutional settings or end up in State or local Correctional facilities due to their cognitive and behavioral disabilities. A recent report issued by the Centers for Disease Control and Prevention (CDC) cited other jail and prison studies indicating that 25–87 percent of inmates report having experienced a TBI as compared to 8.5 percent in a general population reporting a history of TBI.

ABOUT NASHIA

The mission of NASHIA is to assist State government in promoting partnerships and building systems to meet the needs of individuals with brain injury and their families. Since 1990, NASHIA has held an annual State-of-the-States conference, and has served as a resource to State TBI program managers. NASHIA also maintains a website (www.nashia.org) containing State program contacts and other resources. NASHIA members include State officials administering public TBI programs and services, and associate members who are professionals, provider agencies, State affiliates of the Brain Injury Association of America (BIAA), family members and individuals with brain injury.

Should you wish additional information on State services and resources, or other information, please do not hesitate to contact Rebeccah Wolfkiel, Governmental Con-

sultant at 202–480–8901 (office) or rwolfkiel@ridgepolicygroup.com. You may also contact Susan L. Vaughn, Director of Public Policy, at 573–636–6946 or publicpolicy@nashia.org or William A.B. Ditto, Chair of the Public Policy Committee, at williamabditto@aol.com.

Thank you.

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PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF WORKFORCE BOARDS

Thank you for the opportunity to comment on the Administration's proposed 2012 budget for the Department of Labor. The National Association of Workforce Boards (NAWB) is a member association, which represents a majority of the 575 local employer-led Workforce Investment Boards and their nearly 13,000 employer member volunteers.

We write in support of the Administration's fiscal year 2012 overall appropriations request for the Training and Employment Services account under the Department of Labor. Adequate funding for the public workforce system has never been more critical. While the worst of the economic downturn seems behind us, one-stop centers across the Nation continue to deal with large numbers of unemployed individuals who seek advice about career options and whose skills need upgraded. In short, our employment crisis is not expected to ease in the foreseeable future.

The annual Economic Report of the President indicated that unemployment would remain above 8 percent through 2012. In April of this year the rate stood at 9 percent. Federal Reserve Chairman Ben S. Bernanke said the unemployment rate is likely to remain high "for some time" even after the biggest 2-month drop in the jobless rate since 1958.

Mr. Bernanke appearing before the House Budget Committee in February 2011, said that while the declines in the jobless rate in December and January "do provide some grounds for optimism," he cautioned that "with output growth likely to be moderate for a while and with employers reportedly still reluctant to add to their payrolls, it will be several years before the unemployment rate has returned to a more normal level."

Workforce Investment Act programs have been on the front lines of assisting job seekers impacted by the recession. Over the past year, Title I of the Workforce Investment Act (WIA) system has seen over 8 million American workers turn to it for help in navigating the labor market in search of jobs and/or the training individuals need to be competitive in their labor market. This continues the trend of an over 234 percent increase in the numbers of people who have sought assistance over the last two reporting years.

Despite a ratio of four/five job seekers nationally for every available job, over 4 million were helped back into the labor force. In short, those who received WIA services were likely to find jobs with the likelihood increasing the higher the service level. Information for the quarter ending September 30, 2010 shows the following results:

*Performance Results*

Workforce Investment Act Adult Program
—Entered Employment Rate 53.1 percent
—Employment Retention Rate 75.3 percent
—Average 6 months Earnings $13,482
Workforce Investment Act Dislocated Worker Program
—Entered Employment Rate 50.3 percent
—Employment Retention Rate 79 percent
—Average 6 months Earnings $17,227
Workforce Investment Act Youth Program
—Placement in Employment or Education rate 59.5 percent
—Attainment of Literacy and Numeracy gains 49.5 percent

The ability of the pubic workforce system to maintain this level of success on behalf of job seekers and employers seeking skilled workers is incumbent upon the continuation of adequate funding. We encourage the Subcommittee to fund WIA formula programs at a minimum at the administration's request levels, as we expect to continue to face the challenges brought about by high unemployment for the foreseeable future.

*Program Funding*

We applaud the Administration's proposal for a Workforce Innovation Fund. We believe that the State and local workforce boards have developed a host of promising practices since WIA was enacted in 1998, particularly in helping address the large numbers of persons dislocated during this recession or shut-out of the labor market

due to a lack of appropriate skills. The Workforce Innovation Fund will allow local areas to engage with community partners and quickly scale effective practices on behalf of jobseekers in need.

However, we strongly urge the Subcommittee to fully fund the administration's request for WIA formula programs before allocating funding for the Workforce Innovation Fund, as these formula funds are essential to our ability to provide services to job seekers at the local level around the Nation.

The protection of the WIA formula programs to support the locally delivered services is critical as the system continues to deal with large numbers of individuals seeking work. The Continuing Resolution passed in April contained budget reductions that are already having the impact of local areas having to close and consolidate local career one-stop centers.

*Policy Riders*

NAWB would strongly encourage the committee to continue the policy riders that prohibit the re-designation of local areas or changes to the definition of administrative costs until WIA is reauthorized. There have been instances where there has been arbitrary action to reconfigure local areas and NAWB believes these riders will prevent any State v. local conflict until reauthorization.

We urge the Subcommittee to continue to provide the support necessary for the workforce system to help our jobseekers retool for employment in high demand sectors and maintain our global competitiveness.

*Summer Youth employment*

While our testimony is focused on fiscal year 2012 funding, we would be remiss if we did not express our support for summer youth funding. Youth unemployment remains at all-time highs. The unemployment rate in April 2011 was listed as 9 percent for the total civilian labor force, but for youth the rate is over 24 percent for 16–19 year olds. In summer 2009 utilizing ARRA funding for WIA Youth programs, 313,000 young people had a summer job. Youth reported to us that their wages provided much needed income to the household for basic needs of their family and for the expenses in returning to school. Lack of youth funds imperils business finding job-ready youth to fill their employment needs as the "boomer" generation begins to retire. Serving youth that are at-risk and/or school drop-outs with the level of service needed requires intense intervention that combines academic, as well as, experiential learning techniques. The summer youth employment project allowed the system to provide youth practical work experience that reinforced classroom academics. Without it, employers in the private sector become the work-ready trainers; training that we have reason to believe employers are ill-prepared and/or unwilling to provide.

We understand these budget times, but would hope that at some point the Congress would take-up the issue of youth unemployment and we are prepared to assure Congress that any additional funding for WIA Youth programs would allow us to better address the crisis we are facing in youth employment.

Thank you for the opportunity to testify.

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## PREPARED STATEMENT OF THE NATIONAL COALITION FOR CANCER SURVIVORSHIP

It is my pleasure to submit this statement regarding fiscal year 2012 funding for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) on behalf of the National Coalition for Cancer Survivorship (NCCS) and the 12 million cancer survivors living in the United States. NCCS advocates for quality healthcare for survivors of all forms of cancer, and we believe the Federal Government should play a strong leadership role, through basic and clinical cancer research and delivery of survivorship services, to boost the quality of cancer care from diagnosis and for the balance of life. These research and survivorship programs should be conducted in partnership with private sector organizations.

In this statement, NCCS will focus on the need for a balanced program of basic, translational, and clinical research at the National Institutes of Health (NIH) and the National Cancer Institute (NCI) as well as the urgent need for Centers for Disease Control and Prevention (CDC) leadership to strengthen educational and informational services for survivors and improve access to cancer screening for the medically underserved.

Two recent reports—the Annual Report to the Nation on the Status of Cancer, 1975–2007, Featuring Tumors of the Brain and Other Nervous System and the Morbidity and Mortality Weekly Report of March 11, 2011, reporting on the number of cancer survivors in 2007—provide a compelling portrait of the progress the Nation has made in the fight against cancer, the work still to be done, and the pressing

needs of millions of cancer survivors who are still in active treatment or living as long-term survivors.

The Annual Report notes that the incidence of cancer is decreasing; the decrease is statistically significant for women although not for men, because of a recent increase in prostate cancer incidence. The cancer death rates are decreasing for both sexes. The decreases in incidence and mortality are attributed to progress in cancer prevention, early detection, and treatment. Despite the overall progress, there are increasing incidence rates for some cancers and low survival for certain forms of cancer. For example, pediatric cancer incidence is increasing, although death rates are down. The survival from melanoma, pancreatic cancer, liver cancer, and many forms of malignant brain tumors remains much too short.

Those who do survive cancer experience a myriad of late and long-term effects. In the editorial note accompanying the Morbidity and Mortality Weekly Report that found almost 12 million American cancer survivors, CDC stressed the need for more research to identify those cancer survivors at risk of recurrence, second cancers, and the late effects of cancer and its treatment. CDC also recommended that special attention be paid to the burden of survivorship for the medically underserved and the older cancer survivor.

*Recommendations for Fiscal Year 2012 Funding*

NCCS recommends smart, effective, and aggressive Federal investments in initiatives to improve the quality of care and quality of life for cancer survivors. We recommend:

—A strong and sustained investment in NIH and NCI in fiscal year 2012 to support basic, translational, and clinical research aimed at answering fundamental questions about cancer, advancing new and improved cancer treatments, identifying the side effects of cancer treatments, and strengthening interventions for the late and long term effects of cancer and treatment. No reductions should be made in NIH funding in fiscal year 2012, in order to prevent interruption of both basic and clinical studies and to sustain the progress in cancer treatment that we are making through research.

—Steady progress in the overhaul of the NCI clinical trials system. The Institute of Medicine (IOM) has outlined a plan for modernizing the clinical trials system and eliminating inefficiencies, and NCI leaders have taken steps to implement the IOM recommendations. We urge completion of this reform effort, to guarantee that patients are willing to enroll in clinical research studies because they know they will be studies of high quality investigating important issues and treatments. An improved system will also ensure that research studies are efficiently completed and questions related to new treatments are answered without delay.

—A strong investment in survivorship research that will discover those at risk of late and long-term effects from cancer and treatment and appropriate interventions for those individuals.

—A sustained commitment to basic research aimed at detecting subtypes of cancer and contributing to the development of targeted, or personalized, cancer therapies.

—Maintenance of the Federal cancer screening programs—including the breast and cervical cancer screening program and the colorectal cancer screening program—in a manner that will support services to medically underserved individuals and ensure early detection and diagnosis. The proposal to create a block grant of chronic disease programs should not include the screening programs, which do not lend themselves to effective administration through a block grant.

—A strong program of education and information regarding survivorship services for the 12 million cancer survivors living in the United States. CDC has provided grant funding to support a survivorship resource center, and we urge that steps be taken to ensure that the services offered through the center reflect the latest knowledge about the problems of survivors and the most appropriate interventions. Morever, special populations, including the medically underserved and the elderly, should be provided adequate and appropriate information and services.

Federal research and survivorship programs have yielded better treatments and enhanced quality of life for millions of American cancer patients. These programs should be sustained through continued Federal support so that the needs of a growing population of cancer survivors can be met.

PREPARED STATEMENT OF THE NATIONAL COALITION FOR OSTEOPOROSIS AND RELATED BONE DISEASES

The National Coalition for Osteoporosis and Related Bone Diseases (Bone Coalition) would like to take this opportunity to thank you all for your continued visionary support of the National Institutes of Health—the Nation's biomedical research agency. Because of your past efforts and your appreciation of the potential and value of medical research, new scientific opportunities are being pursued that hold potential for better diagnosis, treatment, prevention and eventually cures for diseases such as osteoporosis, osteogenesis imperfecta, Paget's disease of bone, and a wide range of rare bone diseases.

*Recommendation*.—The National Coalition for Osteoporosis and Related Bone Diseases joins with hundreds of health and medical organizations of the Ad Hoc Group for Medical Research Funding in urging the Committee to provide an appropriation of $35 billion in fiscal year 2012 for the National Institutes of Health. This increase will create substantial opportunities for scientific and health advances, while also providing key economic scientific support in communities across the Nation.

Organized in the early 1990s, the Bone Coalition is dedicated to increasing Federal research funding for bone diseases through advocacy and education. Five leading national bone disease groups comprise the Bone Coalition: two professional societies, the American Academy of Orthopaedic Surgeons and the American Society for Bone and Mineral Research; and three voluntary health organizations, the National Osteoporosis Foundation, the Osteogenesis Imperfecta Foundation, and the Paget Foundation for Paget's Disease of Bone and Related Disorders.

Osteoporosis and related bone diseases are omnipresent—affecting people of all ages, ethnicities, and gender. These diseases profoundly alter the quality of life and constitute a tremendous burden to patients, society and the economy—causing loss of independence, disability, pain and death. The annual direct and indirect costs for bone and joint healthcare are $849 billion—7.7 percent of the U.S. gross domestic product.

—Osteoporosis is a bone-thinning disease in which the skeleton can become so fragile that the slightest movement, even a cough or a sneeze can cause a bone to fracture. About 10 million Americans already have the disease, and another 34 million people have low bone density, which puts them at risk for osteoporosis and bone fractures. According to estimated figures, osteoporosis was responsible for more than 2 million fractures in 2005, including hip, spine, wrist, and other fractures. The number of fractures due to osteoporosis is expected to rise to more than 3 million by 2025. Approximately 1 in 2 women and up to 1 in 4 men over age 50 will break a bone because of osteoporosis, and an average of 24 percent of hip fracture patients age 50 and older will die in the year following their fracture. Individuals with certain diseases are at higher risk of developing osteoporosis. For example: diabetes patients are at increased risk for developing an osteoporosis-related fracture; cancer patients are at increased risk because many cancer therapies, such as chemotherapy and corticosteroids, have direct negative effects on bone; and certain cancers, including prostate and breast cancer, may be treated with hormonal therapy, which can cause bone loss.

—Osteogenesis imperfecta, or "brittle bone disease," is an inherited genetic disorder characterized by fragile bones which fracture easily, often from no apparent cause. A severely affected child begins fracturing before birth. Hundreds of fractures can be experienced in a lifetime, as well as hearing loss, short stature, skeletal deformities, weak muscles and respiratory difficulties. As many as 50,000 Americans may be affected by this disease.

—Paget's disease of bone is a geriatric disorder that results in enlarged and deformed bones in one or more parts of the body. Excessive bone breakdown and formation can result in bone which is structurally disorganized, resulting in an overall decrease in bone strength and an increase in susceptibility to bowing of limbs and fractures. Pain is the most common symptom. Other complications include arthritis and hearing loss if Paget's disease affects the skull. Paget's disease of bone affects 1½ to 8 percent of older adults depending on a person's age and where he or she lives. Approximately 700,000 Americans over the age of 60 are affected.

Past investments in NIH by your Committee have paid dividends for patients in the many advances in the bone research field, and these investments have had significant impact on public health. In just one example, researchers have recently discovered that bisphosphonate drugs commonly prescribed for osteoporosis and Paget's disease significantly reduce death rates by preventing fractures among older adults, producing mortality rates five times lower than those over 60 taking no bone medi-

cations. Years of basic research by NIH established the scientific foundation for development of this type of medication now producing significant results.

And while progress to date has clearly been impressive, there is still no cure for osteoporosis, osteogenesis imperfecta, Paget's disease or numerous other diseases and conditions that affect the skeleton. Depending on the disease, the opportunity to build on recent discoveries for new treatments, cures and preventive measures has never been greater. With that in mind, the Coalition has identified the following areas where further intensive investigation is warranted:

*Office of the NIH Director*.—The Coalition urges the Director to work with all relevant Institutes to enhance interdisciplinary research leading to targeted therapies for improving the density, quality and strength of bone for all Americans. More scientific knowledge is needed in a number of key areas involving bone and muscle, fat, and the central nervous system. Research is also urgently needed to improve the identification of populations who might require earlier treatment because they are at risk of rapid bone loss due to a wide range of conditions or diseases: obesity, diabetes, chronic renal failure, cancer, HIV, conditions that affect absorption of nutrients or medications, or addiction to tobacco, alcohol or other opiates. The Coalition encourages NIH to develop a plan to expand genetics and other research on rare bone diseases, including: osteogenesis imperfecta, Paget's disease of bone, fibrous dysplasia, osteopetrosis, fibrous ossificans progressiva, melorheostosis, X-linked hypophosphatemic rickets, multiple hereditary exostoses, multiple osteochondroma, Gorham's disease, and lymphangiomatosis.

*National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)*.—The Coalition urges support for research into the pathophysiology of bone loss in diverse populations. The information gained will be critical in developing targeted therapies to reduce fractures and improve bone density, quality and strength. Efforts are needed to determine appropriate levels of calcium and vitamin D for bone health at different life stages. Research is also needed in assessing bone microarchitecture and remodeling rates for determining fracture risk, anabolic approaches to increase bone mass, novel molecular and cell-based therapies for bone and cartilage regeneration, and discerning the clinical utility of new, non-invasive bone imaging techniques to measure bone architecture and fragility. Support for studies on the molecular basis of bone diseases such as Paget's disease, osteogenesis imperfecta and other rare bone diseases should also be a priority.

*National Cancer Institute (NCI)*.—The Coalition urges investigations on how to repair bone defects caused by cancer cells. Translational research is also needed to understand the impact of metastasis on the biomechanical properties of bone and the mechanisms by which bone marrow and tumor derived cells can influence metastatic growth, survival and therapeutic resistance.

*National Institute on Aging (NIA)*.—The Coalition encourages research to better define the causes of age-related bone loss and fractures, reduced physical performance and frailty, including identifying epigenetic changes, with the aim of translating basic and animal studies into new therapeutic approaches. Critical research is also needed on changes in bone structure and strength with aging, and the relationship of age-related changes in other organ systems. The prevention and treatment of other metabolic bone diseases, including osteogenesis imperfecta, glucocorticoid-induced osteoporosis, and bone loss due to kidney disease should also be priority research areas.

*National Institute of Child Health and Human Development (NICHD)*.—The Coalition urges research in the new, emerging field of metabolic disease and bone in children and adolescents, especially childhood obesity, anorexia nervosa and other eating disorders. Research is also needed on what the optimal Vitamin D levels should be in children to achieve bone health, and the implications of chronic or seasonal Vitamin D deficiency to the growing skeleton. Development and testing of therapies and bone building drugs for pediatric patients are also a pressing clinical need. The committee is encouraged by results thus far from the Bone Mineral Density in Childhood Study (BMDCS) that will serve as a valuable resource for clinicians and investigators to assess bone deficits in children and risk factors for impaired bone health. However the committee is concerned that without further funding to continue the study, there will be inadequate data on bone development in adolescents and different ethnic groups. Therefore the committee encourages NIH to extend the study and to explore research that will lead to better understanding and prevention of osteopenia and osteoporosis.

*National Institute of Dental and Craniofacial Research (NIDCR)*.—The Coalition urges continued research support on the effects of systemic bone active therapeutics on the craniofacial skeleton, including factors predisposing individuals to osteonecrosis of the jaw, as well as new approaches to facilitate bone regeneration.

The Coalition commends NIDCR for its longstanding intramural program on fibrous dysplasia.

*National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).*—The Coalition encourages support for research on the relationship between Vitamin D and morbidity and mortality in chronic kidney disease. Research is also needed on the value of anti-resorptive therapies, the link between renal insufficiency and diabetic bone disease, the differences in calcification of blood vessels, the mechanisms of metastasis of renal cell carcinoma, and diseases that occurs in patients with end stage chronic renal disease on hemodialysis.

*National Institute of Neurological Disorders and Stroke (NINDS).*—The Coalition encourages research support into the pathophysiology of spinal cord, brachial plexus, and peripheral nerve injuries in order to develop targeted therapies to improve neural regeneration and functional recovery.

*National Institute of Biomedical Imaging and Bioengineering (NIBIB).*—The Coalition encourages critical research to advance our ability to treat bone diseases and disorders through bone imaging, as well as managing the loss of bone and soft tissue associated with trauma by advancing tissue engineering strategies to replace and regenerate bone and soft tissue.

*Centers for Disease Control and Prevention*

On another front, prevention is of major concern to the Coalition. As the population ages and the ranks of senior citizen Baby Boomers expand, the annual cost of acute and long-term care for osteoporosis, alone, is projected to increase dramatically from $19 billion annually to more than $25 billion by 2025. Without significant intervention now, chronic diseases such as osteoporosis will overwhelm efforts to contain healthcare costs. Thanks to medical research better diagnosis, prevention and screening strategies and treatment therapeutics are now available to address the growing problem of osteoporosis.

The recent HHS report, "Enhancing Use of Clinical Preventive Services Among Older Adults: Closing the Gap," calls attention to the potential of preventive measures for osteoporosis. The report shows new data outlining critical gaps with a high percentage of women on Medicare reporting never having received osteoporosis screenings. Yet, as the report states, studies have proven that osteoporosis screening using hip scans and follow-up management can reduce hip fractures by 36 percent. In 1999 alone, Medicare spent more than $8 billion to treat injuries to seniors, with fractures accounting for two-thirds of the spending.

The Coalition, therefore, urges the Director of the Centers for Disease Control to develop an education and outreach plan in consultation with the patient and medical community to begin laying the ground work to address osteoporosis on a public health basis.

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## PREPARED STATEMENT OF THE NATIONAL CONSUMER LAW CENTER

The Federal Low Income Home Energy Assistance Program (LIHEAP)[1] is the cornerstone of Government efforts to help needy seniors and families stay warm and avoid hypothermia in the winter, as well as stay cool and avoid heat stress (even death) in the summer. LIHEAP is an important safety net program for low-income, unemployed and underemployed families struggling in this economy. The demand for LIHEAP assistance remains at record high levels for a third year in a row. In fiscal year 2011, the program is expected to help an estimated 9 million low-income households afford their energy bills. The unemployment and poverty forecasts for fiscal year 2012 indicate that the number of struggling households will also remain at these high levels. In light of the crucial safety net function of this program in protecting the health and well-being of low-income seniors, the disabled, and families with very young children, we respectfully request that LIHEAP be fully funded at its authorized level of $5.1 billion for fiscal year 2012 and that advance funding of $5.1 billion be provided for the program in fiscal year 2013.

*LIHEAP Provides Critical Help With Home Energy Bills for The Large Number of Low-Income Households Struggling to Move Forward in These Difficult Economic Times*

Funding LIHEAP at $5.1 billion for the regular program in fiscal year 2011 is essential in light of the sharp increase in poverty and unemployment and the steady

[1] 42 U.S.C. §§ 8621 et seq.

climb in home energy prices in recent years.[2] One indicator of the growing need for energy assistance is the growing number of disconnections. In States like Ohio that track utility disconnections, the disconnection numbers for gas and electric residential customers have increased by 23.9 percent over 5 years. For the year ending December 2010, there were 452,221 disconnections. For the year ending December 2006, there were 364,912 gas and electric disconnections. For the years ending December 2009, 2008, and 2007, there were 476,490, 424,952, and 424,411 gas and electric disconnections respectively. LIHEAP helps bring the cost of essential heating and cooling within reach for an estimated 9 million low-income households and helps keep these struggling households connected to essential utility service.

The demand for LIHEAP increases when residential home energy prices increase, such as the fly up in home heating oil and propane in the winter of fiscal year 2011.[3] Since the winter of 2005–2006, energy costs have increased from $1,337 to $2,291 for households heating with home heating oil; $1,275 to $2,040 for households heating with propane, and $723 to $947 for households heating with electricity. Households heating with natural gas have experience more moderate increases from $813 to $990. Home energy is also more expensive during prolonged periods of extreme temperatures because households use more fuel to keep the home at safe temperatures. For example, a colder than normal winter can result in higher heating bills than in years past. The third variable that drives up the demand for LIHEAP is the number of households that are struggling with unemployment, underemployment and the number of households in poverty.

Unfortunately, the number of households that are struggling to make ends meet remains very high. According a Pew Fiscal Analysis Initiative report, as of December 2010, 30 percent of the 14 million unemployed have been unemployed for a year or longer.[4] While long-term unemployment has affected all age groups, older workers have been hit particularly hard by this downturn.[5] CBO's budget and economic outlook report projects that unemployment will be 8.2 percent by the fourth quarter in fiscal year 2012, far from the 5.3 percent that CBO estimates is the natural rate of unemployment.[6] A recent Brookings Center on Children & Families analysis looks at the correlation between unemployment rates and poverty rates and estimates that the poverty rate will increase to over 15 percent in 2012.[7] Thus indications are that the demand for LIHEAP in fiscal year 2012 will remain very strong as this program helps struggling households in a number of ways. LIHEAP protects the health and safety of the frail elderly, the very young and those with chronic health conditions, such as diabetes, that increase susceptibility to temperature extremes. LIHEAP assistance also helps keep families together by keeping homes habitable during the bitter cold winter and sweltering summers.

*LIHEAP Is a Critical Safety Net Program for the Elderly, the Disabled and Households With Young Children*

*Dire Choices and Dire Consequences*.—Recent national studies have documented the dire choices low-income households face when energy bills are unaffordable. Because adequate heating and cooling are tied to the habitability of the home, low-income families will go to great lengths to pay their energy bills. Low-income households faced with unaffordable energy bills cut back on necessities such as food, medicine and medical care.[8] The U.S. Department of Agriculture has released a study that shows the connection between low-income households, especially those with elderly persons, experiencing very low food security and heating and cooling seasons

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[2] See, Chad Stone, Arloc Sherman and Hannah Shaw, *Administration's Rational For Severe Cut in Low-Income Home Energy Assistance is Weak*, Figure 2 (CBPP calculation of winter fuel price index from EIA) Center on Budget and Policy Priorities, February 18, 2011.

[3] Id.

[4] Pew Economic Policy Group Fiscal Analysis Initiative, *Addendum: A Year or More: The High Cost of Long-Term Unemployment*, January 27, 2011.

[5] Id. ("More than 40 percent of unemployed workers older than 55 have been out of work for at least a year").

[6] CBO, *The Budget and Economic Outlook: Fiscal Years 2011 to 2021*, Summary (January 2011 at Summary Table 2).

[7] Emily Monea and Isabel Sawhill, *An Update to "Simulating the Effect of the 'Great Recession' on Poverty"*, Brookings Center on Children and Families (September 16, 2010).

[8] See e.g., National Energy Assistance Directors' Association, *2008 National Energy Assistance Survey*, Tables in section IV, G and H (April 2009) (to pay their energy bills, 32 percent of LIHEAP recipients went without food, 42 percent went without medical or dental care, 38 percent did not fill or took less than the full dose of a prescribed medicine, 15 percent got a payday loan). Available at http://www.neada.org/communications/press/2009-04-28.htm.

when energy bills are high.[9] A pediatric study in Boston documented an increase in the number of extremely low weight children, age 6 to 24 months, in the 3 months following the coldest months, when compared to the rest of the year.[10] Clearly, families are going without food during the winter to pay their heating bills, and their children fail to thrive and grow. A 2007 Colorado study found that the second leading cause of homelessness for families with children is the inability to pay for home energy.[11]

When people are unable to afford paying their home energy bills, dangerous and even fatal results occur. In the winter, families resort to using unsafe heating sources, such as space heaters, ovens and burners, all of which are fire hazards. Space heaters pose 3 to 4 times more risk for fire and 18 to 25 times more risk for death than central heating. In 2007, space heaters accounted for 17 percent of home fires and 20 percent of home fire deaths.[12] In the summer, the inability to keep the home cool can be lethal, especially to seniors. According to the CDC, older adults, young children and persons with chronic medical conditions are particularly susceptible to heat-related illness and are at a high risk of heat-related death. The CDC reports that 3,442 deaths resulted from exposure to extreme heat during 1999–2003.[13] The CDC also notes that air-conditioning is the number one protective factor against heat-related illness and death.[14] LIHEAP assistance helps these vulnerable seniors, young children and medically vulnerable persons keep their homes at safe temperatures during the winter and summer and also funds low-income weatherization work to make homes more energy efficient.

LIHEAP is an administratively efficient and effective targeted health and safety program that works to bring fuel costs within a manageable range for vulnerable low-income seniors, the disabled and families with young children. LIHEAP must be fully funded at its authorized level of $5.1 billion in fiscal year 2012 in light of unaffordable, but essential heating and cooling needs of millions of struggling households due to the record high unemployment levels.

In addition, fiscal year 2013 advance funding would facilitate the efficient administration of the State LIHEAP programs. Advance funding provides certainty of funding levels to States to set income guidelines and benefit levels before the start of the heating season. States can also better plan the components of their program year (e.g., amounts set aside for heating, cooling and emergency assistance, weatherization, self-sufficiency and leveraging activities) if there is forward funding. Forward funding is critical to LIHEAP running smoothly.

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## PREPARED STATEMENT OF THE NATIONAL COUNCIL OF SOCIAL SECURITY MANAGEMENT ASSOCIATIONS

On behalf of the National Council of Social Security Management Associations (NCSSMA), thank you for the opportunity to submit our written testimony on the fiscal year 2012 funding for the Social Security Administration (SSA) to the Subcommittee. I am the President of NCSSMA and have been the District Manager of the Social Security office in Newburgh, New York for 10 years. I have worked for the Social Security Administration for 31 years, with 27 years in management.

NCSSMA is a membership organization of nearly 3,400 SSA managers and supervisors who provide leadership in 1,299 community based Field Offices and Teleservice Centers throughout the country. We are the front-line service providers for SSA in communities all over the Nation. We are also the Federal employees with whom many of your staff members work to resolve problems and issues for your con-

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[9] Mark Nord and Linda S. Kantor, *Seasonal Variation in Food Insecurity Is Associated with Heating and Cooling Costs Among Low-Income Elderly Americans*, The Journal of Nutrition, 136 (Nov. 2006) 2939–2944.

[10] Deborah A. Frank, MD et al., *Heat or Eat: The Low Income Home Energy Assistance Program and Nutritional and Health Risks Among Children Less Than 3 years of Age*, AAP Pediatrics v.118, no.5 (Nov. 2006) e1293–e1302. See also, Child Health Impact Working Group, *Unhealthy Consequences: Energy Costs and Child Health: A Child Health Impact Assessment Of Energy Costs And The Low Income Home Energy Assistance Program* (Boston: Nov. 2006) and the Testimony of Dr. Frank Before the Senate Committee on Health, Education, Labor and Pensions Subcommittee on Children and Families (March 5, 2008).

[11] Colorado Interagency Council on Homelessness, Colorado Statewide Homeless Count Summer, 2006, research conducted by University of Colorado at Denver and Health Sciences Center (Feb. 2007).

[12] John R. Hall, Jr., *Home Fires Involving Heating Equipment* (Jan. 2010) at ix and 33. Also, 40 percent of home space heater fires involve devices coded as stoves.

[13] CDC, "Heat-Related Deaths—United States, 1999–2003" MMWR Weekly, July 28, 2006.

[14] CDC, "Extreme Heat: A Prevention Guide to Promote Your Personal Health and Safety" available at http://emergency.cdc.gov/disasters/extremeheat/heat_guide.asp.

stituents who receive Social Security retirement, survivors and disability benefits, and Supplemental Security Income. Since the founding of our organization over 41 years ago, NCSSMA has considered our top priority to be a strong and stable Social Security Administration, one that delivers quality and prompt locally delivered service to the American public. We also consider it a top priority to be good stewards of the taxpayers' moneys.

Appropriations to the Social Security Administration are an excellent investment and return on taxpayer dollars. We are very appreciative of the support for SSA funding the Subcommittee has provided in recent years. The additional funding SSA received in fiscal years 2008–2010 helped significantly to prevent workloads from spiraling out of control and assisted with improving service to the American public.

NCSSMA strongly supports the President's fiscal year 2012 budget request for SSA. The total SSA budget request is $12.667 billion, which includes $12.522 billion in administrative funding through the Limitation on Administrative Expenses (LAE) account. We respectfully request that the Subcommittee provides at the least the President's full budget request for SSA in fiscal year 2012. Full funding of this request is critical to maintain staffing in SSA's front-line components, cover inflationary increases, continue efforts to reduce hearing and disability backlogs, and increase deficit-reducing program integrity work.

*Current State of SSA Operations*

NCSSMA has critical concerns about the dramatic growth in SSA workloads, and the need to receive necessary funding to maintain service levels vital to 60 million Americans. Despite agency strategic planning, expansion of online services, significant productivity gains, and the best efforts of management and employees, SSA is still faced with many challenges to providing the service that the American public has earned and deserves.

Over the last 7 years, SSA has experienced a dramatic increase in Retirement, Survivor, Dependent, Disability, and Supplementary Security Income (SSI) claims. The additional claims receipts are driven by the initial wave of the nearly 80 million baby boomers who will be filing for Social Security benefits by 2030—an average of 10,000 per day! Concurrently, there has been a surge in claims filed due to poor economic conditions and rising unemployment levels.

The need for resources in SSA Field Offices is critical to process these additional claims and provide other vital services to the American public. Field Offices are responsible for processing 2.4 million SSI redeterminations in fiscal year 2011, a 100 percent increase compared to fiscal year 2008. Nationally, visitors to Field Offices increased from 41.9 million in fiscal year 2007 to 45.4 million in fiscal year 2010. SSA is also experiencing unprecedented telephone call volumes, and in fiscal year 2010, SSA completed 67 million transactions over the 800 number network—the most ever. In addition to the transactions over the 800 number network, NCSSMA estimates that Field Offices receive 32 million public telephone contacts annually.

*SSA Funding for Fiscal Year 2011*

NCSSMA strongly supported the President's fiscal year 2011 budget request of $12.379 billion for SSA's administrative expenses. Much of this increase was needed to cover inflationary costs for fixed expenses. Funding at this level would have assured that SSA could meet its public service obligations. Despite SSA's enormous challenges, with the Federal deficit concerns, attaining this level of funding was not possible. SSA's fiscal year 2011 appropriation for administrative funding through the LAE account was $10.7755 billion, which is $25 million below the fiscal year 2010 enacted level and $275 million was rescinded from SSA's Carryover Information Technology funds.

Inadequate funding of SSA in fiscal year 2011 and additional rescissions will have major repercussions for SSA including a hiring freeze, reduction of overtime, and postponements of initiatives to improve efficiency. Reducing resources at the same time SSA workloads are increasing is a prescription for making a very productive agency that efficiently uses the taxpayers' moneys into one with significant service delays and backlogs. Service deterioration and backlogs resulting from inadequate fiscal year 2011 funding levels will have a collateral negative impact on fiscal year 2012.

*Field Office Service Delivery Challenges*

SSA Field Offices are experiencing tremendous stress because of increased workloads and additional visitors. The effect of funding SSA in fiscal year 2011 below fiscal year 2010 levels exacerbates the situation and has already had a significant impact on local Field Offices around the country.

—Frontline feedback from our busiest urban offices indicates that some have seen their visitor traffic explode with overflowing reception areas and increased waiting times.
—Most of SSA has been under a hiring freeze because of the current funding situation. A hiring freeze for all of fiscal year 2011 could result in a loss of over 2,500 SSA Federal employees.
—A November 2010, Office of the Inspector General (OIG) Report, "Threats against SSA employees or Property," indicates, "SSA has experienced a dramatic increase in the number of reported threats against its employees or property. The number of threats . . . increased by more than 50 percent in fiscal year 2009 and by more than 60 percent in fiscal year 2010."
—SSA projects 50 percent of its employees, including 66 percent of supervisors, will be eligible to retire by fiscal year 2018. Serious concerns exist about SSA's ability to sustain service levels with the tremendous loss of institutional knowledge from front-line personnel.
—Geographical staffing disparities will occur with attrition leaving some offices significantly understaffed. This is problematic for rural SSA Field Offices, whose customers often live vast distances away, may have no Internet service, and lack access to public transportation.

*SSA Online eServices to Assist with Service Delivery Challenges*

The expansion of services available to the American public via the Internet has helped to alleviate the number of visitors and telephone calls to SSA. However, the Internet is not keeping pace with the increasing demand for service. High-volume transactions, such as Social Security cards and benefit verifications are not available on the Internet, or are only being used to a limited degree. This represents over 40 percent of the 45.4 million visitors to SSA Field Offices.

NCSSMA believes that SSA must be properly funded in fiscal year 2012 and beyond so that it may continue to invest in improved user-friendly online services to allow more online transactions. If individuals were able to successfully transact their request for services online, this would result in fewer contacts with Field Offices, improved efficiencies, and better public service.

*Disability Workload Processes*

Nationwide, over 3.2 million new disability claims were filed and sent to State Disability Determination Services in fiscal year 2010. This surge of increased claims has created backlogs. At the end of fiscal year 2010, the number of pending initial disability claims was at an all-time high of 824,192 cases—a 46 percent increase from the end of fiscal year 2008. SSA's largest backlogs are hearings, appealing initial disability decisions processed by the Office of Disability Adjudication and Review. Hearing receipts continue to rise, and through April 2011, 734,666 hearings were pending which is over 29,000 more hearings than at the end of fiscal year 2010.

Despite these unprecedented challenges, SSA continues to make progress. In March 2011, the average processing time for a hearing was 359 days, the lowest level since December 2003. Unfortunately, the number of claims and hearings pending is still not acceptable to Americans who need Social Security to support their families. Progress was undermined by the fiscal year 2011 budget impasse, resulting in the suspension of opening eight planned Hearing Offices in Alabama, California, Indiana, Michigan, Minnesota, Montana, New York, and Texas. This significantly threatens to prevent SSA from eliminating the hearings backlog by fiscal year 2013.

It is important to understand that annual appropriated funding levels for SSA have a critical impact on the hearings backlog. One of the most significant reasons for the increase in the hearings backlog was the significant underfunding of SSA from fiscal year 2004 through fiscal year 2007.

*President's Proposed Fiscal Year 2012 SSA Budget*

NCSSMA strongly supports the President's fiscal year 2012 budget request for SSA and requests that Congress provide full funding to sustain the momentum achieved to allow the agency to:

—Reduce the initial disability claims backlog to 632,000 by processing over 3 million claims;
—Conduct disability hearings for 822,500 cases and reduce the waiting time for a hearing decision below a year for the first time in a decade;
—Reduce pending hearings to 597,000 from the fiscal year 2010 level of 705,367; and
—Complete additional program integrity workloads yielding nearly $9.3 billion in savings over 10 years, including Medicare and Medicaid savings—process

592,000 medical Continuing Disability Reviews (CDRs) and 2.6 million SSI redeterminations.

SSA issues $800 billion in benefit payments annually to 60 million people and the agency takes its stewardship responsibilities seriously. The fiscal year 2012 budget request includes $938 million dedicated to program integrity. Investment in program integrity reviews saves taxpayer dollars and is fiscally prudent in reducing the Federal budget and deficit.

—CDRs determine whether an individual is still disabled, or if benefits should be ceased because of medical improvement. SSA has accumulated a backlog of nearly 1.5 million CDRs. Medical CDRs yield $10 in lifetime program savings for every $1 spent.

—SSI redeterminations review nonmedical factors of eligibility, such as income and resources, to identify payment errors. SSI redeterminations yield a return on investment of $7 in program savings over 10 years for each $1 spent, including Medicaid savings accruals.

NCSSMA recommends consideration of legislative proposals included in the fiscal year 2012 budget request, which can improve the effective administration of the Social Security program, with minimal effect on program dollars. We believe these proposals have the potential to reduce operational costs and increase administrative efficiency. This includes enacting the Work Incentives Simplification Pilot, requiring quarterly reporting of wages, workers compensation automatic reporting, and developing an automated system to report state and local pensions.

*Conclusion*

NCSSMA recognizes in the current budget environment that it will be difficult to provide adequate funding for SSA. However, Social Security is one of the most successful Government programs in the world and touches the lives of nearly every American family. We are a very productive agency and a key component of the Nation's economic safety net for the aged and disabled, but sufficient resources are necessary. A strong Social Security program equates to a strong America and it must be maintained as such for future generations.

NCSSMA sincerely appreciates the Subcommittee's interest in the vital services Social Security provides, and your ongoing support to ensure SSA has the resources necessary to serve the American public. We respectfully request your support of full funding of the President's fiscal year 2012 budget request on behalf of our agency and the American public we serve. We remain confident increased investments in SSA will benefit our entire Nation.

On behalf of NCSSMA members nationwide, thank you for the opportunity to submit this written testimony. We respectfully ask that you consider our comments, and would appreciate any assistance you can provide in ensuring the American public receives the critical and necessary service they deserve from the Social Security Administration.

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## PREPARED STATEMENT OF THE NATIONAL HEAD START ASSOCIATION

Chairman Harkin, Ranking Member Shelby, and Members of the Subcommittee, thank you for allowing the National Head Start Association (NHSA) to submit written testimony in support of funding for Head Start and Early Head Start. As the Head Start community's voice, NHSA believes that Head Start centers nationwide need the resources necessary to provide quality school readiness opportunities for young children and their families. The essence of Head Start is a national commitment to provide critical early education, health, nutrition, child care, parent involvement and family support services in return for a lifelong measurable impact on the low-income children and families enrolled in Head Start. Today, as our Nation's children face greater obstacles than ever before, there is a significant need to prepare the next generation for success in school and later in life, and Head Start has a proven track record of accomplishing this. The Head Start community is pleased to offer the following recommendation to Congress as it begins its consideration of fiscal year 2012 funding levels.

NHSA is grateful that the President and Congress made a solid commitment to quality early childhood education in the fiscal year 2011 Continuing Resolution by providing the funds necessary to at least maintain services for children currently served by Head Start and Early Head Start programs across the country. Quality early education prepares the Nation's youngest children for a lifetime of learning. In fact, studies show that for every $1 invested in a Head Start child, society earns at least $7 back through increased earnings, employment, and family stability; and decreased welfare dependency, crime costs, grade repetition, and special education.

NHSA supports President Obama's fiscal year 2012 budget request for $8.1 billion for Head Start and Early Head Start. These funds will enable Head Start and Early Head Start centers to continue to serve the entire, increasingly vulnerable Head Start community for an additional school year, and complete some necessary program improvements both to ensure accountability and quality, as well as meet the requirements of the 2007 Head Start Reauthorization Act.

*Increased Needs of an Increased At-Risk Population*

One of Head Start's greatest challenges is an increasingly needy population—both among those served and those eligible for service. Today more than one in five children are born into poverty—less than $22,050 per year for a family of four. In many areas, Head Start directors are seeing a rapid increase of homeless families/children enrolled. The Administration's request aims to address some of this growing need by allocating a significant portion of the additional funds to increasing the number of available Migrant and Seasonal, and American Indian and Alaskan Native spaces.

Though funding for Head Start has increased in recent budget years, the cost of serving families has risen at a much faster pace. When surveyed, a full 83 percent of Head Start centers reported that their costs have increased just over the past year—in fact, 25 percent of those who responded report that their fixed costs, including maintenance, transportation, and insurance, have increased by more than 11 percent over the last 12 months. This puts many local centers in the awkward position of choosing between serving fewer children and families better and according to the statutory quality standards, or serving as many as possible with perhaps lesser quality.

Additionally, Head Start and Early Head Start centers often do not have adequate resources during the enrollment process to perform a comprehensive needs assessment on all potential enrollees. Specifically, targeted funds would enable center directors to coordinate more fully with families before enrollment to determine their needs and match those needs with the capacity of the center, and work with partner organizations that may be better equipped to handle special issues. In Kansas City, Kansas, the Project EAGLE Community Programs has implemented a sort of "community triage" system, whereby families are assessed more fully, and dollars are spent much more wisely. This approach may also enable many more at-risk families that were previously on Head Start waiting lists to receive assistance from a multitude of partnering organizations—placing perhaps a higher income, yet still impoverished family to a more fitting type of service provider and providing a waiting list slot for a needier family.

Though Head Start and Early Head Start centers are able to accept a limited number of children from families with incomes slightly above the poverty threshold (up to 130 percent, or $29,055 for a family of four) and are required to accept children with special needs, the Head Start community shares a commitment to identifying and targeting resources, especially in these economic circumstances, to the absolute neediest of families. Additional program funds to enable better monitoring, needs-assessments, and collaboration will assist Head Start providers in meeting this goal.

*Necessary Accountability Improvements*

Head Start and Early Head Start directors are also eager for the Administration on Children and Families to fully implement the quality improvement provisions included in the 2007 Head Start Reauthorization. The law put in place new minimum education requirements for Head Start and Early Head Start teachers and caretakers. Though employing highly qualified individuals is a goal shared by the National Head Start Association, the education requirements necessitate a higher salary range in many areas to attract and keep these highly educated professionals, putting a strain on the administrative budgets of Head Start and Early Head Start Centers. Head Start directors, when surveyed, report that they are having difficulty competing with other educational entities in their services areas; in many cases, they cannot match the salaries provided to qualified individuals in the K–12 system or in other private pre-schools.

One of the most anticipated provisions yet to be implemented will require Head Start grantees designated as low-performing to compete for continuation of their grant. This competition is an enormous undertaking for the Office of Head Start and will certainly require additional funds to design, fully staff, and execute.

However, the law also enables the creation of rigorous performance standards for each Head Start and Early Head Start center. These have not yet been publicly drafted or finalized, though the Head Start community is eager to work with Office of Head Start to inform the effective design and implementation of these perform-

ance standards. Further, we hope that the centers can be evaluated against these new standards, particularly as they relate to the impending recompetition/redesignation. We very much hope that Congress includes report language directing the Administration to ensure that Head Start and Early Head Start grantees are given the opportunity to realign and monitor themselves against the full set of new performance standards before being judged as to whether they will be subject to a recompetition/redesignation. This will ensure that all grantees, in all areas, are judged on consistent standards in competitions going forward.

*Maintenance of Quality*

Lastly, the National Head Start Association supports the Administration's proposal to provide $202 million for Training and Technical Assistance Activities. Within those funds, we suggest that Congress direct the Administration to continue supporting the 10 Centers of Excellence in Early Childhood that were named last year—in the following localities: Greensburg, Pennsylvania; Baltimore, Maryland; Mount Vernon, Ohio; Houghton, Michigan; Owensboro, Kentucky; Morganton, North Carolina; Birmingham, Alabama; Denver, Colorado; Albuquerque, New Mexico; and Dunkirk, New York. Head Start directors very much value the advice of fellow practitioners, and the resources and tools these Centers have designed and provided to the Head Start community are considered effective, well-designed, and serve as models for other Head Start and Early Head Start programs to emulate. Their innovative practices and collaborative community approaches will be in more demand as practitioners adjust to the requirements of the 2007 law.

*Head Start Works*

Since 1965, Head Start (and now Early Head Start as well) has been providing a proven, evidence-based comprehensive program to prepare at-risk children and families for a stable, successful life. Head Start improves the odds and the options for at-risk kids for a lifetime. Kids that have been through Head Start and Early Head Start are healthier, more academically accomplished, more likely to be employed, commit fewer crimes, and contribute more to society. Head Start is a smart investment—one of the smartest and most effective we make. Study after study has demonstrated that Head Start has yielded a benefit-cost ratio as large as $7 to $1.[1]

Head Start saves our hard-earned tax dollars by decreasing the need for children to receive special education services in elementary schools.[2] For example, data analysis of a recent Montgomery County Public Schools evaluation found that a MCPS child receiving full-day Head Start services requires 62 percent fewer special education services and saves taxpayers $10,100 per child annually.[3] States can save $29,000 per year for each prisoner that they incarcerate because Head Start children are 12 percent less likely to have been charged with a crime.[4]

Head Start families with increased health literacy experience immediate healthcare benefits, including lower Medicaid costs—on average $232 lower per family. The program has also reduced mortality rates for 5- to 9-year olds by as much as 50 percent.[5] Studies have shown that the program reduces healthcare costs for employers and individuals because Head Start children are less obese,[6] 8 percent more likely to be immunized,[7] and 19 to 25 percent less likely to smoke as an adult.[8]

And these benefits last a lifetime. Head Start produces measurable, long-term results such as school-readiness, increased high school graduation rates, and reduced

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[1] Ludwig, J. and Phillips, D. (2007). The Benefits and Costs of Head Start. Social Policy Report. 21 (3: 4); Meier, J. (2003, June 20). Interim Report. Kindergarten Readiness Study: Head Start Success. Preschool Service Department, San Bernardino County, California.

[2] Barnett, W. (2002, September 13). The Battle Over Head Start: What the Research Shows. Presentation at a Science and Public Policy Briefing Sponsored by the Federation of Behavioral, Psychological, and Cognitive Sciences.

[3] NHSA Public Policy and Research Department analysis of data from a Montgomery County Public Schools evaluation. See Zhao, H. & Modarresi, S. (2010, April). Evaluating lasting effects of full-day prekindergarten program on school readiness, academic performance, and special education services. Office of Shared Accountability, Montgomery County Public Schools.

[4] Reuters. (2009, March). Cost of locking up Americans too high: Pew study; Garces, E., Thomas, D. and Currie, J. (2002, September). Longer-term effects of Head Start. American Economic Review, 92 (4): 999–1012.

[5] Ludwig, J. and Phillips, D. (2007) Does Head Start improve children's life chances? Evidence from a regression discontinuity design. The Quarterly Journal of Economics, 122 (1): 159–208.

[6] Frisvold, D. (2006, February). Head Start participation and childhood obesity. Vanderbilt University Working Paper No. 06–WG01.

[7] Currie, J. and Thomas, D. (1995, June). Does Head Start Make a Difference? The American Economic Review, 85 (3): 360.

[8] Anderson, K.H., Foster, J.E., & Frisvold, D.E. (2009). Investing in health: The long-term impact of Head Start on smoking. Economic Inquiry, 48 (3), 587–602.

needs for special education. And the more than 27 million Head Start graduates are working every day in our communities to make our country and our economy strong.

The Head Start community understands the budgetary pressures the Federal Government is facing and while reductions in early childhood education may produce short-term savings, as a Nation we cannot afford the lasting impact such cuts would impose on our most vulnerable children today and on our children's futures. The research shows that the "achievement gap" is apparent as early as the age of 18 months—we will spend substantially more downstream if these same young people are not prepared to graduate high-school, attend college and lead prosperous lives. We urge the Subcommittee to fully fund the President's budget request of $8.1 billion for Head Start and Early Head Start in fiscal year 2012.

Thank you for your time and consideration.

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PREPARED STATEMENT OF THE NATIONAL HEALTH COUNCIL

The National Health Council (NHC) is the only organization of its kind that brings together all segments of the healthcare community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes approximately 50 of the Nation's leading patient advocacy groups, which control its governance. Other members include professional societies and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, biotechnology, and insurance companies.

The NHC is well aware of the challenging fiscal environment facing the Subcommittee—indeed the entire country. We recognize that Federal resources must be carefully targeted to ensure that such investments produce the greatest good for the American people. This will involve very tough decisions on healthcare priorities by the Subcommittee.

As work begins on the fiscal year 2012 Labor-HHS appropriations bill, the NHC urges the Subcommittee to take a "global" view of the healthcare system as it identifies funding priorities for the coming year. The NHC and its membership, particularly those groups representing the patient community, stress that no one aspect of the healthcare system—research, public health, healthcare delivery—can be considered as a separate, stand-alone component. For a true benefit and service to the American people, especially those living with chronic conditions, the healthcare system must function through the effective and productive interaction of its many parts.

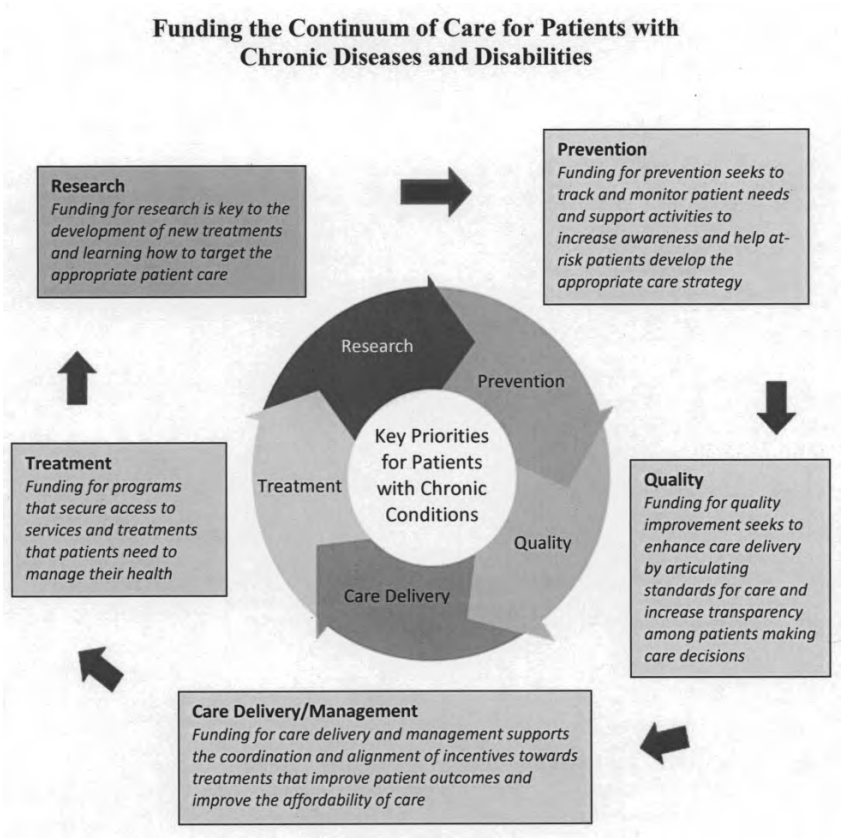
NHC's members have specific interests that span the entire healthcare system. However, a recent survey of our members demonstrated that they share a common concern for the entire continuum of the healthcare system.

One aspect of the healthcare system that is of concern to the NHC is patient access to care. With healthcare costs rising and a growing number of uninsured Americans, far too many people living with chronic conditions are not able to access the care needed to maintain their health and productivity. This is a concern not just for each individual patient but the health system as a whole, which will face greater costs due to declining public health. While the NHC views the entire healthcare system as important, we recognize that the most vitally important piece is for patients to be able to obtain high quality, patient-focused care. Without this, the various components are unable to serve their intended function and the system as a whole falters.

Another large concern of the patient community is the lack of effective cures and treatments. Too many people who are facing serious and life-threatening conditions are doing so without the hope of a cure or even a treatment for their symptoms. Funding for biomedical research at the National Institutes of Health (NIH) offers this hope. But the drug development pipeline does not end with the NIH. Many therapeutics are taking longer to reach patients due to a backlog at the Food and Drug Administration (FDA). While the scope of FDA regulation has grown to the point that it is now regulating one-third of the U.S. economy, the agency's funding has remained relatively consistent. This fact is troubling to the patient advocacy organizations that represent people who lack effective cures and treatments. Both NIH and FDA must be adequately funded to increase the likelihood that these patients will live longer, healthier, and more productive lives.

The NHC appreciates the opportunity to submit this written testimony to the Subcommittee. We understand that you face many hard decisions and again urge that you focus on the healthcare system as continuum that patients must be able

to access in order to best serve the needs of Americans living with chronic conditions.

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PREPARED STATEMENT OF THE NATIONAL HEALTHY MOTHERS HEALTHY BABIES COALITION

Highlighting the urgent need to address the startling infant mortality rates in the United States by strengthening programs at HRSA's Maternal and Child Health Bureau.

Mr. Chairman and Members of the Subcommittee, thank you for giving the National Healthy Mothers, Healthy Babies Coalition (HMHB) the opportunity to provide testimony as the Subcommittee begins to consider funding priorities for fiscal year 2012. My name is Judy Meehan and I am the Chief Executive Officer of HMHB, an organization founded in 1981, prompted by the U.S. Surgeon General's conference on infant mortality. Since its founding, HMHB has become a recognized leader and resource in maternal and child health, reaching an estimated 10 million healthcare professionals, parents, and policymakers annually through its membership of over 100 local, State and national organizations.

Mr. Chairman, I would like to limit my testimony today to discuss an exciting program of HMHB, referred to as the text4baby program. This program is focused on improving the health outcomes of mothers and babies and demonstrating the potential of mobile health technology to reach underserved populations with critical health information. Of the 33 countries that the International Monetary Fund describes as "advanced economies" the United States now has the highest infant mortality rate according to data from the World Bank. In 1980, we were 13th and in 2000 we were 2d. In the United States approximately 28,000 babies die before their first birthday, despite a volume of science around behaviors that improve a baby's

chances for a healthy birth and opportunity to thrive. The text4baby program was launched to help address this problem.

Though the text4baby program has been financed by generous funding from Founding Sponsor Johnson & Johnson, with technical and in-kind support from Voxiva and CTIA—The Wireless Foundation, we are hopeful that with your leadership, the Health Resources and Services Maternal and Child Health Bureau can commit to helping us expand this program in two States where there is demonstrated and significant need. The Maternal and Child Health Block Grant program provides a flexible source of funding that allows States to target their most urgent maternal and child health needs. The program supports a broad range of activities including reducing infant mortality. HMHB recommends that funding from within the base of the block grant's Special Projects of Regional and National Significance (SPRANS) be provided to text4baby so that enrollment in this program could be expanded to targeted and special populations in Louisiana and Mississippi, the two States that have the worst infant mortality outcomes. Mr. Chairman, HMHB also recommends fiscal year 2012 funding for the Maternal and Child Health Block Grant program of $695 million, an increase of $33 million or 5 percent above the level provided in the fiscal year 2011 continuing resolution.

*Text4baby Program*

Text4baby, a free mobile information service designed to promote maternal and child health, was developed to deliver evidence-based health information to the women who need it most: the 1.5 million women on Medicaid who give birth each year. While many of these women may lack access to the Internet and other sources of health information, the vast majority of them do have a cell phone, and a reported 80 percent of Medicaid beneficiaries are active texters. Text4baby provides pregnant women and new moms with information they need to take care of their health and give their babies the best possible start in life. Women who sign up for the service receive free SMS text messages each week, timed to their due date or baby's date of birth. Since its launch in February 2010, text4baby has enrolled over 157,000 users and delivered over 12 million evidence-based tips to help them women keep themselves and their babies healthy. That's a great start but it's not enough. Thanks to the grassroots efforts of more than 500 text4baby partners across the country, we are on track to achieve our goal of bringing the service to 1 million moms by 2012 and delivering over 100 million timely and relevant health messages.

The text4baby program was developed in collaboration with the Centers for Disease Control and Prevention (CDC), Health Resources and Services, Administration (HRSA), American Academy of Pediatrics (AAP), and other experts. Text4baby messages cover topics like immunization, nutrition, smoking cessation, safe sleep, and the importance of early prenatal care. The content also connects women to services such as health insurance, childcare, and toll-free "quitlines" for assistance in becoming smoke- and drug-free. Text4baby has also delivered urgent infant product alerts at the request of the Food and Drug Administration and outbreak and immunization alerts at the request of CDC. Just last month, text4baby moms saw: "Breaking news! The American Academy of Pediatrics announced new car seat guidelines. Kids should now ride in rear facing-car safety seats until age 2."

*Evaluation of the Program*

Mr. Chairman, we know that the program is effective. Over 96 percent of those enrolled in the program say they would refer a friend to the service. Also, preliminary data analysis indicates that text4baby is reaching the target audience: for example, analysis of enrollment data in Virginia in October, 2010 showed that text4baby utilization is highest in zip codes with lower income levels and higher incidence rates of low birth weight babies. However, we also want to understand if and how text4baby is improving knowledge and changing behavior. There are currently six formal evaluations underway to examine text4baby's impact. The largest study, funded by the Department of Health and Human Services (HHS) and conducted by Mathematica Policy Research, is a mixed mode study and includes a mobile survey of text4baby users, focus groups, a community survey, electronic health record review, and interviews with key partners. This study will assess utilization of recommended care during prenatal and postpartum periods (considering things such as prenatal visits, postpartum visit, well-child visits, dental visits, and immunization); adherence to recommended health practices (such as breastfeeding and infant sleep position); and adoption of healthy behaviors (such as smoking cessation, healthy eating and exercise).

Even before the formal study results are in, we know that delivering over 12 million important evidence-based health tips to over 160,000 individuals (and, by the

end of next year, 100 million messages to 1 million moms) is an important national service.

*Expanding the Program*

Glaring disparities in infant mortality exist within certain populations in the United States suggesting the need for a targeted expansion of the program. For example, babies born to African American mothers are most at risk with a rate of 13.5 deaths per 1,000 births. The States with the highest rates of infant mortality are Louisiana (10 babies per 1,000 died before their first birthday) and Mississippi (10.5 babies per 1,000 died before their first birthday). In order to demonstrate the full impact of text4baby, HMHB proposes a targeted outreach and support initiative in those two States. Specifically, HMHB proposes to leverage its great array of activities at the national, regional, State, and local level to meet the ultimate goal of seeing that every woman in Louisiana and Mississippi who is pregnant or a mother of a child less than 1 year enrolls in the service and receives the valuable health information she needs. This targeted outreach will include the development of statewide implementation teams, technical assistance in the way of event planning and media relations, fulfillment of requests for information, speakers and promotional materials, and support for local data and assessment activities. It will also include targeted outreach for African-American and Hispanic communities. HMHB's zip-code based analysis will allow tracking of the impact of targeted outreach activities with enrollment in real time.

*Mississippi and Louisiana Statistics*

Since its launch in February 2010, text4baby has enlisted 1,276 users in Mississippi and over 2,768 users in Louisiana; however, in 2007, 46,491 babies were born in Mississippi and 66,301 babies were born in Louisiana. So, clearly, there is work to be done to increase enrollment in these States. Unfortunately, these two States are among the bottom in the Nation in terms of preterm births, low birth weight, and rates of death among children before their first birthday. They are also among the top in terms of smoking and obesity rates (see table below). These are two States in desperate need of a new way to receive information to help them care for their health and give their babies the best possible start in life.

[In percent]

| | Mississippi | Louisiana | National |
|---|---|---|---|
| Preterm | 18.3 | 16.6 | 12.7 |
| Low birth weight | 12.3 | 11.2 | 8.2 |
| IMR | 10.5 | 10.0 | 6.7 |
| Women smokers | 21.9 | 22.1 | 19.6 |
| Men smokers | 27.2 | 25.1 | 19.6 |
| Obesity in women | 37.1 | 31.5 | 24.4 |

*Summary and Conclusion*

Mr. Chairman, again we wish to thank the Subcommittee for the opportunity to submit testimony and for your leadership in these difficult times. While HMHB recognizes the demands on our Nation's resources, we believe the continuing decline of our Nation's health and the increase in infant mortality justifies a targeted and specific effort. In conclusion, we specifically urge that funding from within the Maternal and Child Health Bureau's SPRANS program be made available for a targeted effort to increase program enrollment among disproportionately impacted populations in Louisiana and Mississippi, the two States with the worst overall outcomes. We also recommend that $695 million be provided in fiscal year 2012 for the Maternal and Child Health Block Grant Program, an increase of $33 million or 5 percent over the fiscal year 2011 continuing resolution.

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## Prepared Statement of the National Hispanic Council on Aging (NHCOA)

Thank you for the opportunity to submit written testimony. The National Hispanic Council on Aging (NHCOA) is the leading organization working to improve the lives of Hispanic older adults, their families, and caregivers—the fastest growing segment of the U.S.'s rapidly expanding aging population. For more than 30 years, NHCOA has been a strong voice dedicated to ensuring our Nation's Hispanic seniors enjoy healthy and happy golden years. Alongside its nearly 40 local affiliates across the country, NHCOA reaches ten million Hispanics each year.

Hispanic older adults experience myriad challenges as they seek to obtain a good quality of life in their later years, including health inequities and economic insecurity. They are disproportionately affected by several health afflictions—among them diabetes, hypertension, obesity, and Alzheimer's disease. Exacerbating these problems is the low rate of access to preventative care. Hispanics are disproportionately employed in low-paying jobs that require low levels of formal education or skills and often depend on Social Security as their sole source of income later in life.

NHCOA writes to you today to urge an increase in the funding for the Corporation for National and Community Service's Senior Corps and the Administration on Aging's Older Americans Act Programs. Senior Corps' three programs, the Retired Senior Volunteer Program (RSVP), the Foster Grandparent Program, and the Senior Companion Program, keep the elderly active and allow the community to benefit from their years of wisdom and experience. RSVP connects seniors to volunteer opportunities available in their communities. Foster Grandparents tutor and mentor at-risk children. The Senior Companion Program provides support to volunteers ages 55+ who provide care and friendship to frail elderly. Increasing funding to Senior Corps would provide valuable services to communities while saving Federal funds. According to Pamela Carre of Senior Volunteer Services in Broward County, Florida, during fiscal year 2009, the volunteer work provided by Senior Volunteer Services valued $6.3 million. All of this work came from Senior Corps volunteers. The Older Americans Act provides a wide variety of nutrition, caretaking, and training programs to thousands of service providers across the country.

The Older Americans Act's National Family Caregiver Support Program and Senior Corps' Senior Companion Program are particularly effective and beneficial for Hispanic older adults. Additional funding to these programs will help meet the needs of Hispanic older adults in a culturally sensitive and effective manner while also easing the financial burden on Medicare and Medicaid.

The Senior Companion program reduces the isolation that can easily trap an elderly person. The Program trains volunteers ages 55+ to assist vulnerable elderly people. In addition to training and placement, the Program also provides a stipend of $2.65 an hour, reimbursed travel expenses, and accident and liability insurance. Senior Companions assist the elderly, whether by accompanying them on visits to the doctor or running their errands. Administrators of the Senior Companion Program, like Ms. Carre, highlight the importance of the flexible and individualized service these companions provide to other older adults. The main service that all Senior Companions provide is friendship.

The Senior Companion Program benefits the elderly and the economy. Senior Companions provide assistance that allows elderly people to remain independent and out of institutionalized care. Keeping the elderly out of nursing homes and assisted living facilities reduces the cost of healthcare and keeps people from using Medicaid funds. According to Ms. Carre, it costs $4,800 to support one Senior Companion annually, while one year in a nursing home costs over $70,000. Additionally, Senior Companions can act as home health aides, providing assistance in the basic activities of daily living. Senior Companions are able to cook for elders, remind them to take their medication, perform housekeeping, and keep family aware of their loved one's needs and condition. This service, also offered by Medicaid and Medicare, can be fulfilled in a cost-effective manner through the Senior Companion Program. In a conversation about the value of senior volunteer programs, Becky Snider, of Pacific Retirement Services in Medford, Oregon, explained that State and local governments recognize the great value these programs provide.

The Senior Companion program has the potential to effectively serve Hispanic older adults in a way that other programs cannot. Many in this group view formal service providers as impersonal and lacking in cultural sensitivity. A dearth of services able to adequately provide assistance to Hispanic older adults further exacerbates this problem. The Senior Companion program can effectively serve Hispanic older adults by offering them friendly and linguistically and culturally sensitive services in their own homes. Senior Companions can help Hispanic older adults manage their health while also providing attention and friendship in a way that home health aides and doctors do not. Ms. Leticia Martinez, the administrator of Senior Companion Volunteer Service of Los Angeles, states that she has heard from many older adults that Senior Companions are often the only people they see on a regular basis and that, "they wouldn't be around without their Senior Companion." Instead of receiving treatment from a home health aide, Senior Companions provide a daily visit from a good friend.

Like a good friend, Senior Companions advocate for, and protect, the older adults with whom they interact. Ms. Martinez stressed that many Senior Companions helped their clients identify and avoid financial abuse. The Senior Companion Program saves money for our seniors.

Although the Senior Companion program can improve the health of seniors and our economy, it is underfunded. The Edward M. Kennedy Serve America Act authorized $55 million to be appropriated in fiscal year 2010, however, only $46.9 million was appropriated that year. In fact, the Senior Companion program has not received a substantial increase in funding in at least 10 years. The Senior Companion program deserves an appropriation of at least $55 million in order to carry out its important duties.

Similar to the Senior Companion Program, the Administration on Aging's National Family Caregiver Support Program (NFCSP) plays a vital role in protecting older adults. The NFCSP provides grants to States to create programs to assist people who care for elderly relatives. These programs support family members in providing the best care possible. The Administration on Aging grants funds for five broad categories: (1) providing information to caregivers about effective caretaking methods and available services; (2) assistance in accessing services; (3) creation of caregiver support groups and training sessions; (4) funds for home health aides to give respite to family caregivers; and (5) on a limited basis, supplemental services.

The NFCSP reduces the financial strain on Medicare and Medicaid. By focusing on maintenance of health and prevention of serious problems, the NFCSP can keep Hispanic older adults out of nursing homes and off Medicaid. Additionally, the ability of NFCSP to provide funding for home health aides and training and respite for family caregivers makes it less likely for older adults to require a Medicare-financed home health aide.

The NFCSP is perfectly suited to help Hispanic older adults, their families, and caregivers. There are valuable, effective programs available to help older adults afford healthcare and nursing home treatment, but many Hispanics feel that traditional healthcare and nursing home programs are too impersonal. The NFCSP addresses this problem by providing respite care and training for effective caregiving and by improving access to caregiving services. Delivering effective, personalized care for older adults in their homes can help manage health issues in a comfortable setting. Furthermore, home health aide services can provide enough respite care for a family caregiver to take on a part-time job, reducing the likelihood that the family will have to turn to Medicaid or other forms of public assistance.

The NFCSP provides support to people who are unexpectedly drawn into helping an older family member. While cleaning and errands may be the first help given to an elderly loved one, these tasks can quickly multiply. The NFCSP teaches family members how to effectively care for their elderly relatives and cope with the stress of such care. Regarding the value of caregiver training and support groups, Mr. Jose Perez, Executive Director of Senior Community Outreach Services in Alamo, Texas says, "I have seen people break down into tears because the stress of caring for their father and how close it brought them to physically abusing their loved one. Training and support groups help them ease this burden."

President Obama's fiscal year 2012 budget request recognizes the importance of the NFCSP and requests a substantial funding increase. In the last several years, the program has received between $153 million and $155 million. For fiscal year 2012, President Obama has requested over $192 million for the NFCSP. This increased funding will help to reduce healthcare costs for seniors while also allowing them to maintain their independence and receive effective treatment from those who know them best. Hispanic older adults will benefit from increased NFCSP funding due to the program's ability to deliver culturally sensitive care to a group that traditional healthcare providers have thus far struggled to adequately serve.

Mr. Perez describes the effectiveness of these two programs with a simple phrase: "Everybody wins." Senior Companions win the satisfaction of helping their fellow citizens and the pride of earning wages for productive work. The elderly win by receiving the care and attention that they deserve. Families win when they learn how to care for their loved ones. The government wins because these programs keep the elderly healthy, independent, and off Medicaid.

NHCOA urges you to appropriate at least $55 million for the Corporation for National and Community Service's Senior Companion Program. Additionally, we request that you follow President Obama's recommendation and appropriate at least $192 million for the Administration on Aging's National Family Caregiver Support Program. These two programs will not only effectively serve Hispanic older adults in a way other programs do not, but they will also ease the financial strain on Medicare and Medicaid. Thank you for your consideration, and please feel free to contact NHCOA with any questions or concerns.

PREPARED STATEMENT OF THE NATIONAL KIDNEY FOUNDATION

In 2008, the number of Americans with End Stage Renal Disease (ESRD), which requires dialysis or a kidney transplant to survive, reached 535,000. In that year alone, 110,000 progressed to ESRD. Medicare covers dialysis or transplantation regardless of age or other disability, the only disease-specific coverage under the program. Despite this social and economic impact, no national public health program focusing on early detection and treatment existed until fiscal year 2006, when Congress provided $1.8 million for the first of 5 years of support to initiate a Chronic Kidney Disease Program at the Centers for Disease Control and Prevention (CDC). Congressional concern regarding kidney disease education and awareness also is found in Sec. 152 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Public Law 110–275), in which it directed the Secretary to establish pilot projects to increase screening for Chronic Kidney Disease (CKD) and enhance surveillance systems to better assess the prevalence and incidence of CKD. Treatments exist to potentially slow progression of kidney disease and prevent its complications, but only if individuals are diagnosed before the latter stages of CKD.

The CDC program is designed to identify members of populations at high risk for CKD, develop community-based approaches for improving detection and control, and educate health professionals about best practices for early detection and treatment. The National Kidney Foundation respectfully urges the Committee to maintain line-item funding in the amount of $2.1 million for the Chronic Kidney Disease Program in the CDC's Division of Diabetes Translation. We are encouraged by the fiscal year 2011 Operating Plan for CDC, which recommends only a $39,000 reduction from the fiscal year 2010 appropriation for the CKD program. Continued support will benefit kidney patients and Americans who are at risk for kidney disease, advance the objectives of Healthy People 2020 and the National Strategy for Quality Improvement in Health Care, and fulfill the mandate created by Sec. 152 of MIPPA.

The prevalence of CKD in the United States, when last measured, was higher than a decade earlier. This is partly explained by the increasing prevalence of the related diseases of diabetes and hypertension. It is estimated that CKD affects 26 million adult Americans [1] and that the number of individuals in this country with CKD who will have progressed to kidney failure, requiring chronic dialysis treatments or a kidney transplant to survive, will grow to 712,290 by 2015 [2]. Furthermore, a task force of the American Heart Association noted that decreased kidney function has consistently been found to be an independent risk factor for cardiovascular disease (CVD) outcomes and all-cause mortality and that the increased risk is present with even mild reduction in kidney function.[3] Therefore addressing CKD is a way to achieve one of the priorities in the National Strategy for Quality Improvement in Health Care: Promoting the Most Effective Prevention and Treatment of the Leading Causes of Mortality, Starting with Cardiovascular Disease.

Despite the extent of the problem, CKD is an under-recognized and under-treated public health challenge in the United States. Accordingly, Healthy People 2020 Objective CKD–2 is to "increase the proportion of persons with chronic kidney disease (CKD) who know they have impaired renal function." One reason CKD is neglected is that it is often asymptomatic, especially in the early stages, and, therefore, laboratory testing is required to detect it. Increasing the proportion of persons with CKD who know they are affected requires expanded public and professional education programs and screening initiatives targeted at populations who are at high risk for CKD. Thanks to the interest that this Committee has expressed in CKD in the past, through directed appropriations, the National Center for Chronic Disease Prevention and Health Promotion at CDC has instituted a series of projects that could assist in attaining the Healthy People 2020 objective. However, this forward momentum will be stifled and CDC's investment in CKD to date jeopardized if line-item funding is not continued.

As noted in CDC's Preventing Chronic Disease: April 2006, Chronic Kidney Disease meets the criteria to be considered a public health issue: (1) the condition places a large burden on society; (2) the burden is distributed unfairly among the overall population; (3) evidence exists that preventive strategies that target economic, political, and environmental factors could reduce the burden; and (4) evi-

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[1] Josef Coresh, et al. "Prevalence of Chronic Kidney Disease in the United States," JAMA, November 7, 2007.

[2] D.T. Gilbertson, et al., *Projecting the Number of Patients with End-Stage Renal Disease in the United States to the Year 2015*. J Am Soc Nephrol 16: 3736–3741, 2005.

[3] Mark J. Sarnak, et al. Kidney Disease as a Risk Factor for the Development of Cardiovascular Disease: A Statement from the American Heart Association Councils on Kidney in Cardiovascular Disease, High Blood Pressure Research, Clinical Cardiology, and Epidemiology and Prevention. Circulation 2003: 108: 2154–69.

dence shows such preventive strategies are not yet in place. Furthermore, CDC convened an expert panel in March 2007 to outline recommendations for a comprehensive public health strategy to prevent the development, progression, and complications of CKD in the United States.

The CDC Chronic Kidney Disease program consists of three projects to promote kidney health by identifying and controlling risk factors, raising awareness, and promoting early diagnosis and improved outcomes and quality of life for those living with CKD. These projects include the following:

— Establishing a surveillance system for Chronic Kidney Disease in the United States.

—Demonstrating effective approaches for identifying individuals at high risk for chronic kidney disease through State-based screening (CKD Health Evaluation and Risk Information Sharing, or CHERISH).

—Conducting an economic analysis by the Research Triangle Institute, under contract with the CDC, on the economic burden of CKD and the cost-effectiveness of CKD interventions.

Pursuant to CHERISH, individuals at high risk for CKD have been screened in eight locations in four States. The goals of the demonstration project have been:

—To educate providers and the public that simple tests can be used to identify CKD in the target population and to assess risk factors for intervention (obesity, hypertension, cardiovascular disease, lipid disorders, diabetes, and glycemic control).

—Evaluate whether providers change practice patterns after being consulted by a person who went through the detection program.

The demonstration project should be replicated at eight sites in four additional States in order to confirm initial findings. If we fail to do so, we could be forfeiting the valuable insight that has been gained thus far.

We believe it is possible to distinguish between the CKD program and other categorical chronic disease initiatives at CDC, because the CKD program does not provide funds to State health departments. Instead, CDC has been making available seed money for feasibility studies in the areas of epidemiological research and health services investigation. Because the CKD program does not provide funds to State health departments, we maintain it should be exempted from the changes in the structure and budget of the National Center for Chronic Disease Prevention and Health Promotion, at least until surveillance planning, and studies of detection feasibility and economic impact are completed.

Thank you for your consideration of our testimony.

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## PREPARED STATEMENT OF THE NATIONAL LEAGUE FOR NURSING

The National League for Nursing (NLN) is the premiere organization dedicated to promoting excellence in nursing education to build a strong and diverse nursing workforce to advance the Nation's health. With leaders in nursing education and nurse faculty across all types of nursing programs in the United States—doctorate, master's, baccalaureate, associate degree, diploma, and licensed practical—the NLN has more than 1,200 nursing school and healthcare agency members, 34,000 individual members, and 24 regional constituent leagues.

The NLN urges the subcommittee to fund the following Health Resources and Services Administration (HRSA) nursing programs:

—The Nursing Workforce Development Programs, as authorized under Title VIII of the Public Health Service Act, at $313.075 million in fiscal year 2012; and

—The Nurse Managed Health Clinics, as authorized under Title III of the Public Health Service Act, at $20 million in fiscal year 2012.

*Nursing Education is a Jobs Program*

According to the U.S. Bureau of Labor Statistics (BLS), the registered nurse (RN) workforce will grow by 22 percent from 2008 to 2018, resulting in 581,500 new jobs. This growth will be much faster than the average for all occupations. The April 1, 2011 BLS Employment Situation Summary—March 2011 likewise reinforces the strength of the nursing workforce to the Nation's job growth. While the Nation's overall unemployment rate was little changed at 8.8 percent for March 2011, the employment in healthcare increased in March with the addition of 37,000 jobs (i.e., a 36.6 percent rise from February 2011) at ambulatory healthcare services, hospitals, and nursing and residential care facilities.

Nursing is the predominant occupation in the healthcare industry, with more than 3.78 million active, licensed RNs in the United States in 2009. BLS notes that healthcare is a critically important industrial complex in the Nation. Growing stead-

ily even during the depths of the recession, healthcare is virtually the only sector that added jobs to the economy on a net basis since 2001. Over the last 12 months, healthcare added 283,000 jobs, or an average of 24,000 jobs per month.

The Nursing Workforce Development Programs provide training for entry-level and advanced degree nurses to improve the access to, and quality of, healthcare in underserved areas. These Title VIII nursing education programs are fundamental to the infrastructure delivering quality, cost-effective healthcare. The NLN applauds the subcommittee's bipartisan efforts to recognize that a strong nursing workforce is essential to a health policy that provides high-value care for every dollar invested in capacity building for a 21st century nurse workforce.

Yet, the current $243.872 million in fiscal year 2010 for the Title VIII programs falls short of the healthcare inequities facing our Nation. Absent consistent support, recent boosts to Title VIII will not fulfill the expectation of paying down on asset investments to generate quality health outcomes; nor will episodic increases in funding fill the gap generated by a 13-year nurse shortage felt throughout the entire U.S. health system.

*The Nurse Pipeline and Education Capacity*

Although the recession resulted in some stability in the short-term for the nurse workforce, policy makers must not lose sight of the long-term growing demand for nurses in their own districts and States. For the complete perspective, the NLN's findings from the Annual Survey of Schools of Nursing—Academic Year 2009–2010 cast a wide net on all types of nursing programs, from doctoral through diploma, to determine rates of application, enrollment, and graduation. The survey creates a true picture of nursing education. Key findings include:

—Expansion of nursing education programs impeded by shortage of faculty and clinical placements. The overall systemic capacity of prelicensure nursing education continues to fall well short of demand. Fully 42 percent of all qualified applications to basic RN programs were met with rejection in 2010. Associate degree in nursing (ADN) programs rejected 46 percent of qualified applications, compared with 37 percent of baccalaureate of science in nursing (BSN) programs. Notably, the Nation's practical nursing (PN) programs turned away 40 percent of qualified applications.

—Yield rates continued to grow. Yield rates—a classic indicator of the competitiveness of college admissions—remain extraordinarily high among both pre- and post-licensure nursing programs. A stunning 94 percent of all applicants accepted into ADN programs, and 93 percent of those accepted in PN programs, went on to enroll in 2010. Yield rates among the other program types were nearly as high, averaging 89 percent for RN-to-BSN programs; 86 percent for RN diploma programs, master's in nursing (MSN) programs, and doctoral programs; and 84 percent for BSN programs.

*Nurse Shortage Affected by Faculty Shortage*

A strong correlation exists between the shortage of nurse faculty and the inability of nursing programs to keep pace with the demand for new RNs. Increasing the productivity of education programs is a high priority in most States, but faculty recruitment is a glaring problem that likely will grow more severe. Without faculty to educate our future nurses, the shortage cannot be resolved.

The NLN's findings from the 2009 Faculty Census show that:

—Shortages of faculty and clinical placements impeded expansion. A shortage of faculty continues to be cited most frequently as the main obstacle to expansion by RN-to-BSN and doctoral programs—indicated by 47 and 53 percent, respectively. By contrast, prelicensure programs are more likely to point to a lack of available clinical placement settings as the primary obstacle to expanding admissions.

—Inequities in faculty salaries added to shortage difficulties. Despite a national shortage of nurse educators, in 2009 the salaries of nurse educators remained notably below those earned by similarly ranked faculty across higher education. At the professor rank nurse educators suffer the largest deficit with salaries averaging 45 percent lower than those of their non-nurse colleagues. Associate and assistant nursing professors were also at a disadvantage, earning 19 and 15 percent less than similarly ranked faculty in other fields, respectively.

*Title VIII Federal Funding Reality*

Today's undersized supply of appropriately prepared nurses and nurse faculty does not bode well for our Nation. The Title VIII Nursing Workforce Development Programs are a comprehensive system of capacity-building strategies that provide students and schools of nursing with grants to strengthen education programs, including faculty recruitment and retention efforts, facility and equipment acquisition,

clinical lab enhancements, and loans, scholarships, and services that enable students to overcome obstacles to completing their nursing education programs. HRSA's Title VIII data below provide perspective on a few of the current Federal investments.

*Nurse Education, Practice, Quality, and Retention Grants (NEPQR).*—NEPQR funds projects addressing the critical nursing shortage via initiatives designed to expand the nursing pipeline, promote career mobility, provide continuing education, and support retention. In fiscal year 2010, NEPQR funded 108 infrastructure grants, including the launching of 22 nurse-managed health centers, four nurse internships, and five new accelerated baccalaureate programs. Also in fiscal year 2010, the program expanded with the Nursing Assistant (NA) and Home Health Aide (HHA) program awarding grants to 10 colleges or community-based training programs.

*Comprehensive Geriatric Education Program (CGEP).*—CGEP funds training, curriculum development, faculty development, and continuing education for nursing personnel who care for older citizens. In academic year 2009–2010, 27 CGEP grantees provided education and training to 3,030 RNs/RN students; 260 advanced practice registered nurses (APRNs); 221 faculty; 110 HHSs; 483 LPNs/LPN students; 730 NAs; 810 allied health professionals; and 929 laypersons, guardians, activity directors.

*Advanced Nursing Education (ANE) Program.*—ANE supports infrastructure grants to schools of nursing for advanced practice programs preparing nurse-midwives, nurse anesthetists, clinical nurse specialists, nurse administrators, nurse educators, public health nurses, or other advanced level nurses. In addition, the Advanced Nursing Education Expansion (ANEE) program provides grants to schools of nursing to accelerate the production of primary care advanced practice nurses. In fiscal year 2009, 151 schools of nursing received grants through the ANE Program and enrolled 7,518 advanced nursing education students. In fiscal year 2010, 26 schools of nursing received grants under ANEE to support the production of over 600 primary care APRNs.

*Nurse Managed Health Clinics (NMHC)*

Most leading authorities recognize that there will be a shortage of primary care providers over the next decade. With the recent growth of NMHCs, APRNs have demonstrated their flexibility as they practice independently or collaborate with physicians in both primary care and specialty areas. This shift suggests that professionals' practice can be directed to changing workforce and population needs as the increased use of APRNs holds the potential for improving access, reducing costs for high-value care, and changing patterns of care.

NMHCs deliver comprehensive primary healthcare services, disease prevention, and health promotion in medically underserved areas for vulnerable populations. Approximately 58 percent of NMHC patients either are uninsured, Medicaid recipients, or self-pay. The complexity of care for these patients presents significant financial barriers, heavily affecting the sustainability of these clinics.

In fiscal year 2010, HRSA awarded $15,268,000 for 10 3-year infrastructure grants to community-based NMHCs. While providing access points in areas where primary care providers are in short supply, the expansion of the NMHCs also increased the number of structured clinical teaching sites available to train nurses and other primary care providers. These clinics funded by HRSA in fiscal year 2010 expect to train 900 primary care nurse practitioners during their 3-year grants. Appropriating $20 million in fiscal year 2012 to NMHCs would increase access to primary care for thousands of uninsured people in rural and underserved urban communities. The funding of additional NMHCs likewise will enable schools of nursing to increase innovative clinical teaching site opportunities for nursing students, which will directly expand the capacity of nursing school enrollments.

The NLN can state with authority that the deepening health inequities, inflated costs, and poor quality of healthcare outcomes in this country will not be reversed until the concurrent shortages of nurses and qualified nurse educators are addressed. Your support will help ensure that nurses exist in the future who are prepared and qualified to take care of you, your family, and all those who will need our care. Without national efforts of some magnitude to match the healthcare reality facing our Nation today, a calamity in nurse education and in healthcare generally may not be avoided.

The NLN urges the subcommittee to strengthen the Title VIII Nursing Workforce Development Programs by funding them at a level of $313.075 million in fiscal year 2012. We also recommend that the Nurse Managed Health Clinics, as authorized under Title III of the Public Health Service Act, be funded at $20 million in fiscal year 2012.

## PREPARED STATEMENT OF THE NATIONAL MARFAN FOUNDATION

Mr. Chairman, thank you for the opportunity to submit testimony regarding the fiscal year 2012 budget for the National Heart, Lung and Blood Institute, the National Institute of Arthritis, Musculoskeletal and Skin Diseases, and the Centers for Disease Control and Prevention. The National Marfan Foundation is grateful for the subcommittee's strong support of the NIH and CDC, particularly as it relates to life-threatening genetic disorders such as Marfan syndrome. Thanks in part to your leadership we are at a time of unprecedented hope for our patients.

It is estimated that 200,000 people in the United States are affected by Marfan syndrome or a related condition. Marfan syndrome is a genetic disorder of the connective tissue that can affect many areas of the body, including the heart, eyes, skeleton, lungs and blood vessels. It is progressive condition and can cause deterioration in each of these body systems. The most serious and life-threatening aspect of the syndrome is a weakening of the aorta. The aorta is the largest artery carrying oxygenated blood from the heart. Over time, many Marfan syndrome patients experience a dramatic weakening of the aorta which can cause the vessel to dissect and tear.

Early surgical intervention can prevent a dissection and strengthen the aorta and the aortic valves. If preventive surgery is performed before a dissection occurs, the success rate of the procedure is over 95 percent. If surgery is initiated after a dissection has occurred, the success rate drops below 50 percent. Aortic dissection is a leading killer in the United States, and 20 percent of the people it affects have a genetic predisposition, like Marfan syndrome, to developing the complication.

Fortunately, new research offers hope that a commonly prescribed blood pressure medication might be effective in preventing this frequent and devastating event.

### FISCAL YEAR 2012 APPROPRIATIONS RECOMMENDATIONS

*National Institutes of Health*

Mr. Chairman, hope for a better quality of life for patients with Marfan syndrome and related connective tissue disorders lies in NIH-sponsored biomedical research. With that in mind, NMF joins with other voluntary patient and medical organizations in recommending an appropriation of $35 billion for the National Institutes of Health in fiscal year 2012. , This level of funding will ensure continued expansion of research on rare diseases like Marfan syndrome and build upon the significant investment provided to the NIH in the American Recovery and Reinvestment Act.

*National Heart, Lung, and Blood Institute*

*Pediatric Heart Network Clinical Trial*

NMF applauds the National Heart, Lung and Blood Institute for its leadership in advancing a landmark clinical trial on Marfan syndrome. Under the direction of Dr. Lynn Mahoney and Dr. Gail Pearson, the institute's Pediatric Heart Network (PHN) has spearheaded a multicenter study focused on the potential benefits of a commonly prescribed blood pressure medication (losartan) on aortic growth in Marfan syndrome patients.

Dr. Hal Dietz, the Victor A. McKusick Professor of Genetics in the McKusick-Nathans Institute of Genetic Medicine at the Johns Hopkins University School of Medicine, and the director of the William S. Smilow Center for Marfan Syndrome Research, is the driving force behind this groundbreaking research. Dr. Dietz uncovered the role that the growth factor TGF-beta plays in aortic enlargement, and demonstrated the benefits of losartan in halting aortic growth in mice. He is the reason we have reached this time of such promise and NMF is proud to have supported Dr. Dietz's cutting-edge research for many years.

After 4 years of recruitment and patient screening, the PHN trial reached its enrollment target of 604 subjects on February 2, 2011. Marfan syndrome patients (age 6 months to 25 years) are enrolled in the study. Patients are randomized onto either losartan or atenolol (a beta blocker that is the current standard of care for Marfan patients with an enlarged aortic root).

We anxiously await the results of this first-ever clinical trial for our patient population. It is our hope that losartan will emerge as the new standard-of-care and greatly reduce the need for surgery in at-risk patients.

Mr. Chairman, NMF is proud to actively support the losartan clinical trial in partnership with the Pediatric Heart Network. Throughout the life of the trial we have provided support for patient travel costs, coverage of select echocardiogram examinations, and funding for ancillary studies. These ancillary studies will explore the impact that losartan has on other manifestations of Marfan syndrome.

*Evaluation of Surgical Options for Marfan Syndrome Patients*

Mr. Chairman, we are grateful for the subcommittee's previous recommendations encouraging NHLBI to support research on surgical options for Marfan syndrome patients.

For the past several years, the NMF has supported an innovative study looking at outcomes in Marfan syndrome patients who undergo valve-sparing surgery compared with valve replacement. Initial findings were published last year in the Journal of Thoracic and Cardiovascular Surgery. Some short term questions have been answered, most importantly that valve-sparing can be done safely on Marfan patients by an experienced surgeon. The consensus among the investigators however is that long-term durability questions will not be answered until patients are followed for at least 10 years.

Confirming the utility and durability of valve sparing procedures will save our patients a host of potential complications associated with valve replacement surgery. We hope to partner with the NIH on this important work moving forward.

*NHLBI "Working Group on Research in Marfan Syndrome and Related Conditions"*

In 2007, NHLBI convened a "Working Group on Research in Marfan Syndrome and Related Conditions." Chaired by Dr. Dietz, this panel was comprised of experts in all aspects of basic and clinical science related to the disorder. The panel was charged with identifying key recommendations for advancing the field of research in the coming decade. The recommendations of the Working Group are as follows:

Scientific opportunities to advance this field are conferred by technological advances in gene discovery, the ability to dissect cellular processes at the molecular level and imaging, and the establishment of multi-disciplinary teams. The barriers to progress are addressed through the following recommendations, which are also consistent with Goals and Challenges in the NHLBI Strategic Plan.

—Existing registries should be expanded or new registries developed to define the presentation, natural history, and clinical history of aneurysm syndromes.

—Biological and aortic tissue sample collection should be incorporated into every clinical research program on Marfan syndrome and related disorders and funds should be provided to ensure that this occurs. Such resources, once established, should be widely shared among investigators.

—An Aortic Aneurysm Clinical Trials Network (ACTnet) should be developed to test both surgical and medical therapies in patients with thoracic aortic aneurysms.

—The identification of novel therapeutic targets and biomarkers should be facilitated by the development of genetically defined animal models and the expanded use of genomic, proteomic and functional analyses. There is a specific need to understand cellular pathways that are altered leading to aneurysms and dissections, and to develop robust in vivo reporter assays to monitor TGFb and other cellular signaling cascades.

—The developmental underpinnings of apparently acquired phenotypes should be explored. This effort will be facilitated by the dedicated analysis of both prenatal and early postnatal tissues in genetically defined animal models and through the expanded availability to researchers of surgical specimens from affected children and young adults.

We look forward to working closely with NHLBI to pursue these important research goals and ask the Subcommittee to support the recommendations of the Working Group.

*National Institute of Arthritis and Musckuloskeletal and Skin Diseases*

NMF is proud of its longstanding partnership with the National Institute of Arthritis and Musculoskeletal and Skin Diseases, which is celebrating its 25th anniversary this year. Dr. Steven Katz has been a strong proponent of basic research on Marfan syndrome during his tenure as NIAMS director and has generously supported several "Conferences on Heritable Disorders of Connective Tissue." Moreover, the Institute has provided invaluable support for Dr. Dietz's mouse model studies. The discoveries of fibrillin-1, TGF-beta, and their role in muscle regeneration and connective tissue function were made possible in part through collaboration with NIAMS.

As the losartan trial continues to move forward, we hope to expand our partnership with NIAMS to support related studies that fall under the mission and jurisdiction of the Institute. One of the areas of great interest to researchers and patients is the role that losartan may play in strengthening muscle tissue in Marfan patients. We would welcome an opportunity to partner with NIAMS on this and other research.

*Centers for Disease Control and Prevention*

Mr. Chairman, one of the most important things we can do to prevent untimely deaths from aortic aneurysms is to increase awareness of Marfan syndrome and related connective tissue disorders.

Last year, the American College of Cardiology and the American Heart Association issued landmark practice guidelines for the treatment of thoracic aortic aneurysms and dissections. The NMF is promoting awareness of the new guidelines in collaboration with other organizations through a new Coalition known as TAD; the Thoracic Aortic Disease Coalition. We hope to partner with the CDC in fiscal year 2012 to increase awareness of the guidelines so all patients will be adequately diagnosed and treated. For fiscal year 2012, NMF joins with the CDC Coalition in recommending an appropriation of $7.7 billion for CDC's core-programs.

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PREPARED STATEMENT OF THE NATIONAL MINORITY AIDS COUNCIL

The National Minority AIDS Council (NMAC) represents a coalition of over 3,000 community based organizations and AIDS service organizations delivering HIV/AIDS services in communities of color nationwide. Our constituents are on the front lines of the HIV epidemic and are the most affected when funding for HIV/AIDS programs are reduced or eliminated.

Our Nation is facing difficult decisions on how to stabilize the economy and pass a sensible Federal budget. Although we support efficient, cost-effective spending, we cannot support reducing healthcare funding which would adversely affect the health and well being of the most vulnerable: minority communities, with higher rates of poverty where poor health outcomes are often linked to poor access to care. While budget negotiations often focus on cold numbers, it is easy to lose sight of the fact that human lives are at stake.

Cost-effective research and prevention programs that prevent life-threatening diseases such as HIV/AIDS, as well as life-saving access to care and medications for those already infected are critical in preventing avoidable infections, serious illness, and deaths. Although funding has failed to keep up with demand, it is impossible to deny the strides in prevention, research, and treatment of HIV/AIDS that has been supported by previous appropriations.

We now have a National HIV/AIDS Strategy which sets attainable goals in reducing the devastation caused by this epidemic. The Strategy calls for a reduction of new infections by 25 percent in the next 5 years as well as improved access to care for those already infected. As we continue to move forward in trying to reduce new infections and saving precious lives through the Strategy, it is imperative that the existing public health and safety net infrastructure be adequately funded.

*Health Care Reform*

In addition to the Strategy, implementation of healthcare reform offers a monumental opportunity to make progress in reducing the impact of the domestic HIV epidemic by greatly increasing the number of Americans eligible for healthcare access. As such, we request full funding of the President's fiscal year 2012 budget request for healthcare reform programs aimed at reducing health disparities. Many of the programs under the Patient Protection and Affordable Care Act (ACA) are funded through discretionary budgets. Increased access to medical care through venues such as Community Health Centers are welcomed as they provide care in cost effective settings when compared to the emergency room, which are too often the primary source of medical care for communities of color.

*Minority AIDS Initiative (MAI)*

MAI programs seek to improve HIV-related health outcomes for racial and ethnic minority communities that are disproportionately affected by HIV/AIDS. Central to these goals is the MAI's focus on efforts to strengthen the organizational capacity of community-based providers, in particular minority providers; improve the quality of HIV services; and expand the pool of HIV service providers. NMAC strongly recommends this Committee fund MAI programs at $610 million for fiscal year 2012 as minority communities continue to carry a disproportionate burden of the epidemic. NMAC does appreciate the President's fiscal year 2012 budget request of $430.7 million as a minimum budget for MAI.

*HIV/AIDS Bureau of the Health Resources and Services Administration (HRSA)*

The number of people living with HIV in the United States has grown to over 1.1 million people. That fact coupled with the skyrocketing costs of medical care creates a dire need for substantial increases in funding for care and treatment. We urge you to increase funding for the Ryan White program by $350 million in fiscal year

2012. At minimum, we strongly urge you to support the President's proposed fiscal year 2012 increase of $69.3 million for the Ryan White program over fiscal year 2010.

As a payer of last resort, Ryan White provides critical access to treatment and medications to under-insured and uninsured people. Part A funds are used to provide a continuum of care for people living with HIV disease. To support this critical component, we request an increase of $74.2 million when compared to fiscal year 2010. Part B funds are provided to States to improve their capacity to provide medical care. It also funds the AIDS Drug Assistance program (ADAP), which currently has a wait list of over 8,100 people with no other means to access medications. Eleven States have implemented waiting lists and many others have implemented cost containment strategies since funding is not keeping up with demand. We request an increase of $76.8 million in funding to States as compared to fiscal year 2010 and an increase of $106 million for ADAP.

*Centers for Disease Control and Prevention's (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)*

With over 56,000 new infections annually, a renewed emphasis on prevention and early HIV screening is critical at this juncture. NMAC urges total fiscal year 2012 funding of $1,983.9 million for the CDC's NCHHSTP. This includes funding of $1,325.7 million for HIV prevention and surveillance, $59.8 million for viral hepatitis and $231 million for tuberculosis prevention. We appreciate that the President proposed a $1,178.5 million budget for HIV prevention at the CDC, and at a bare minimum we urge the Committee to meet this request.

*National Institutes of Health (NIH)—Office of AIDS Research*

HIV/AIDS research has made great strides in understanding and improving HIV treatment, viral suppression, and various prevention tools. Continued commitment to a thorough AIDS research portfolio is necessary to build on past innovation. In order to build on this research and continue to see how these interventions affect communities of color, NMAC requests $3.5 billion to support the Office of AIDS Research. Additionally, NMAC believes that $35 billion to fund NIH's overall programs and infrastructure.

Investments in prevention, treatment and research for HIV, as well as comorbidities, must keep pace with the epidemic if we are to see real progress in reducing new infections, disease burden, and untimely deaths due to this devastating disease.

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## PREPARED STATEMENT OF THE NATIONAL MINORITY CONSORTIA

The National Minority Consortia (NMC) submits this statement on the fiscal year 2014 Advance appropriation for the Corporation for Public Broadcasting (CPB). The NMC is a coalition of five national organizations dedicated to bringing the unique voices and perspectives from America's diverse communities into all aspects of public broadcasting and to other media, including content transmitted digitally over the Internet. The role we fulfill in this regard has been crucial to public broadcasting's mission for over 30 years. We are unique as organizations and as a coalition of organizations in the services we provide in access, training and support for important and timely public interest content to our communities and to public broadcasting. We ask the Committee to:

—Direct CPB to increase its efforts for diverse programming with commensurate increases for minority programming and for organizations and stations located within underserved communities;

—Direct CPB to establish a percentage basis for biennial funding of the National Minority Consortia to permit long range financial and strategic planning;

—Direct CPB to establish an annual "report card" on diversity to track efforts to better represent the full breadth of the American people and their experiences through public television, public radio and non-profit media online;

—Direct CPB to publish on the Internet clear and enforced guidelines for all CPB-directed funding, including funds jointly administered by PBS and NPR, and end the closed-door funding processes historically in place, especially as the current practices favor existing relationships and can be seen as biased against minority applicants, in particular.

*Report Language*.—We ask for report language, which recognizes the contribution of the NMC and directs that the CPB partnership with us be expanded. Specifically:

"The Committee recognizes the importance of the partnership CPB has with the National Minority Public Broadcasting Consortia, which helps develop, acquire, and

distribute public television programming to serve the needs of African American, Asian American, Latino, Native American, Pacific Islander, and many other viewers. As many communities in the Nation welcome increased numbers of citizens of diverse ethnic backgrounds, the local public television stations should strive to meet these viewers' needs. With an increased focus on programming to meet local community needs, the Committee encourages CPB to support and expand this critical partnership."

*Fiscal Year 2014 Appropriation*.—We support a fiscal year 2014 advance appropriation for CPB of $495 million, which recognizes the need to develop content that reaches across traditional media boundaries, such as those separating television and radio. However, we feel strongly that should CPB receive this appropriation, CPB should be directed to engage in transparent and fair funding practices that guarantee all applicants equal access to these public resources. In particular, we urge Congress to direct CPB to insert language in all of its funding guidelines that encourages and rewards public media that fully represents and reaches a diverse American public.[1]

While public broadcasting continues to uphold strong ethics of responsible journalism and thoughtful examination of American history, life and culture, including the ways we are a part of a global society, it has not kept pace with our rapidly changing public as far as diversity is concerned. Members of minority groups continue to be underrepresented on both the programming and oversight levels within public broadcasting as well as on the content production side. There are fewer than five executives of diverse background at the highest levels in the three leading organizations within public broadcasting. This is unacceptable in America today, where minorities comprise over 35 percent of the population.

Public broadcasting has the potential to be particularly important for our Nation's growing minority and ethnic communities, especially as we transition to a broadband-enabled, 21st century workforce that relies on the skills and talent of all of our citizens. While there is a niche in the commercial broadcast and cable world for quality programming about our communities and our concerns, it is in the public broadcasting sphere where minority communities and producers should have more access and capacity to produce diverse high-quality programming for national audiences. We therefore, urge Congress to insert strong language in this act to ensure that this is the case and that these opportunities are made available to minorities and other underserved communities.

*About the National Minority Consortia*.—With primary funding from the CPB, the NMC serves as an important component of American public television as well as content delivered over the Internet. By training and mentoring the next generation of minority producers and program managers as well as brokering relationships between content makers and distributors (such as PBS, APT and NETA), we are in a perfect position to ensure the future strength and relevance of public television and radio television programming from and to our communities. However, these efforts are vulnerable because of chronic underfunding and lack of meaningful and ongoing representation within CPB's decisionmaking processes. This instability, coupled with what is essentially a decrease in our funding over time, are the primary reasons that have led to a public media that has become less diverse over the past 5 years.[2]

This is obviously not the case in the rest of America. With minority populations already estimated at over 35 percent of the U.S. population, it is more important that our public institutions reflect this reality.

Individually, each Consortia organization is engaged in cultivating ongoing relationships with the independent producer community by providing technical assistance and program funding, support and distribution. Often the funding we provide is the initial seed money for a project, thus allowing it to develop. We also provide numerous hours of programming to individual public television and radio stations, programming that is beyond the production reach of most local stations. To have

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[1] According to the 2008 Public Radio Tech Survey, 90 percent of public radio listeners are white. Of those, 84 percent are college-educated, with 48 percent having graduate degrees. This compares to just 9 percent of Americans who have postgraduate degrees. It is therefore mandatory that we prioritize actually "reaching" a diverse audience of Americans and not simply reflecting diverse and often misleading staffing numbers to measure public media's effectiveness in serving all of the American taxpayers that fund CPB.

[2] CPB funding for the NMC remained flat for 13 years until fiscal year 2008, at approximately $1 million per year per consortia. At that time, we received a one-time increase of $150,000 per organization. In fiscal year 2009, we received another one-time increase of approximately $500,000 each, but have been told that does not reflect a permanent increase. Over this same 13-year period, CPB's budget nearly doubled.

a real impact, we need funding that recognizes and values the full extent of minority participation in public life.

While the Consortia organizations work on projects specific to their communities, the five organizations also work collaboratively. An example of a joint production in which the NMC provided the initial seed money is "Unnatural Causes: Is Inequality Making Us Sick?", a multi-part series that uncovers the roots of racial and socio-economic disparities in health and spotlights community initiatives to achieve health equality. Our seed money enabled the project to go forward and to attract additional funding. We are also co-producers of and presenters in this series. Additionally, we jointly funded an online initiative around the Presidential Election in 2008 and continue to explore as a group other topics of national importance.

*CPB Funds for the National Minority Consortia*.—The NMC receives funds from two portions of the CPB budget: organizational support funds from the Systems Support and programming funds from the Television Programming funds. The organizational support funds we receive are used for operations requirements and also for programming support activities and for outreach to our communities and systemwide within public broadcasting. The programming funds are re-granted to producers, used for purchase of broadcast rights and other related programming activities. Each organization solicits applications from our communities for these funds. A brief description of our organizations follows:

*Center for Asian American Media (CAAM)*.—CAAM's mission is to present stories that convey the richness and diversity of Asian American experiences to the broadest audience possible. We do this by funding, producing, distributing and exhibiting works in film, television and digital media. Over our 25-year history we have provided funding for more than 200 projects, many of which have gone on to win Academy, Emmy and Sundance awards, examples of which are *Daughter from Danang*; *Of Civil Rights and Wrongs: The Fred Korematsu Story*; and *Maya Lin: A Strong Clear Vision*. CAAM presents the annual San Francisco International Asian American Film Festival and distributes Asian American media to schools, libraries and colleges. CAAM's newest department, Digital Media is becoming a respected leader in bringing innovative content and audience engagement to public media. CAAM is partnering with Pacific Islanders in Communications on a documentary about YouTube ukulele sensation Jake Shimabukuro.

*Latino Public Broadcasting (LPB)*.—LPB supports the development, production and distribution of public media content that is representative of Latino people, or addresses issues of particular interest to Latino Americans. Since 1998, LPB has awarded over $6 million to Latino Independent Producers, provided over 120 hours to public television, funded over 200 projects and conducted over 150 professional development workshops. LPB also produces *Voces*, the only Latino anthology series on public television, which showcases the impact of Latino culture on American life through music, sports, education and public service. In addition, LPB had several high profile programs on PBS including the concert special, *In Performance at the White House: Fiesta Latina*, that was re-broadcast on Telemundo and V-me and *Latin Music USA*, a four part series about the history and impact of Latino music on American culture which reached 14.7 million viewers, 16 percent of whom were Hispanic households (well above the PBS average). This past year, LPB launched the Equal Voice Community Engagement Campaign using the documentary film *Raising Hope: The Equal Voice Story*, a film about strategies to overcome poverty. The community engagement campaign helped PBS stations demonstrate how they too can become advocates for their communities. Currently, LPB is working on a 6 hour series titled *The Latino Americans*, about the history of Latinos in the United States.

*The National Black Programming Consortium (NBPC)*.—NBPC develops, produces and funds television and more recently audio and online programming about the black experience for American public media outlets. Since its founding in 1979, NBPC has provided hundreds of broadcast hours documenting African American history, culture and experience to public television and launched major initiatives that have brought important public media content to diverse audiences. In 2010, the National Black Programming Consortium launched an ambitious new project designed to re-engineer public media to better involve and inform diverse users in the digital era: The Public Media Corps (PMC). The PMC is a new national public media service that helps local stations to forge relationships with underserved communities through content production, local events, and digital media training. By recruiting, training and supporting the work of young, tech savvy "fellows" from these communities the PMC provides both stations and community partner organizations with a blueprint for not only connecting with audiences who have traditionally not found public broadcasting relevant to their lives, but also by providing them with access to emerging participatory platforms.

*Native American Public Telecommunications (NAPT).*—NAPT shares Native stories with the world through support of the creation, promotion and distribution of Native media. Founded in 1977, through various media—public television and radio, and the Internet—NAPT brings awareness of Indian and Alaska Native issues.

In 2010 NAPT presented eight Native American documentaries to PBS stations nationwide and launched a search capable educational micro-site featuring educational guides, post-viewer discussion guides, digital media clips, and interactive time lines. NAPT offered producers numerous workshops related to media maker topics such as preparation for broadcast, marketing your film on a budget, station carriage, online promotional tools, podcasting and more through nationwide media maker training offerings and conference attendance opportunities. In addition NAPT launched the Multimedia Fellowship Program, where two full-time Native American journalists wrote and produced multimedia projects about national Native American issues. Through our location at the University of Nebraska-Lincoln, we offer student employment, internships and fellowships. Reaching the general public and the global market is the ultimate goal for the dissemination of Native-produced media.

*Pacific Islanders in Communications (PIC).*—Since 1991, PIC has delivered programs and training that bring voice and visibility to Pacific Islander Americans. PIC produced the award winning film *One Voice* which tells the story of the Kamehameha Schools Song Contest. Other PBS broadcasts include *There Once Was an Island*, about the devastating effects of global warming on the Pacific Islands and *Polynesian Power: Islanders in Pro Football*. Currently PIC is developing a multi-part series, *Expedition: Wisdom*, in partnership with the National Geographic Society. PIC offers a wide range of development opportunities for Pacific Island producers through travel grants, seminars and media training. Producer training programs are held in the U.S. territories of Guam and American Samoa, as well as in Hawai'i, on a regular basis.

Thank you for your consideration of our recommendations. We see new opportunities to increase diversity in programming, production, audience, and employment in the new media environment, and we thank Congress for support of our work on behalf of our communities.

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## PREPARED STATEMENT OF THE NATIONAL MULTIPLE SCLEROSIS SOCIETY

Multiple sclerosis (MS), an unpredictable, often disabling disease of the central nervous system, interrupts the flow of information within the brain, and between the brain and body. Symptoms range from numbness and tingling to blindness and paralysis. The progress, severity, and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are moving us closer to a world free of MS. Most people with MS are diagnosed between the ages of 20 and 50, with at least two to three times more women than men being diagnosed with the disease. MS affects more than 400,000 people in the United States.

The National MS Society recommends the following funding levels for agencies and programs that are of vital importance to Americans living with MS in fiscal year 2012.

*Lifespan Respite Care Program*

Respite care services are a critical part of ensuring quality home-based care for people living with MS. Because of the importance of these services, the National MS Society requests the inclusion of $50 million in the fiscal year 2012 Labor-HHS-Education appropriations bill to fund lifespan respite programs. The Lifespan Respite Care Program, enacted in 2006, provides competitive grants to states to establish or enhance statewide lifespan respite programs, improve coordination, and improve respite access and quality. States provide planned and emergency respite services, train and recruit workers and volunteers, and assist caregivers in gaining access to services. Perhaps the most critical aspect of the program for people living with MS is that Lifespan Respite serves families regardless of special need or age—literally across the lifespan. Much existing respite care has age eligibility requirements and since MS is typically diagnosed between the ages of 20 and 50, Lifespan Respite Programs are often the only open door to needed respite services.

Up to one-quarter of individuals living with MS require long-term care services at some point during the course of the disease. Often, a family member steps into the role of primary caregiver to be closer to the individual with MS and to be involved in care decisions. Approximately 65 million family caregivers in the Nation are responsible for 80 percent of long-term care. The value of uncompensated family care giving services keeps growing and is currently estimated at $375 billion per year—more than total Medicaid spending and almost as high as Medicare spending.

Family caregiving, while essential, can be draining and stressful, with caregivers often reporting difficulty managing emotional and physical stress, finding time for themselves, and balancing work and family responsibilities. The impact is so great, in fact, that American businesses lose an estimated $17.1 to $33.36 billion each year due to lost productivity costs related to caregiving responsibilities. Providing $50 million for Lifespan Respite in fiscal year 2012 would provide the critical infrastructure to states to improve access to respite services, allowing family caregivers to take a break from the daily routine and stress of providing care, improve overall family health, and help alleviate the monstrous financial impact that caregiver strain currently has on American businesses.

*National Institutes of Health*

We urge Congress to continue its investment in innovative medical research that can help prevent, treat, and cure diseases such as MS by providing $35 billion for the National Institutes of Health (NIH) in fiscal year 2012.

The NIH conducts and sponsors a majority of the MS related research carried out in the United States. Approximately $151 million of fiscal year 2010 and Recovery Act appropriations were directed to MS-related research. An invaluable partner, the NIH has helped make significant progress in understanding MS. NIH scientists were among the first to report the value of MRI in detecting early signs of MS, before symptoms even develop. Advancements in MRI technology allow doctors to monitor the progression of the disease and the impact of treatment.

Research during the past decade has enhanced knowledge about how the immune system works, and major gains have been made in recognizing and defining the role of this system in the development of MS lesions. These NIH discoveries are helping find the cause, alter the immune response, and develop new MS therapies that are now available to modify the disease course, treat exacerbations, and manage symptoms. The NIH also directly supports jobs in all 50 States and 17 of the 30 fastest growing occupations in the United States are related to medical research or healthcare. More than 83 percent of the NIH's funding is awarded through almost 50,000 competitive grants to more than 325,000 researchers at over 3,000 universities, medical schools, and other research institutions in every State. To continue the forward momentum in the ability to aggressively combat, treat, and one day cure diseases like MS, the National MS Society requests Congress provide $35 billion for the NIH in fiscal year 2012.

*Centers for Medicare & Medicaid Services*

*Medicare*

Medicare programs are a lifeline for people living with MS, as approximately one-quarter of people living with MS rely on Medicare for access to essential medical care. These programs ensure that individuals living with MS have access to doctors, diagnostic equipment, durable medical devices, MRIs, and prescription drugs among other lifesaving treatments. Medicare also ensures full access to home healthcare, which is vital for keeping individuals with disabilities, like MS, in their communities and in their homes. Without Medicare, people living with MS may not have access to some forms of medical care and their quality of life may decrease.

The National MS Society is concerned about recent budget proposals that would essentially convert Medicare from an entitlement program to a voucher-type program. While proponents of these proposals believe that they will cut costs of the program, in reality the voucher system would primarily shift costs from the Medicare program to patients and consumers. In fact, the Congressional Budget Office has estimated that by 2030, the typical Medicare beneficiary would be required to pay more than two-thirds of their medical costs. Additionally, according the Kaiser Family Foundation, a typical 65-year-old retiring in 2022 would be expected to devote nearly half their monthly Social Security checks toward healthcare costs, more than double what they would spend under current Medicare law.

Beginning in 2022, the proposed system would give new beneficiaries money to purchase insurance from the private market, under the assumption that beneficiaries can make better and more cost-effective decisions about healthcare than the government and that this open market will create competition that will help keep costs down. However, the size of Medicare allows the program to impose lower rates on medical services and thus, private plans on average are more expensive. Therefore, the proposed voucher system may reduce costs within the Medicare program but not within the overall healthcare system because it will shift more cost to some of the most vulnerable patients in the healthcare system. In order to continue to provide the adequate and necessary care individuals with MS and other disabilities require, Medicare must maintain its status as an entitlement program.

*Medicaid*

The National MS Society urges Congress to maintain funding for Medicaid and reject proposals to cap or block grant the program.

Approximately 10 percent of people living with MS rely on Medicaid. The program has a strong track record of providing services that grant individuals with disabilities access to employment, cost-effective health services, home- and community-based services, and long-term care.

Capping or block-granting Medicaid will merely shift costs to states, forcing states to shoulder a seemingly insurmountable financial burden or cut services on which our most vulnerable rely. Capping and block-granting could result in many more individuals becoming uninsured, compounding the current problems of lack of coverage, over flowing emergency rooms, limited access to long term services, and increased healthcare costs in an overburdened system. By capping funds that support home- and community-based care, such proposals would also likely lead to an increased reliance on costlier institutional care that contradicts the principles laid forth in the 1999 U.S. Supreme Court Olmstead decision of integrating and keeping people with disabilities in their communities.

While the economic situation demands leadership and thoughtful action, the National MS Society urges Congress to remember people with MS and all disabilities, their complex health needs, and the important strides Medicaid has made for persons living with disabilities, particularly in the area of community-based care and not modify the program to their detriment.

*Social Security Administration*

The National MS Society urges Congress to provide $12.522 billion for the Social Security Administration's (SSA) Limitations on Administrative (LAE) Expenses to fund SSA's day-to-day operational responsibilities and make key investments in addressing increasing disability and retirement workloads, in program integrity, and in SSA's Information Technology (IT) infrastructure.

Because of the unpredictable nature and sometimes serious impairment caused by the disease, SSA recognizes MS as a chronic illness or "impairment" that can cause disability severe enough to prevent an individual from working. During such periods, people living with MS are entitled to and rely on Social Security Disability Insurance (SSDI) or Supplemental Security Income (SSI) benefits to survive. People living with MS, along with millions of others with disabilities, depend on SSA to promptly and fairly adjudicate their applications for disability benefits and to handle many other actions critical to their well-being including: timely payment of their monthly benefits; accurate withholding of Medicare Parts B and D premiums; and timely determinations on post-entitlement issues, e.g., overpayments, income issues, prompt recording of earnings.

With an expected increase in disability claims of nearly 29 percent between fiscal year 2008 and fiscal year 2010, SSA faces an unprecedented backlog in unprocessed disability claims. The average processing time is fortunately improving due to recent investments in and appropriations to SSA and as of March 2010, was approximately 437 days or a little more than 14 months. This progress must continue.

Providing at least $12.522 billion for the SSA is necessary to continue these programs and advancements, which are integral parts of efficiently and effectively getting benefits to individuals with disabilities, including those with MS.

*Food and Drug Administration*

Because of the tremendous impact the FDA has on the development and availability of drugs and devices for individuals with disabilities, the National MS Society requests that Congress provide a 15 percent increase over the fiscal year 2011 budget.

Advancements in medical technology and medical breakthroughs play a pivotal role in decreasing the societal costs of disease and disability. The FDA is responsible for approving drugs for the market and in this capacity has the ability to keep healthcare costs down. Each dollar invested in the life-science research regulated by the FDA has the potential to save upwards of $10 in health gains. Breakthroughs in medication and devices can reduce the potential costs of disease and disability in Medicare and Medicaid and can help support the healthier, more productive lives of people living with chronic diseases and disabilities, like MS. The approval of low-cost generic drugs saved the healthcare system $140 billion last year and nearly $1 trillion over the past decade. However, recent funding constraints have resulted in a 2 year backlog of generic drug approval applications and could potentially cost the Federal Government and patients billions of dollars in the coming years. The potential for these cost-saving medical breakthroughs and overall healthcare savings re-

lies on a vibrant industry and an adequately funded FDA. Therefore, Congress is urged to provide the FDA with a 15 percent increase to address this backlog.

*Conclusion*

The National MS Society thanks the Committee for the opportunity to provide written testimony and our recommendations for fiscal year 2012 appropriations. The agencies and programs we have discussed are of vital importance to people living with MS and we look forward to continuing to working with the Committee to help move us closer to a world free of MS.

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PREPARED STATEMENT OF THE NATIONAL NETWORK TO END DOMESTIC VIOLENCE

*Introduction*

I am submitting testimony to request a targeted investment of $196 million in the Family Violence Prevention and Services Act (FVPSA) and the Violence Against Women Act (VAWA) programs administered by the U.S. Department of Health and Human Services fiscal year 2012 budget (specific requests detailed below).

Labor, Health and Human Services Chairman Harkin, Ranking Member Shelby, Chairman Inouye, Ranking Member Cochran and distinguished members of the Appropriations Committee, thank you for this opportunity to submit testimony to the Committee on the importance of investing in FVPSA and VAWA programs. I sincerely thank the Committee for its ongoing support and investment in these lifesaving programs. These investments help to bridge the gap created by an increased demand and a lack of available resources.

I am the President of the National Network to End Domestic Violence (NNEDV), the Nation's leading voice on domestic violence. We represent the 56 State and territorial domestic violence coalitions, including those in Iowa, Alabama, Hawaii and Mississippi, their 2,000 member domestic violence and sexual assault programs, as well as the millions of victims they serve. Our direct connection with victims and victim service providers gives us a unique understanding of their needs and the vital importance of continued Federal investments.

*Incidence, Prevalence, Severity and Consequences of Domestic and Sexual Violence*

The crimes of domestic and sexual violence are pervasive, insidious and life-threatening. Nearly one in four women are beaten or raped by a partner during adulthood[1] and 2.3 million people are raped and/or physically assaulted by a current or former spouse or partner each year.[2] One in six women and 1 in 33 men have experienced an attempted or completed rape.[3] Of course the most heinous of these crimes is murder. Every day in the United States, an average of three women are killed by a current or former intimate partner.[4]In 2005 alone, 1,181 women were murdered by an intimate partner in the United States[5] and approximately one-third of all female murder victims are killed by an intimate partner.[6]

The cycle of intergenerational violence is perpetuated as children are exposed to violence. Approximately 15.5 million children are exposed to domestic violence every year.[7] One study found that men exposed to physical abuse, sexual abuse and adult domestic violence as children were almost 4 times more likely than other men to have perpetrated domestic violence as adults.[8]

In addition to the terrible cost domestic and sexual violence have on the lives of individual victims and their families, these crimes cost taxpayers and communities. In fact, the cost of intimate partner violence exceeds $5.8 billion each year, of which

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[1] AU.S. Department of Justice, National Institute of Justice and Centers for Disease Control and Prevention. (July 2000). Extent, Nature, and Consequences of Intimate Partner Violence: Finding from the National Violence Against Women Survey. Washington, DC. Tjaden, Pl., & Thoennes., N.

[2] Ibid.

[3] U.S. Department of Justice, Prevalence, Incidence, and Consequences of Violence Against Women: Findings from the National Violence Against Women Survey (1998).

[4] Bureau of Justice Statistics (2008). Homicide Trends in the U.S. from 1976–2005. Dept. of Justice.

[5] Ibid.

[6] Bureau of Justice Statistics, Homicide Trends from 1976–1999. (2001)

[7] McDonald, R., et al. (2006). "Estimating the Number of American Children Living in Partner-Violence Families." Journal of Family Psychology, 30(1), 137–142.

[8] Greenfield, L. A. (1997). Sex Offences and Offenders: An Analysis of Date on Rape and Sexual Assault. Washington, DC. Bureau of Justice Statistics, U.S. Department of Justice.

$4.1 billion is for direct medical and mental healthcare services.[9] Research shows that intimate partner violence costs a health insurance plan $19.3 million each year for every 100,000 women between the ages of 18 and 64 who are enrolled.[10] Domestic violence costs U.S. employers an estimated $3 to $13 billion annually.[11] Between one-quarter and one-half of domestic violence victims report that they lost a job, at least in part, due to domestic violence.

Despite this grim reality, we know that when a coordinated response is developed and immediate, essential services are available, victims can escape from life-threatening violence and begin to rebuild their shattered lives. Funding these programs is fiscally sound, as they save lives, prevent future violence, keep families and communities safe, and save our Nation money. While Federal funding cannot meet all the needs of victims, it leverages State, private and local dollars to provide consistent funding streams to lifesaving services. To address unmet needs and build upon its successes, VAWA/FVPSA should receive targeted investments in fiscal year 2012.

Family Violence Prevention and Services Act (FVPSA) (Administration for Children and Families)—$140 million request. Since its passage in 1984 as the first national legislation to address domestic violence, FVPSA has remained the only funding directly for shelter programs. For more than 25 years, FVPSA has made substantial progress toward ending domestic violence. Despite the progress and success brought by FVPSA, a strong need remains for FVPSA-funded services for victims.

Domestic violence is more than a crime—it is a public health issue. To address this issue, there are more than 2,000 community-based domestic violence programs for victims and their children (approximately 1,500 of which are FVPSA-funded through State formula grants). These programs offer services such as emergency shelter, counseling, legal assistance, and preventative education to millions of women, men and children annually and are at the heart of our Nation's response to domestic violence.[12] These effective programs save and rebuild lives. A recently released multi-state study conclusively shows that the Nation's domestic violence shelters are addressing victims' urgent and long-term needs and are helping victims protect themselves and their children. This same study indicated that, if shelters did not exist, the consequences for victims would be dire, including "homelessness, serious losses including children [or] continued abuse or death."

According to a report by the National Network to End Domestic Violence, in one day in 2010, more than 70,000 victims of domestic violence received services, of which 50 percent found refuge in emergency shelters and transitional housing. Of the 23,743 victims in emergency shelter that day, more than 50 percent were children. However, on that same day, more than 9,500 requests for services by adults and children were unmet due to lack of funding.

*Addressing the Needs of Children and Breaking the Intergenerational Cycle of Violence*

In addition to providing crisis services to adults fleeing violence, FVPSA helps to break the intergenerational cycle of violence. Approximately one-half to two-thirds of residents in domestic violence shelters are children. In 2010, Congress reauthorized FVPSA that included a newly authorized program, Specialized Services for Abused Parents and Their Children. In fiscal year 2010, Congress appropriated nearly $131 million for FVPSA, which for the first time triggered spending dedicated to specialized service for children who witness domestic violence.

The newly authorized Children's program is an important step in the Federal Government's response to domestic violence. It will build an evidence base for services, strategies, advocacy and interventions for children and youth exposed to domestic violence. Although many domestic violence programs currently serve children, this program will expand the capacity of domestic violence programs to address the needs of children and adolescents coming into emergency shelters. To ensure that children's needs are met in the community, the program will create statewide and local improvements in systems and responses to children and youth exposed to domestic violence. Finally, the program will eventually lead to nationwide dissemination of lessons learned and strategies for implementation in communities across the country.

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[9] National Center for Injury Prevention and Control. Costs of Intimate Partner Violence Against Women in the United States. Atlanta (GA): Centers for Disease Control and Prevention; 2003.

[10] Ibid.

[11] Bureau of National Affairs Special Rep. No. 32, Violence and Stress: The Work/Family Connection 2 (1990); Joan Zorza, Women Battering: High Costs and the State of the Law, Clearinghouse Rev., Vol. 28, No. 4, 383, 385; Supra, see endnote 10.

[12] National Coalition Against Domestic Violence, Detailed Shelter Surveys (2001).

Currently, four States have received modest funding grants to build upon their work and lay groundwork for the national project. The New Jersey Coalition for Battered Women will expand an established model program, Peace: A Learned Solution (PALS), which provides children ages 3 through 17 with creative arts therapy to help them heal from exposure to domestic violence. The Wisconsin Coalition Against Domestic Violence will launch the Safe Together Project, which will increase the capacity of Wisconsin domestic violence programs, particularly those serving under-represented or culturally specific populations, to support non-abusing parents and mitigate the impact of exposure to domestic violence on their children. The Alaska Network on Domestic Violence and Sexual Assault will improve services and responses to Alaska's families by addressing the lack of coordination between domestic violence agencies and child welfare systems. Together, grantees will serve as leaders for expanding a broader network for support; developing evidence-based interventions for children, youth and parents exposed to domestic violence; and building national implementation strategies that will lead to local improvements in domestic violence program and community systems interventions.

Unfortunately, the rescission in the final fiscal year 2011 budget cut all funding for the new children's program. If the funding is not restored to at least $140 million in fiscal year 2012, these innovative and cost-saving projects will be in jeopardy.

*The Increased Need for Funding*

Many programs across the country use their FVPSA funding to keep the lights on and their doors open. We cannot overstate how important this is: victims must have a place to flee to when they are escaping life-threatening violence. Countless shelters across the country would not be able to operate without FVPSA funding. As increased training for law enforcement, prosecutors and court officials has greatly improved the criminal justice system's response to victims of domestic violence, there is a corresponding increase in demand for emergency shelter, hotlines and supportive services. Additionally, demand has increased as a result of the economic downturn and victims with fewer personal resources become increasingly vulnerable. Since the economic crisis began, three out of four domestic violence shelters have reported an increase in women seeking assistance from abuse.[13] As a result, shelters overwhelmingly report that they cannot fulfill the growing need for these services.

In the current economic climate, the demand for domestic violence services has increased precisely at the time when programs are struggling to maintain State and private funding to meet the demand. In fact, the National Domestic Violence Census found that in 2010, 1,441 (82 percent) domestic violence programs reported a rise in demand for services, while at the same time, 1,351 (77 percent) programs reported a decrease in funding.[14] Between 2009 and 2010, domestic violence programs laid off or did not replace nearly 2,000 staff positions including counselors, advocates and children's advocates, and a number of shelters around the country closed. In 2009, although FVPSA-funded domestic violence programs provided shelter and nonresidential services to more than 1 million victims, an additional 167,069 requests for lifesaving shelter went unmet due to lack of capacity. In Alabama, the problem reflects the rest of the Nation. More than 30 percent of Alabama programs reported that they did not have enough funding for needed programs and services and 17 percent reported no available beds or funding for hotels. In Iowa, nine programs statewide have already closed their doors due to funding shortages and many other programs have been forced to reduce the types of services provided, including eliminating child advocate positions and prevention programs dedicated to breaking the cycle of violence.

We cannot allow the gap between available resources and the desperate need of victims to widen. For those individuals who are not able to find safety, the consequences can be extremely dire, including continued exposure to life-threatening violence or homelessness. It is absolutely unconscionable that victims cannot find safety for themselves and their children due to a lack of adequate investment in these services. In order to meet the immediate needs of victims in danger and to continue to break the intergenerational cycle of violence, FVPSA funding must be increased to at least $140 million in fiscal year 2012.

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[13] Mary Kay's Truth About Abuse. Mary Kay Inc. (May 12, 2009).

[14] Domestic Violence Counts 2010: A 24-Hour census of domestic violence shelters and services across the United States. The National Network to End Domestic Violence. (Jan. 2011).

*Additional Requests*

*National Domestic Violence Hotline (Administration for Children and Families)—$5 million request*

For the past 15 years the Hotline has provided 24-hour, toll-free and confidential services, immediately connecting callers to local service providers. During this economic downturn, crisis calls to the Hotline have increased. Additionally, to address the specific needs of dating violence victims, the Hotline launched the National Dating Abuse Helpline, which has seen increased traffic recently.

*DELTA Prevention Program (Centers for Disease Control and Injury Prevention)—$6 million request*

DELTA is one of the only sources of funding for domestic violence prevention work. The program supports statewide projects that integrate primary prevention principles and practices into local coordinated community responses that address and reduce the incidence of domestic violence. Currently, DELTA funds 56 Coordinated Community Response Coalitions nationwide. In the first 3 years that DELTA funded these projects, the primary prevention activities in communities increased ten-fold. Nineteen States, including Alabama and Iowa, are currently funded as DELTA Prep states by the Robert Wood Johnson Foundation. Without additional DELTA funding, these States, ready in 2012 to fully participate, may not be able to access CDC funding.

*Rape Prevention and Education (RPE) (Centers for Disease Control and Injury Prevention)—$42.6 million request*

This VAWA program administered through CDC strengthens national, State and local sexual violence prevention efforts and the operation of rape crisis hotlines. RPE funding provides formula grants to States and territories to support rape prevention and education programs conducted by rape crisis centers, State sexual assault coalitions and other public and private nonprofit entities. Funding also supports the National Sexual Violence Resource Center, which provides up-to-date information regarding sexual violence to policymakers, Federal and State agencies, college campuses, sexual assault and domestic violence coalitions, local programs, the media, and the general public. Despite its critical work, RPE has faced funding decreases since fiscal year 2006.

*Violence Against Women Health Initiative (Office of Women's Health)—$2.3 million request*

This eight State and two tribe initiative promotes public health programs that integrate domestic and sexual violence assessment and intervention into basic care. Congress has included the program in the last 3 fiscal years, but after the first year, the funding has not been on top of the agency's overall budget. As a result, HHS has been forced to cut other violence prevention activities to fund the program. Funding is needed to identify best practices, conduct general evaluation and disseminate the results to the field so that victims nationwide can benefit.

*Conclusion*

Together, these LHHS programs work to prevent and end domestic and sexual violence. While our country has made continued investments in the criminal justice response to these heinous crimes, we need an equal investment in the human service, public health and prevention response in order to holistically address and end violence against women. We know that our Nation is facing a difficult financial time and that there is pressure to reduce spending. Investments in these vital, cost-effective programs, however, help break the cycle of violence, reduce related social ills and will save our Nation money now and in the future.

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PREPARED STATEMENT OF THE NATIONAL POSTDOCTORAL ASSOCIATION

Thank you for this opportunity to testify in regard to the fiscal year 2012 funding for the National Institutes of Health (NIH). We are writing today in regard to support for postdoctoral scholars, specifically in support of the 4-percent increase in the NIH Ruth L. Kirschstein National Research Service Awards (NRSA) training stipends, as requested in the President's budget.

*Background: Postdocs are the Backbone of U.S. Science and Technology*

According to estimates by The National Science Foundation (NSF) Division of Science Resource Statistics, there are approximately 89,000 postdoctoral scholars in

the United States[1]. The NIH and the NSF define a "postdoc" as: An individual who has received a doctoral degree (or equivalent) and is engaged in a temporary and defined period of mentored advanced training to enhance the professional skills and research independence needed to pursue his or her chosen career path. The number of postdocs has been steadily increasing. The incidence of individuals taking postdoc positions during their careers has risen, from about 25 percent of those with a pre-1972 doctorate to 46 percent of those receiving their doctorate in 2002–05[2]. Moreover, the number of science and engineering doctorates awarded each year is steadily rising with doctorates awarded in the medical/life sciences almost tripling between 2003 and 2007[3].

Postdocs are critical to the research enterprise in the United States and are responsible for the bulk of the cutting edge research performed in this country. Consider the following:

—According to the National Academies, postdoctoral researchers "have become indispensable to the science and engineering enterprise, performing a substantial portion of the Nation's research in every setting."[4]

—Postdoctoral training has become a prerequisite for many long-term research projects.[5] In fact, the postdoc position has become the de facto next career step following the receipt of a doctoral degree in many disciplines.

—The retention of women and under-represented groups in biomedical research depends upon their successful and appropriate completion of the postdoctoral experience.

—Postdoctoral scholars carry the potential to solve many of the world's most pressing problems; they are the principal investigators of tomorrow.

Unfortunately, postdocs are routinely exploited. They are paid a low wage relative to their years of training and are often ineligible for workman's compensation, disability insurance, paid maternity or paternity leave, employer-sponsored medical benefits, and retirement accounts.

The National Postdoctoral Association (NPA) advocates for policies that support and enhance postdoctoral training. NPA members advocate for policy change on the national level and also within the research institutions that host postdoctoral scholars. To date, more than 150 institutions have adopted portions of the NPA's recommended practices, but low compensation remains one of the serious issues faced by the postdoctoral community.

*Problem: NRSA Stipends are Low and Don't Meet Cost-of-Living Standards; For Better or Worse, Postdoc Compensation is Based on NRSA Stipends*

The NIH leadership has been aware that the NRSA training stipends are too low since 2001, after the publication of the results of the National Academy of Sciences (NAS) study, Addressing the Nation's Changing Needs for Biomedical and Behavioral Scientists. In response, the NIH pledged (1) to increase entry-level stipends to $45,000 by raising the stipends at least 10 percent each year and (2) to provide automatic cost-of-living increases each year thereafter to keep pace with inflation. Most recently, the 2011 NAS study, Research Training in the Biomedical, Behavioral, and Clinical Research Sciences, called for, among other recommendations, increased funding to support more NRSA positions and to fulfill the NIH's 2001 commitment to increase pre-doctoral and postdoctoral stipends.

Without sufficient appropriations from Congress, the NIH has not been able to fulfill its pledge. In 2007, the stipends were frozen at 2006 levels and since then have not been significantly increased. The stipends were increased by 1 percent each year in 2009 and 2010 and by 2 percent in 2011. The 2011 entry-level training stipend remains low, at $38,496, the equivalent of a GS–8 position in the Federal Government (NIH Statement NOT–OD–10–047), despite the postdocs' advanced degrees and specialized technical skills. Furthermore, this stipend remains far short of the promised $45,000. Certainly, it is not reflective of any cost-of-living increases (please see Figure 1).

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[1] National Science Foundation Division of Science Resource Statistics. (January 2010). Science and engineering indicators 2010. Arlington, VA: National Science Board.

[2] Ibid.

[3] Ibid.

[4] COSEPUP. (June 2001). Enhancing the postdoctoral experience for scientists and engineers. Washington, D.C.: National Academy Press. p. 10.

[5] COSEPUP. (June 2001). Enhancing the postdoctoral experience for scientists and engineers. Washington, D.C.: National Academy Press. p. 11.

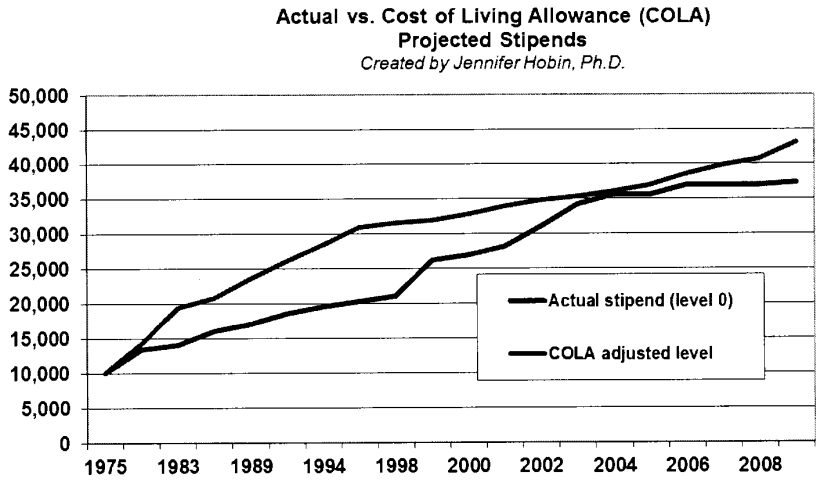


FIGURE 1

It is not only the NRSA fellows who remain undercompensated; the impact of the low stipends extends beyond the NRSA-supported postdocs. The NPA's research has shown that the NIH training stipends are used as a benchmark by research institutions across the country for establishing compensation for postdoctoral scholars. Thus, an unintended consequence is that institutions undercompensate all of their postdocs, who must then struggle to make ends meet, which in turn affects their productivity and undermines their efforts to solve the world's most critical problems. Additionally, many are leaving their research careers behind because of the low compensation. In order to keep the "best and the brightest" scientists in the U.S. research enterprise, the NPA believes that it is crucial that Congress appropriate funding for the 4-percent increase in training stipends, as a moderate yet substantial step toward reaching the recommended entry-level stipend of $45,000.

*Solution: Keep the NIH's Original Promise to Raise the Minimum Stipends*

We ask the Subcommittee to appropriate $794 million for the 4-percent stipend increase, as requested in the President's proposed budget (http://www.nih.gov/about/director/budgetrequest/NIH_BIB_020911.pdf): As part of the President's initiative in fiscal year 2012 to emphasize support for science, technology, engineering, and mathematics (STEM) education programs, the budget proposes a 4 percent stipend increase for predoctoral and postdoctoral research trainees supported by NIH's Ruth L. Kirschstein National Research Service Awards program. A total of $794 million is requested in fiscal year 2012 for this training program. The proposed increase in stipends will allow NIH to continue to attract high quality research trainees that will be available to address the Nation's future biomedical, behavioral, and clinical research needs.

The NPA believes it is fair, just, and necessary to increase the compensation provided to these new scientists, who make significant contributions to the bulk of the research discovering cures for disease and developing new technologies to improve the quality of life for millions of people in the United States. Please do not hesitate to contact us for more information. Thank you for your consideration.

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## PREPARED STATEMENT OF THE NATIONAL PRIMATE RESEARCH CENTERS

The Directors of the eight National Primate Research Centers (NPRCs) respectfully submit this written testimony for the record to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies. The NPRCs appreciate the commitment that the Members of this Subcommittee have made to biomedical research through your support for the National Institutes of Health (NIH) and recommend that you provide $31.987 billion for NIH in fiscal year 2012, which represents a 3.4 percent increase above the fiscal year 2011 level. Within this proposed increase the NPRCs also respectfully request that the Subcommittee provide strong support for the NPRC P51 (base grant) program, which

is essential for the operational costs of the eight NPRCs. This support would help to ensure that the NPRCs and other animal research resource programs continue to serve effectively in their role as a vital national resource.

The mission of the National Primate Research Centers is to use scientific discovery and nonhuman primate models to accelerate progress in understanding human diseases, leading to better health. The NPRCs collaborate as a transformative and innovative network to support the best science and act as a resource to the biomedical research community as efficiently as possible. There is an exceptional return on investment in the NPRC program; $10 is leveraged for every $1 of research support for the NPRCs. It is important to sustain funding for the NPRC program and the NIH as a whole to continue to grow and develop the innovative plan for the future of NIH.

*NPRCs Contributions to NIH Priorities*

The NPRCs activities are closely aligned with NIH's priorities. In fact, NPRC investigators conduct much of the Nation's basic and translational nonhuman primate research, facilitate additional vital nonhuman primate research that is conducted by hundreds of investigators from around the country, provide critical scientific expertise, train the next generation of scientists, and advance cutting-edge technologies. The NPRCs currently are engaged with NIH staff in a comprehensive strategic planning process to further enhance the capabilities of the NPRCs to serve as a resource across all NIH institutes and centers. The NPRC consortium strategic plan has as its center and driving force the scientific priorities that drive translational work into better interventions and diagnostics for improved human health. Outlined below are a few of the overarching goals of the plan, including specifics of how the NPRCs are striving to achieve these through programs and activities across the centers.

*Advance Translational Research Using Animal Models*.—Nonhuman primate models bridge the divide between basic biomedical research and implementation in a clinical setting. Currently, seven of the eight NPRCs are affiliated and collaborate with NIH Clinical and Translational Science Awards (CTSA) program through their host institution. Specifically, the nonhuman primate models at the NPRCs often provide the critical link between research with small laboratory animals and studies involving humans. As the closest genetic model to humans, nonhuman primates serve in the development process of new drugs, treatments, and vaccines to ensure safe and effective use for the Nation's public.

*Strengthen the Research Workforce*.—The success of the Federal Government's efforts in enhancing public health is contingent upon the quality of research resources that enable scientific research ranging from the most basic and fundamental to the most highly applied. Biomedical researchers have relied on one such resource—the NPRCs—for nearly 50 years for research models and expertise with nonhuman primates. The NPRCs are highly specialized facilities that foster the development of nonhuman primate animal models and provide expertise in all aspects of nonhuman primate biology. NPRC facilities and resources are currently used by over 2,000 NIH funded investigators around the country.

The NPRCs are also supportive of getting students interested in the biomedical research workforce pipeline at an early age. For example, the Yerkes NPRC supports a program that connects with local high schools and colleges in Atlanta, Georgia, and invites students to participate in research projects taking place at their field station location.

*Offer Technologies to Advance Translational Research and Expand Informatics Approaches to Support Research*.—The NPRCs have been leading the development of a new Biomedical Informatics Research Network (BIRN) for linking brain imaging, behavior, and molecular informatics in nonhuman primate preclinical models of neurodegenerative diseases. Using the cyberinfrastructure of BIRN for data-sharing, this project will link research and information to other primate centers, as well as other geographically distributed research groups.

*Translational Science at the NPRCs*

Animal models are an essential tool for translating basic biomedical research to treatments and cures for patients, and the NPRCs are a national resource instrumental to this effort. The network of the eight NPRCs collaborates across many disciplines and institutions, with the goal of advancing biomedical knowledge to understand disease and improve human and animal health. Below are specific examples of translational research conducted at each of the eight NPRCs.

In work conducted at the California National Primate Research Center, Immunoglobulin G (IgG) antibodies purified from mothers of children with autism and mothers of typically developing children were injected into pregnant rhesus monkeys. The offspring were then evaluated both neurologically and behaviorally.

Offspring of mothers who received IgG from mothers of children with autism demonstrated significantly higher levels of repetitive behaviors than the offspring who received control antibodies. There are currently no diagnostic tests for autism. This research identifies one potential autoimmune cause of autism. Moreover, detection of the maternal autoantibodies may become an early diagnostic test for increased risk of having a child with autism. This research, which relied on treating pregnant rhesus monkeys, could not have been conducted without the facilities provided by the national primate center.

Rhesus monkeys are widely used as animal models across many fields of biomedical research because of their genetic, physiological, behavioral, and anatomical similarities to humans. Scientists at the New England National Primate Research Center are taking advantage of the genetic similarity between rhesus monkeys and humans to create the first monkey model of alcoholism genetics. Recent studies in human alcoholics who are treated with naltrexone, a leading medication for alcohol dependence, have shown that the medication works better in people who have a specific genetic variant in the OPRM1 gene. Scientists at the New England NPRC identified a similar genetic change in the rhesus monkey OPRM1 gene, and have shown that monkeys with the genetic change not only drink more alcohol but also have a comparable genetically determined response to naltrexone to that seen in some human alcoholics. This animal model gives scientists a new way to create personalized medications for the treatment of alcoholism.

A new technique developed by a research team at the Oregon National Primate Research Center offers a way for women with mitochondrial diseases to have their own children without passing on defective genetic material. According to the scientists, defective genes in mitochondria can be passed to children at a frequency of 1 in 4,000 births and can lead to a variety of diseases. Symptoms of these potentially fatal illnesses include dementia, movement disorders, blindness, hearing loss, and problems of the heart, muscle, and kidney. Following this successful study in a nonhuman primate model, scientists believe that the technique could be applied quickly to humans to prevent devastating diseases.

In 2005, researchers were looking for an animal model in which to test a prototype device which might ameliorate degenerative disc disease, a major cause of disability in working-age adults. The baboon was chosen as an appropriate animal model for safety testing of the new device because of its upright posture and the high magnitude of forces placed on the vertebral column during the baboon's natural movement. After a small pilot study, two subsequent pre-clinical studies were performed at the Southwest National Primate Research Center. This was an international effort in which specialists from Denmark, Canada, and the United Kingdom visited the Primate Center on numerous occasions to participate in the studies. The data from these studies along with data from human clinical trials are now being assembled for submission to the U.S. Food and Drug Administration for approval to use the artificial disc in the United States as an alternative for the treatment of degenerative lumbar spinal disease.

Testing the safety and efficacy of potential compounds in nonhuman primates is virtually essential to advancing microbicide candidates to clinical trials to prevent HIV transmission. There are far too many microbicide candidates in development for all of them to be tested in human trials. Over the years, the Tulane National Primate Research Center has facilitated microbicide studies in nonhuman primates that have led to human clinical trials, and have been the only successful predictor of success or failure of compounds in these trials. Furthermore, candidates that were not sufficiently tested in nonhuman primates prior to human trials were shown to fail, and later studies, once performed in macaques, confirmed they would have been predictive of failure.

Studies completed at the Tulane NPRC have resulted in Merck releasing one of these compounds to the International Partnership for Microbicides (IPM) for microbicide development and human clinical testing. Based on the positive results in macaque studies, the IPM also has been granted license to pursue topical development of Pfizer's Maraviroc as a microbicide. Nonhuman primate testing has resulted in a wealth of information that has prevented expensive clinical trials in humans that would have otherwise been fruitless.

Recovery of function after stroke, traumatic brain injury or spinal cord injury is a significant medical challenge for millions of patients in the United States. A promising new treatment for many of these disabled survivors is an implantable recurrent brain-computer interface (R–BCI). The Washington National Primate Research Center developed R–BCI, a "neurochip" that records neural activity from the brain and transforms that activity into stimuli delivered to the brain, spinal cord, or muscles during free behavior. R–BCI technology has the clinical potential to aid patients paralyzed by ALS or spinal cord injury to regain some motor control directly from

cortical cells and may also be used to strengthen weak connections impaired by stroke.

Researchers and physicians are getter closer to a novel diagnostic test for polycystic ovary syndrome (PCOS), which has staggering adverse physiological, psychological, and financial consequences for women's reproductive health. Scientists at the Wisconsin National Primate Research Center are studying the profile of metabolites in both monkey and patient samples of blood, urine, sweat, and breath molecules to identify signals in the body's internal chemistry that are consistent with the syndrome. From the vast pool of metabolites in their samples, they have found a handful that rise to the surface as indicators of PCOS. These telltale molecules could become the basis for the first-ever diagnostic test for the syndrome.

A recent study based on work conducted at the Yerkes National Primate Research Center with nonhuman primates illustrates the promise of the Visual Paired Comparison (VPC) task for the detection of mild memory impairment associated with Alzheimer's disease (AD). To investigate this possibility, the Yerkes NPRC recently extended their collaborations to include the Department of Computer Sciences at Emory University. The results show that eye movement characteristics including fixation duration, saccade length and direction, and re-fixation patterns can be used to automatically distinguish impaired and normal subjects. Accordingly, this generalized approach has proven useful for improving early detection of AD, and may be applied, in combination with other behavioral tasks, to examine cognitive impairments associated with other neurodegenerative diseases. Researchers at the Yerkes NPRC have developed two patents based on this work.

*The Need for Facilities Support*

The NPRC program is a vital resource for enhancing public health and spurring innovative discovery. In an effort to address many of the concerns within the scientific community regarding the need for funding for infrastructure improvements, the NPRCs support the continuation of a robust construction and instrumentation grant program at NIH.

Animal facilities, especially primate facilities, are expensive to maintain and are subject to abundant "wear and tear." In prior years, funding was set aside that fulfilled the infrastructure needs of the NPRCs and other animal research facilities. The NPRCs ask the Subcommittee to provide strong support for construction and renovation of animal facilities through C06 and G20 programs. Without proper infrastructure, the ability for animal facilities, including the NPRCs, to continue to meet the high demand of the biomedical research community will be unattainable.

Thank you for the opportunity to submit this written testimony and for your attention to the critical need for primate research and the continuation of infrastructure support, as well as our recommendations concerning funding for NIH in the fiscal year 2012 appropriations bill.

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## PREPARED STATEMENT OF THE NATIONAL PSORIASIS FOUNDATION

### INTRODUCTION AND OVERVIEW

The National Psoriasis Foundation (the Foundation) appreciates the opportunity to submit written public witness testimony regarding fiscal year 2012 Federal funding for psoriasis and psoriatic arthritis data collection and research. The Foundation is the largest psoriasis patient advocacy organization and charitable funder of psoriatic disease research worldwide, and has a primary mission of finding a cure for psoriasis and psoriatic arthritis. Psoriasis, the Nation's most prevalent autoimmune disease, affecting as many as 7.5 million Americans, is a noncontagious, chronic, inflammatory, painful and disabling disease for which there is no cure. It appears on the skin, most often as red, scaly patches that itch, can bleed and require sophisticated medical intervention. Up to 30 percent of people with psoriasis also develop potentially disabling psoriatic arthritis that causes pain, stiffness and swelling in and around the joints. There are other serious risks associated with psoriasis—for example, diabetes, cardiovascular disease, stroke and some cancers. Of serious concern is that, beyond its terrible physical and psychosocial toll on individuals, psoriasis also costs the Nation $11.25 billion annually.

The Foundation works with the research community and policymakers at all levels of government to advance policies and programs that will reduce and prevent suffering from psoriasis and psoriatic arthritis. In 2009, after examining existing scientific literature, clinical practice and other components of psoriasis and psoriatic arthritis research and care, the Foundation's medical and scientific advisors recommended the creation of a federally organized, public health research program for psoriasis and psoriatic arthritis to collect the information necessary to address the

key scientific questions in the study and treatment of psoriatic disease. Responding to this recommendation, recognizing the significant economic and social costs of psoriasis and psoriatic arthritis and acknowledging the sizeable gap in the understanding of these devastating conditions, in fiscal year 2010, Congress provided $1.5 million to the Centers for Disease Control and Prevention (CDC) to commence the first-ever Government effort to collect data on psoriasis and psoriatic arthritis. Following this initial investment, in its fiscal year 2011 Labor, Health and Human Services, Education (LHHS) funding bill, the Senate provided a second allocation of $1.5 million to continue these critical public health efforts. While that measure was not enacted, we want to thank you and your colleagues for recognizing the importance of psoriasis data collection and ask for your support again in fiscal year 2012.

Since the initial appropriation, considerable progress has been made in developing this data collection program in a thoughtful and deliberate manner, and we commend CDC for its excellent methodology and undertaking of this important effort. Thus far, Federal investment in this effort has allowed the CDC, along with other Federal stakeholders, to identify the key gaps in psoriatic disease data, including: prevalence, age of onset, health-related quality of life, healthcare utilization, burden of disease (employment, work, etc.), direct and indirect costs, health disparities (age, gender, racial and ethnic), comorbidities and an understanding of the course of the disease over time. To uncover these important public health issues, in 2010, CDC researchers collaborated with the Foundation's scientific and medical advisors to establish a process by which a common basis for defining and diagnosing psoriasis will be created and validated. This work, in turn, will provide the insight, information and tools CDC researchers need to determine the key psoriasis and psoriatic arthritis public health questions to be pursued.

While the Foundation acknowledges the fiscal realities currently facing Congress and this Nation, scientific discovery, at this moment, is poised to advance the understanding and treatment of psoriasis and psoriatic arthritis. As such, we respectfully request that Congress continue to support this important initiative by appropriating level funding, $1.5 million, in fiscal year 2012, to enable CDC to refine and implement the psoriasis and psoriatic data collection process that has been defined with previous funding. With fiscal year 2012 funding, CDC researchers will be able to build upon the initial investment and integrate psoriasis and psoriatic arthritis questions into existing federally funded public health surveys, allowing economies of scale and leveraging scarce resources to maximum their utility. The information gleaned from this effort will help improve treatments and disease management, identify new pathways for future research and drug development and inform efforts to reduce the burden of disease on patients, their families and society in general.

In addition, the Foundation urges the Subcommittee to support robust fiscal year 2012 funding for the National Institutes of Health (NIH). Sustaining Federal investment in biomedical research will help support new investigator-initiated research grants for genetic, clinical and basic research related to the understanding of the cellular and molecular mechanisms of psoriasis and psoriatic arthritis. Epidemiologic research at CDC, coupled with biomedical investigations through NIH, will help further the Nation's understanding of psoriasis and psoriatic arthritis and contribute to the development of better therapies, improved treatments and disease management and identification of ways in which comorbid conditions (e.g., heart attack, cancer and diabetes) can be prevented or mitigated, in turn, helping to save money and lives.

### THE IMPACT OF PSORIASIS AND PSORIATIC ARTHRITIS ON THE NATION

Psoriasis requires steadfast treatment and lifelong attention, especially since it most often strikes between ages 15 and 25. People with psoriasis also have significantly higher healthcare resource utilization, which costs more than that for the general population. Of serious and increasing concern is mounting evidence that people with psoriasis are at elevated risk for myriad other serious, chronic and life-threatening conditions, including cardiovascular disease, diabetes, stroke and some cancers. A higher prevalence of atherosclerosis, chronic obstructive pulmonary disease, Crohn's disease, lymphoma, metabolic syndrome and liver disease are found in people with psoriasis, as compared to the general population. In addition, people with psoriasis experience higher rates of depression and anxiety, and people with severe psoriasis die 4 years younger, on average, than people without the disease.

Despite some recent breakthroughs, many people with psoriasis and psoriatic arthritis remain in need of effective, safe, long-term and affordable therapies to allow them to function normally without both physical and emotional pain. Due to the nature of the disease, patients often have to cycle through available treatments, and while there are an increasing number of methods to control the disease, there is no

cure. Many of the existing treatments can have serious side effects and can pose long-term risks for patients (e.g., suppress the immune system, deteriorate organ function, etc.). The lack of viable, long-term methods of control for psoriasis can be addressed through Federal commitment to epidemiological, genetic, clinical and basic research. NIH and CDC research, taken together, hold the key to improved treatment of these diseases, better diagnosis of psoriatic arthritis and eventually a cure.

THE ROLE OF CDC IN PSORIASIS AND PSORIATIC ARTHRITIS RESEARCH

Despite our increased understanding of the autoimmune underpinnings of psoriasis and its treatments, there is a dearth of population-based epidemiology data on psoriatic disease. The majority of existing studies of psoriasis are based on case reports, case series and cross-sectional studies, which are likely biased toward more severe disease. Several analytical studies have been performed to identify potentially modifiable risk factors (e.g., smoking, diet, etc.) and some have yielded conflicting, or inconsistent, results. Most case-control studies looking for risk factors have been hospital-based, or specialty clinic-based, and again may be biased toward more severe disease, limiting their value for the larger population with psoriasis. Broadly representative population-based studies of psoriasis reflecting the full spectrum of disease are lacking and needed because there are still wide gaps in our knowledge and understanding of psoriatic disease.

The CDC's psoriatic data collection effort will help to provide scientists and clinicians with critical information to further their understanding of: (a) how early intervention can prevent or delay the development of comorbid conditions; (b) what can trigger relapses and remissions; (c) some of the underlying causes of disease; (d) how differentiating lifestyle and other environmental triggers might lead to approaches that minimize exposure to these factors, thus reducing the incidence and severity of disease; and (e) best practice treatments, which in turn, would assist in streamlining appropriate patient care and help reduce the use of ineffective, unnecessary and costly treatments with challenging side effects.

PSORIASIS AND PSORIATIC ARTHRITIS RESEARCH AT NIH

It has taken nearly 30 years to understand that psoriasis is, in fact, not solely a disease of the skin, but also of the immune system. In recent years, scientists finally have identified some of the immune cells involved in psoriasis. The last decade has seen a surge in our understanding of these diseases, accompanied by new drug development. Scientists are poised, as never before, to make major breakthroughs.

Within the NIH, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is the principal Federal Government agency that currently supports psoriasis research. We commend NIAMS for its leadership role and very much appreciate its steadfast commitment to supporting psoriasis research. Additionally, we are pleased that research activities that relate to psoriasis or psoriatic arthritis also have been undertaken at the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Center for Research Resources (NCRR) and the National Human Genome Research Institute (NHGRI); however, the Foundation maintains that many more NIH institutes and centers—such as the National Heart, Lung, and Blood Institute (NHLBI) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)—have a role to play, especially with respect to the myriad comorbidities of psoriasis, as noted earlier. Although overall NIH funding levels improved for psoriasis research in fiscal year 2010, and funding was boosted through stimulus funding awards of $3 million in fiscal year 2009 and (an estimated) $2 million in fiscal year 2010, the Foundation remains concerned that total NIH funding generally is not keeping pace with psoriasis and psoriatic arthritis research needs. Our scientific advisors believe a strong Federal investment in genetic, immunological and clinical studies focused on understanding the mechanisms of psoriasis and psoriatic arthritis is needed.

Given the myriad factors involved in psoriatic disease and its comorbid conditions, the Foundation advocates increasing overall NIH funding, with a focus on the aforementioned institutes. We recognize and appreciate that the Nation faces significant budgetary challenges; however, we maintain that an increased investment in the Nation's biomedical research enterprise will help strengthen both the economy and our understanding of psoriasis and psoriatic arthritis.

CONCLUSION/SUMMARY

On behalf of the more than 7.5 million people with psoriasis and psoriatic arthritis, I want to thank the Committee for affording us the opportunity to submit written testimony regarding the fiscal year 2012 investments we believe are necessary

to ensure that our Nation adequately addresses the needs of individuals and families affected by psoriatic disease. By sustaining the Nation's biomedical research efforts at NIH, coupled with a specific allocation of $1.5 million for the CDC's psoriasis data collection efforts, Congress will help ensure that the Nation makes progress in understanding the connection between psoriasis and its comorbid conditions; uncovering the biologic aspects of psoriasis and other risk factors that lead to higher rates of comorbid conditions; and identifying ways to prevent and reduce the onset of comorbid conditions associated with psoriasis.

Please feel free to contact the Foundation at any time; we are happy to be a resource to Subcommittee members and your staff. Again, we very much appreciate the Committee's attention to, and consideration of, our fiscal year 2012 requests.

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## PREPARED STATEMENT OF THE NATIONAL REACH COALITION

The National REACH Coalition represents more than 40 communities and coalitions in 22 States working to eliminate racial and ethnic health disparities and improve the health of Native American/Native Hawaiian, African American, Latino, and Asian/Pacific Islander populations and communities. The coalition is an outgrowth of the Racial and Ethnic Approaches to Community Health (REACH U.S.) 2010 initiative, launched in 1999 by the Centers for Disease Control and Prevention (CDC). REACH programs are embedded in communities with disproportionately higher rates of chronic disease, hospitalization, and premature death than other cities and counties across the country. They provide coordination and leadership for the advancement and translation of community-based participatory research into evidence-based practices, policies, and community engagement.

For the fiscal year 2012 funding cycle, the National REACH Coalition requests the Labor, Health and Human Services, Education and Related Agencies (Labor-HHS) Subcommittee to fully fund, at current levels, the CDC's REACH program as a discrete line item in CDC's National Center for Chronic Disease Prevention and Health Promotion or as a specific initiative within the Public Health and Prevention Trust.

The NRC gratefully acknowledges the strong bipartisan support that the Senate Labor-HHS Subcommittee has provided to the REACH U.S. program over the years. Working in communities that are among the hardest hit by the recession, REACH programs provide a cost effective strategy to improve health outcomes and close the health gap. We understand the purpose of the newly established Community Transformation Grants (CTG) program to address health disparities in addition to chronic disease. However, the severity of discrepancy in health conditions among REACH-serving populations requires specific and intentional interventions and it is not sufficient for this to occur only through the CTG program. The generalized approach offered by CTG has been used over the last several decades and has resulted in no significant reduction in health disparities. Research data support the conclusion that to effectively close the gap in health outcomes in our country, there remains a definitive need for a program committed solely to the elimination of racial and ethnic health disparities.

REACH programs have been successful in mobilizing community resources, addressing policy, systems, and environmental change, and creating a shared vision to achieve healthy communities for racial and ethnic minorities. REACH programs focus on a variety of health issues, most notably chronic diseases such as cardiovascular disease, diabetes, HIV/AIDS, and cancer, as well as the contributors to these diseases, which include smoking, low physical activity, obesity, poor screening rates, and lack of prevention and disease management activities. Chronic diseases account for the largest health gap among racial and ethnic minority populations and are the Nation's leading cause of morbidity and mortality, accounting for 70 percent of all deaths. Collectively, chronic diseases are responsible for 75 cents of every dollar spent on healthcare in the United States.

REACH U.S. programs are working hard to eliminate these health disparities and many have seen successful outcomes in their communities. REACH programs nationwide have engaged hundreds of local coalition members and improved the lives of thousands of program participants. As a result, REACH communities are testing, evaluating, and implementing practice and evidence-based interventions that reduce the human and financial cost of these preventable diseases and associated risk factors. REACH has achieved significant policy and/or systems change in public policy, healthcare and preventative services, and health education.

Some of our recent successes in program intervention and policy change include:

—In South Carolina, the REACH Charleston and Georgetown Diabetes Coalition reports that a 21 percent gap in blood sugar testing between African Americans

and the general population has been virtually eliminated. Amputations among African-American males with diabetes have been reduced by over 33 percent.

—In Macon County, Alabama, the REACH Alabama Breast and Cervical Cancer Coalition reports that disparities in mammography screening between the general population and African American women decreased from 15 percent to 2 percent within 5 years.

—In Lawrence, Massachusetts, Latino CEED: REACH New England improved 14 healthcare indicators and outcomes for over 3200 Latinos with diabetes over the past decade, including four indicators now on par with the U.S. general population. One significant improvement was the percentage of Latino patients whose blood sugar was controlled, increasing from 15 percent to 45 percent as a result of REACH interventions.

—In New York City, Bronx Health REACH led local partners in the "1 percent Or Less" campaign to eliminate whole milk and reduce the availability of sweetened milk in NYC public schools, where 25 percent of children in elementary schools are obese. By eliminating whole milk, the NYC Department of Health and Mental Hygiene calculated that per student per year almost 5,960 calories and 619 grams of fat were eliminated, or more than one pound of weight per child per year.

—In South Los Angeles, Community Health Councils, a REACH grantee, addressed the lack of healthy food options in a predominantly African American community by advocating for local policy changes. These included an incentive package to attract 3 new grocery stores and sit-down restaurants into vulnerable communities and the adoption of an ordinance by the city to prohibit new stand-alone fast food restaurants within one half mile of an existing fast food chain.

In addition to the individual community improvements, data from the REACH national behavioral risk factor survey show that the REACH program is having a significant impact in risk reduction and disease management across communities and program wide. In 11 REACH communities evaluated between 2003 and 2009, there was meaningful improvement for all races in 34 out of 48 health risk factors, which include smoking prevalence, diabetes management, vaccination, and physical activity. REACH has demonstrated for the first time at a significant level that the elimination of health disparities is a "winnable battle".

The success of REACH communities in reducing health risk and improving patient compliance and disease management is particularly striking when compared to overall U.S. trends. Some recent data trends include:

—From 2001 to 2009, the smoking prevalence in REACH communities for Asian men decreased from 30.5 percent to 13.8 percent in contrast to the 16.9 percent of Asian men that smoke in the U.S. overall. Smoking prevalence in Hispanic men decreased from 28.8 percent to 17.6 percent in contrast to the 19 percent of Hispanic men that smoke in the U.S. overall.

—From 2001 to 2004, African Americans transitioned from being less likely to more likely than the general population to have their cholesterol checked.

—Health education interventions in REACH communities resulted in larger rates (as much as 66 percent) of improvement across racial and ethnic populations for smoking, physical activity, consumption of fruits and vegetables, etc., than national trends between 2001 and 2009.

In addition to improving health outcomes, REACH programs also build capacity in the communities in which they operate. REACH programs train community and coalition members to work at the grassroots level on health issues, which can lead to employment opportunities at local health centers or community outreach programs. REACH also builds the capacity of local organizations and institutions to better serve their communities by addressing disparities and distributing resources where they are most needed. REACH is broadening the field of public health by engaging the food retail industry, local parks and recreation departments, city and regional land use, planning, housing, and transportation agencies, as well as healthcare providers.

REACH communities across the United States have spent the last decade leveraging CDC funding with public private partnerships in order to effectively address health disparities. We have demonstrated through our research and our community programs that health disparities in racial and ethnic populations, once considered expected, are not intractable. Though we have made significant progress since REACH's inception, we could do a lot more. To move forward and eliminate health disparities, we must continue our work within underserved communities across the United States and build upon the successes achieved to date. Without continued funding for REACH programs, communities with high minority populations will continue to bear a disproportionate share of the national chronic disease

burden. This not only keeps vulnerable communities at an increased disadvantage, but drives up healthcare costs by requiring long-term and costly medical intervention to treat chronic diseases that may have been prevented or better managed.

The success and cost effectiveness of the REACH program would suggest it both practical and fiscally prudent to increase funding for the program to expand into additional communities across the country. However, given the current budget constraints we strongly urge the Committee to fully fund, at current levels, the CDC's REACH program in a discrete line item in CDC's National Center for Chronic Disease Prevention and Health Promotion or as a specific initiative within the Public Health and Prevention Trust. By doing so, we can continue our work in underserved communities and achieve marked improvements in the health of all Americans. We believe that our efforts will help to decrease the approximately 83,000 deaths that occur each year as a result of racial and ethnic health disparities, decrease the estimated $60 billion a year we spend in direct healthcare expenditures as a result of these disparities, and improve health access, quality, and outcomes for many people.

We thank you for this opportunity to present our views to this Subcommittee. We look forward to working with you to improve the health and safety of all Americans.

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## PREPARED STATEMENT OF THE NATIONAL RESPITE COALITION

Mr. Chairman, I am Jill Kagan, Chair of the ARCH National Respite Coalition, a network of respite providers, family caregivers, State and local agencies and organizations across the United States who support respite. Thirty State respite coalitions are also affiliated with the NRC. This statement is presented on behalf of the these organizations, as well as the members of the Lifespan Respite Task Force, a coalition of over 80 national and 100 State and local groups who supported the passage of the Lifespan Respite Care Act (Public Law 109–442). Together, we are requesting that the Subcommittee include funding for the Lifespan Respite Care Program administered by the U.S. Administration on Aging in the fiscal year 2011 Labor, HHS, and Education Appropriations bill at $50 million. Given the serious fiscal constraints facing the Nation, this request has been reduced by one-half below the previous fiscal year's authorized and requested amount. This will enable:

—State replication of best practices in Lifespan Respite to allow all family caregivers, regardless of the care recipient's age or disability, to have access to affordable respite, and to be able to continue to play the significant role in long-term care that they are fulfilling today;
—Improvement in the quality of respite services currently available;
—Expansion of respite capacity to serve more families by building new and enhancing current respite options, including recruitment and training of respite workers and volunteers; and
—Greater consumer direction by providing family caregivers with training and information on how to find, use and pay for respite services.

*Who Needs Respite?*

In 2009, a national survey found that over 65 million family caregivers are providing care to individuals of any age with disabilities or chronic conditions (Caregiving in the U.S. 2009. Bethesda, MD: National Alliance for Caregiving (NAC) and Washington, DC: AARP, 2009). Family caregivers provide an estimated $375 billion in uncompensated care, an amount almost as high as Medicare spending ($432 billion in 2007) and more than total spending for Medicaid, including both Federal and State contributions and both medical and long-term care ($311 billion in 2005) (Gibson and Hauser, 2008).

Family caregiving is not just an aging issue, but a lifespan one for the majority of the Nation's families. While the aging population is growing rapidly, the majority of family caregivers are caring for someone under age 75 (56 percent); 28 percent of family caregivers care for someone between the ages of 50–75, and 28 percent are caring for someone under age 50, including children (NAC and AARP, 2009). Many family caregivers are in the sandwich generation—46 percent of women who are caregivers of an aging family member and 40 percent of men also have children under the age of 18 at home (Aumann, Kerstin and Ellen Galinsky, et al. 2008). And 6.7 million children, are in the primary custody of an aging grandparent or other relative.

Families of the wounded warriors—those military personnel returning from Iraq and Afghanistan with traumatic brain injuries and other serious chronic and debilitating conditions—are at risk for limited access to respite. Even with enactment of the new VA Family Caregiver Support Program, the need for respite will remain high among all veterans and their family caregivers. Among family caregivers of

veterans whose illness, injury or condition is in some way related to military service surveyed in 2010, only 15 percent had received respite services from the VA or other community organization within the past 12 months. Caregivers whose veterans have PTSD are only about half as likely as other caregivers to have received respite services (11 percent vs. 20 percent) (NAC, Caregivers Of Veterans—Serving On The Homefront, November 2010). Sixty-eight percent of veterans' caregivers reported their situation as highly stressful compared to 31 percent of caregivers nationally who feel the same and three times as many say there is a high degree of physical strain (40 percent vs. 14 percent) (NAC, 2010). Veterans' caregivers specifically asked for up-to-date resource lists of respite providers in their local communities and help to find services—the very thing Lifespan Respite is charged to provide (NAC, 2010).

National, State and local surveys have shown respite to be the most frequently requested service of the Nation's family caregivers (Evercare and NAC, 2006). Other than financial assistance for caregiving through direct vouchers payments or tax credits, respite is the number one national policy related to service delivery that family caregivers prefer (NAC and AARP, 2009). Yet respite is unused, in short supply, inaccessible, or unaffordable to a majority of the Nation's family caregivers. The NAC 2009 survey found that despite the fact that among the most frequently reported unmet needs of family caregivers were "finding time for myself" (32 percent), "managing emotional and physical stress" (34 percent), and "balancing work and family responsibilities" (27 percent), nearly 90 percent of family caregivers across the lifespan are not receiving respite services at all.

Together, these family caregivers provide an estimated 80 percent of all long-term care in the United States. This percentage will only rise in the coming decades with an expected increase in the number of chronically ill veterans returning from war, greater life expectancies of individuals with Down's Syndrome and other disabling and chronic conditions, the aging of the baby boom generation, and the decline in the percentage of the frail elderly who are entering nursing homes.

*Respite Barriers and the Effect on Family Caregivers*

Barriers to accessing respite include reluctance to ask for help, fragmented and narrowly targeted services, cost, and the lack of information about how to find or choose a provider. Even when respite is an allowable funded service, a critically short supply of well-trained respite providers may prohibit a family from making use of a service they so desperately need. Lifespan Respite is designed to help States eliminate these barriers through improved coordination and capacity building.

While most families take great joy in helping their family members to live at home, however, it has been well documented that family caregivers experience physical and emotional problems directly related to their caregiving responsibilities. A majority of family caregivers (51 percent) caring for someone over the age of 18 have medium or high levels of burden of care, measured by the number of activities of daily living with which they provide assistance, and 31 percent of all family caregivers were identified as "highly stressed" ((NAC and AARP, 2009). While family caregivers of children with special healthcare needs are younger than caregivers of adults, they give lower ratings to their health. Only 4 out of 10 consider their health to be excellent or very good (44 percent) compared to 6 in 10 (59 percent) caregivers of adults; 26 percent say their health is fair or poor, compared to 16 percent of those caring for adults. Caregivers of children are twice as likely as the general adult population to say they are in fair/poor health (26 percent vs 13 percent) (Provisional summary Health Statistics for US Adults, National Health Interview Survey, 2008, dated August 2009).

The decline of family caregiver health is one of the major risk factors for institutionalization of a care recipient, and there is evidence that care recipients whose caregivers lack effective coping styles or have problems with depression are at risk for falling, developing preventable secondary complications such as pressure sores and experiencing declines in functional abilities (Elliott & Pezent, 2008). Care recipients may also be at risk for encountering abuse from caregivers when the recipients have pronounced need for assistance and when caregivers have pronounced levels of depression, ill health, and distress (Beach et al., 2005; Williamson et al., 2001).

Supports that would ease their burden, most importantly respite, are too often out of reach or completely unavailable. Even the simple things we take for granted, like getting enough rest or going shopping, become rare and precious events. Restrictive eligibility criteria also preclude many families from receiving services or continuing to receive services for which they once were eligible. A mother of a 12-year-old with autism was denied respite by her State DD (Developmental Disability) agency because she was not a single mother, was not at poverty level, was not exhibiting any

emotional or physical conditions herself, and had only one child with a disability. As she told us, "Do I have to endure a failed marriage or serious health consequences for myself or my family before I can qualify for respite? Respite is supposed to be a preventive service."

For the millions of families of children with disabilities, respite has been an actual lifesaver. However, for many of these families, their children will age out of the system when they turn 21 and they will lose many of the services, such as respite, that they currently receive. In fact, 46 percent of U.S. State units on aging identified respite as the greatest unmet need of older families caring for adults with lifelong disabilities.

Respite may not exist at all in some States for adult children with disabilities still living at home, or individuals under age 60 with conditions such as ALS, MS, spinal cord or traumatic brain injuries, or children with serious emotional conditions. In Tennessee, a young woman in her twenties gave up school, career and a relationship to move in and take care of her 53 year-old mom with MS when her dad left because of the strain of caregiving. Fortunately, she lives in Tennessee with a State Lifespan Respite Program. Now 31, she wrote, "And I was young—I still am—and I have the energy, but—it starts to weigh. Because we've been able to have respite care, it has made all the difference."

*Respite Benefits Families and is Cost Saving*

Respite has been shown to be a most effective way to improve the health and well-being of family caregivers that in turn helps avoid or delay out-of-home placements, such as nursing homes or foster care, minimizes the precursors that can lead to abuse and neglect, and strengthens marriages and family stability. A U.S. Department of Health and Human Services report prepared by the Urban Institute found that higher caregiver stress among those caring for the aging increases the likelihood of nursing home entry. Reducing key stresses on caregivers, such as physical strain and financial hardship, through services such as respite would reduce nursing home entry (Spillman and Long, USDHHS, 2007). The budgetary benefits that accrue because of respite are just as compelling. Delaying a nursing home placement for just one individual with Alzheimer's or other chronic condition for several months can save thousands of dollars. In an Iowa survey of parents of children with disabilities, a significant relationship was demonstrated between the severity of a child's disability and their parents missing more work hours than other employees. It was also found that the lack of available respite appeared to interfere with parents accepting job opportunities. (Abelson, A.G., 1999)

Moreover, data from an ongoing research project of the Oklahoma State University on the effects of respite care found that the number of hospitalizations, as well as the number of medical care claims decreased as the number of respite care days increased (Fiscal Year 1998 Oklahoma Maternal and Child Health Block Grant Annual Report, July 1999). A Massachusetts social services program designed to provide cost-effective family centered respite care for children with complex medical needs found that for families participating for more than 1 year, the number of hospitalizations decreased by 75 percent, physician visits decreased by 64 percent, and antibiotics use decreased by 71 percent (Mausner, S., 1995).

In the private sector, the Metropolitan Life Insurance Company and the National Alliance for Caregivers found that U.S. businesses lose from $17.1 billion to $33.6 billion per year in lost productivity of family caregivers. (MetLife and National Alliance for Caregiving, 2006). A more recent study from the National Alliance on Caregiving and Evercare demonstrated that the economic downturn has had a particularly harsh effect on family caregivers. Of the 6 in 10 caregivers who are employed, 50 percent of them are less comfortable during the economic downturn with taking time off from work to care for a family member or friend. A similar percentage (51 percent) says the economic downturn has increased the amount of stress they feel about being able to care for their relative or friend. Respite for working family caregivers could help improve job performance and employers could potentially save billions.

*Lifespan Respite Care Program Will Help*

The Lifespan Respite Care Program is based on the success of statewide Lifespan Respite programs in Oregon, Nebraska, Wisconsin and Oklahoma. The Federal Lifespan Respite program is administered by the U.S. Administration on Aging, Department of Health and Human Services (HHS). AoA provides competitive grants to State agencies in concert with Aging and Disability Resource Centers working in collaboration with State respite coalitions or other State respite organizations. The program was authorized at $53.3 million in fiscal year 2009 rising to $95 million in fiscal year 2011. Congress appropriated $2.5 million in fiscal year 2009 and again

in fiscal year 2010 and fiscal year 2011. Twenty-four States have received 3-year $200,000 Lifespan Respite Grants from AoA since 2009. Another 9 or 10 States are expected to receive grants by August 2011.

The purpose of the law is to expand and enhance respite services, improve coordination, and improve respite access and quality. States are required to establish State and local coordinated Lifespan Respite care systems to serve families regardless of age or special need, provide new planned and emergency respite services, train and recruit respite workers and volunteers and assist caregivers in gaining access to services. Those eligible would include family members, foster parents or other adults providing unpaid care to adults who require care to meet basic needs or prevent injury and to children who require care beyond that required by children generally to meet basic needs.

Lifespan Respite, which is a coordinated system of community-based respite services, helps States use limited resources across age and disability groups more effectively, instead of each separate State agency or community-based organization being forced to reinvent the wheel or beg for small pots of money. Pools of providers can be recruited, trained and shared, administrative burdens can be reduced by coordinating resources, and savings used to fund new respite services for families who may not qualify for existing Federal or State programs. For the growing number of veterans returning home with TBI or other polytrauma, the shortage of staff qualified to provide respite to this population is especially critical. Lifespan Respite systems can make all the difference by ameliorating special barriers for this population. The Government Accountability Office summarized the innovative activities being taken by the 24 States to implement these State Lifespan Respite Systems in its report to Congress, Respite Care: Grants and Cooperative Agreements Awarded to Implement the Lifespan Respite Care Act. GAO–11–28R, October 22, 2010.

The Administration recommended $10 million for Lifespan Respite in fiscal year 2012. This is a doubling of the Administration's previous request in fiscal year 2011 of $5 million as part of their Middle Class Initiative. We are heartened to see that support for family caregiving is recognized as a critical component of a typical family's economic and social well-being and extremely grateful for the Administration's support. Still, we must not neglect that fact that 90 percent of the Nation's family caregivers are not receiving respite at all. More than half of them are caring for someone under age 75 with MS, ALS, traumatic brain or spinal cord injury, mental health conditions, developmental disabilities or cancer. $10 million will not address the need for respite. Based on expenditures by State funded Lifespan Respite programs in the original best practice States, we estimate that an average sized State will need at least $1 million to build a Lifespan Respite System that can better coordinate its services and funding streams, maximize use of existing resources, and leverage new dollars in both the public and private sectors to build respite capacity and serve the unserved.

No other Federal program mandates respite as its sole focus. No other Federal program would help ensure respite quality or choice, and no current Federal program allows funds for respite start-up, training or coordination or to address basic accessibility and affordability issues for families. We urge you to include $50 million in the fiscal year 2012 Labor, HHS, Education appropriations bill so that Lifespan Respite Programs can be replicated in the States and more families, with access to respite, will be able to continue to play the significant role in long-term care that they are fulfilling today.

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## Prepared Statement of the National Rural Health Association

The National Rural Health Association (NRHA) is pleased to provide the Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittee with a statement for the record on fiscal year 2012 funding levels for programs with a significant impact on the health of rural America.

The NRHA is a national nonprofit membership organization with more than 20,000 members that provides leadership on rural health issues. The Association's mission is to improve the health of rural Americans and to provide leadership on rural health issues through advocacy, communications, education and research. The NRHA membership consists of a diverse collection of individuals and organizations, all of whom share the common bond of an interest in rural health.

The NRHA is advocating for continued full funding for a group of rural health programs that assist many rural communities in maintaining and building a strong healthcare delivery system into the future. Most importantly, these programs help increase the capacity of the rural healthcare delivery system. Additional capacity that will be absolutely necessary with the addition of many newly insured Ameri-

cans under the Patient Protection and Affordable Care Act. These programs have been successful in increasing access to healthcare in rural areas, helping communities create new health programs for those in need and training the future health professionals that will give care to rural America. With modest investments, these programs are able to evaluate, study, and implement quality improvement programs and health information technology systems.

While recognizing the constraints of the current economic and budgetary climate, we would like to remind you of the critical importance of these rural health programs and request modest increases to ensure that these programs do not lose any ground. Even small investments in these "rural health safety net" programs go a long way and generate big returns in rural communities. Cuts to these programs do more hard than good and in the long run the Federal government will pay a much higher cost should these rural programs go away.

Some important rural health programs supported by the NRHA are outlined below.

Rural Health Outreach and Network Grants provide capital investment for planning and launching innovative projects in rural communities that later become self-sufficient. These grants are unique in the Federal system as they allow the community to choose what is most important for their own situation and then build a program around that. These grants have led to projects dealing with obesity and diabetes, information technology networks, oral screenings, preventive services, and many other health concerns. Due to the community nature of the grants and a focus on self-sustainability after the terms of the grant have run out—85 percent of the Outreach Grantees continue to deliver services even 5 full years after Federal funding had ended. Request: $59.8 million

Rural Health Research and Policy forms the Federal infrastructure for rural health policy. Without these funds, rural America has no coordinated voice in the Department of Health and Human Services (HHS). In addition to the expertise provided to agencies such as the Centers for Medicare and Medicaid Services, this line item also funds rural health research centers across the country. These research centers provide the knowledge and the evidence needed for good policy making, both in the Federal Government and across the Nation. Additionally, we urge the Subcommittee to include in report language instructions to the Office of Rural Health Policy to direct additional funding to the State rural health associations. The State associations serve to coordinate rural health activities at the State level and have a strong record of positive outcomes. Request: $10.76 million

State Offices of Rural Health are the State counterparts to the Federal rural health research and policy efforts, and form the State infrastructure for rural health policy. They assist States in strengthening rural healthcare delivery systems by maintaining a focal point for rural health within each State and by linking small rural communities with State and Federal resources to develop long term solutions to rural health problems. Without these funds, States would have diminished capacity to administer many of the rural health programs that are so critical to access to care. Request: $10 million

Rural Hospital Flexibility Grants fund quality improvement and emergency medical service projects for Critical Access Hospitals across the country. This funding is essential. CAHs are by definition small hospitals with fewer than 25 beds; they do not have the size, volume or the expertise to do the types of quality improvement or information technology activities that they need to do. These grants allow statewide coordination and provide expertise to CAHs. Also funded in this line is the Small Hospital Improvement Program (SHIP), which provides grants to more than 1,500 small rural hospitals (50 beds or less) across the country to help improve their business operations, focus on quality improvement and to ensure compliance provisions related to health information privacy. Request: $43.46 million

Rural and Community Access to Emergency Devices assists communities in purchasing emergency devices and training potential first responders in their use. Defibrillators double a victim's chance of survival after sudden cardiac arrest, which an estimated 163,221 Americans experience every year. Request: $3.49 million

The Office for the Advancement of Telehealth supports distance-provided clinical services and is designed to reduce the isolation of rural providers, foster integrated delivery systems through network development and test a range of telehealth applications. Long-term, telehealth promises to improve the health of millions of Americans, provide constant education to isolated rural providers and save money through reduced office visits and expensive hospital care. These approaches are still new and unfolding and continued investment in the infrastructure and development is needed. Request: $12.3 million

National Health Service Corps (NHSC) plays a critical role in providing primary healthcare services to rural underserved populations by placing healthcare providers

in our Nation's most underserved communities. Invesment in our healthcare workforce is absolutely vital to support the newly insured population resulting from health reform. Programs like the NHSC help to maximize the capacity of our health system to care for patients. The Patient Protection and Affordable Care Act provided additional funding to the NHSC through the HHS Secretary's Community Health Center fund. The NRHA is supporting the President's request, which will ensure that the NHSC has access to the additional dedicated funding through the CHC Fund. Request: $173.2 million

Title VII Health Professions Training Programs (with a significant rural focus):

—Rural Physician Pipeline Grants will help medical colleges to develop special rural training programs and recruit students from rural communities, who are more likely to return to their home regions to practice. Newly created under the Patient Protection and Affordable Care Act, this "grow-your-own" approach is one of the best and most cost-effective ways to ensure a robust rural workforce into the future. Request: $

—Area Health Education and Centers (AHECs) financially support and encourage those training to become healthcare professionals to choose to practice in rural areas. Without this experience and support while in medical school, far fewer professionals would make the commitment to rural areas and facilities including Community Health Centers, Rural Health Clinics and rural hospitals. It has been estimated that nearly half of AHECs would shut down without Federal funding. The success of this program was recognized through increased authorized levels in the Patient Protection and Affordable Care Act. Request: $75 million

—Geriatric Programs train health professionals in geriatrics, including funding for Geriatric Education Centers (GEC). There are currently 47 GECs nationwide that ensure access to appropriate and quality healthcare for seniors. Rural America has a disproportionate share of the elderly and could see a shortage of health providers without this program. Request: $ 35.6 million

The NRHA appreciates the support throughout the fiscal year 2011 continuing resolution process and the opportunity to provide our recommendations for your fiscal year 2012 appropriations bill. Our request for continued funding for the rural health safety net is critical to maintaining access to high quality care in rural communities. We greatly appreciate the support of the Subcommittee and look forward to working with Members of Congress to continue making these important investments in rural health in fiscal year 2012 and into the future.

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PREPARED STATEMENT OF THE NATIONAL SENIOR CORPS ASSOCIATION

Mr. Chairman, Members of the Committee, I testify today on behalf of the National Senior Corps Association, representing the interests and ideals of 500,000 senior volunteers and the directors, staff, and friends of local Foster Grandparent, Senior Companion, and RSVP programs throughout the country.

The recent agreement for fiscal year 2011 appropriations included a 20 percent cut in funding for RSVP—a devastating setback that threatens to deny 100,000 seniors the opportunity to serve their communities. We urge that this funding be restored, first and foremost, and that the Corporation for National and Community Service (CNCS) take particular care to do so in protecting opportunities for senior volunteers without interruption.

For fiscal year 2012, NSCA requests $111,100,000 for the Foster Grandparent Program (FGP), $63,000,000 for RSVP, and $47,000,000 for the Senior Companion Program (SCP). This is an aggregate increase of $200,000 over the fiscal year 2010 enacted level. In addition, we support an appropriation of $5 million for demonstration projects to increase high school graduation rates through the Foster Grandparent Program and to support independent living for veterans through the Senior Companion Program.

SENIOR CORPS is a federally authorized and funded network of national service programs that provides older Americans with the opportunity to apply their life experiences to volunteer service. Senior Corps is comprised of the Foster Grandparent Program, RSVP, and the Senior Companion Program, through which Americans age 55 and older provide essential services to cost-effectively address critical community needs.

*Foster Grandparent Program*.—29,000 Foster Grandparents in 328 projects provide a cost-effective means to reach and support more than 280,000 at-risk children with special or exceptional needs annually who otherwise may not have the opportunity to receive individual assistance and attention from a caring adult. In 2009, Foster Grandparents volunteered 24.3 million hours.

—81 percent of children served demonstrated improvements in academic performance. Mentored children have reduced truancy resulting in reduced school costs and, ultimately, reduced high school dropout rates and increased lifetime earnings.
—90 percent demonstrated increased self-image. This includes improved health outcomes such as reductions in teen pregnancy and reduced or delayed use of tobacco, alcohol, or illicit drugs.
—56 percent reported improved school attendance leading to increased graduation rates, increased post-secondary education, and higher lifetime earnings.
—59 percent reported reduction in risky behavior, including reduced juvenile violence and property crimes, saving victim and court expenses, costly treatment of juvenile offenders, costs of adult crime, crime losses of victims and the societal costs of prosecuting and incarcerating adult offenders.
—In 2009, FGP volunteers mentored 41,767 children and youth, of which 5,400 were children of prisoners at high risk of repeating their parent's path.
—FGP intervention reduced need for social services, both short-term costs of counseling and long-term costs of public assistance.
—Based on conservative assumptions about outcomes and valuations, studies indicate a return benefit of $2.72 for every dollar of resources used for mentoring programs. (Analyzing the Social Return on Investment in Youth Mentoring Programs, prepared by: Paul A. Anton, Wilder Research; and Prof. Judy Temple, University of Minnesota).

*Foster Grandparent Program Profiles*.—Foster Grandparent Birda Dillon completed the ninth grade, worked doing factory assembly for 25 years, raised 20+ children—14 of her own as well as grandchildren. She is a remarkable Foster Grandparent as the following remarks from her teacher in Benton Harbor, Michigan begin to illustrate: "Grandma is so good with these students. She knows just how to work with them to get them to read the words themselves. She is positive and knows how to get the students to sound the words out. George is reading so much better. I was surprised when he told me recently, 'I need another book!'" I can't spend one-on-one time with them, and she can. Birda is one of the best reading tutors I've encountered in my many years of teaching. She knows all of the tricks and tools to help the students help themselves. She said much of what she knows she has learned through her training as a Foster Grandparent. I appreciate her giftedness very much. We hope we can be together for a long, long time." From Professional Volunteer who assists with site visits (a retired veteran teacher): "I complimented her on her teaching of reading and told her I was a reading teacher, too. I told her she was a natural! She said she hadn't had any formal training; she wished she'd been a teacher, and I told her she was." Three of the children Birda tutors have incarcerated parents.

Foster Grandparent Leila Williams: Leila serves in a first grade classroom at Washington Elementary School in Coloma, Michigan. "I had no idea how rewarding it would be. And I feel so much better. I love having a schedule, being busy, and I sleep so good at night. Thank you, for making my life better. I'm 91 years old, and getting younger." Leila is matched with two children with parents in active military service. Leila's teacher reports that as a result of Leila's one-on-one attention, her two assigned students have developed positive relationships with Leila, improved socialization skills and have both improved reading skills, especially sight word recognition and fluency.

*RSVP*.—405,000 RSVP volunteers contributed 62 million hours of service in 2009 through 741 projects nationwide working with more than 65,000 community organizations. The average cost to support one RSVP volunteer is approximately $145 a year, whereas the average annual value per volunteer is more than $3,000. RSVP volunteers saved local communities $1.25 billion in 2009.

—RSVP is continually strengthening its leadership role in engaging volunteers 55+ by providing nonprofit agencies with volunteers trained to recruit and coordinate other community members in support of the nonprofits mission and goals. In 2009, RSVP volunteers recruited 38,000 additional community volunteers.
—RSVP projects demonstrate that their volunteer services increase literacy scores for the 74,326 children they mentor—the National Education Association states the lowest hourly rate for teacher aides is $10.31 reflecting a savings of $16,858,623 in remedial reading assistance.
—24,370 RSVP volunteers increased the capacity of the organizations where they serve by enhancing both the quality and quantity of services.
—In 2009, RSVP volunteers mentored 6,400 children of prisoners at high risk of repeating their parent's path.

—RSVP volunteers provided 23,300 caregivers with respite services. A recent AARP survey of working caregivers reports that 30 percent of family caregivers either quit their jobs or reduce their work hours to take on more care giving responsibilities.
—RSVP volunteers supported 509,000 with Independent Living Services.
—30 percent of RSVP volunteers provided at least one service in the area of Health/Nutrition which includes in-home and congregate meals, food distribution/collection, immunization, etc. valued at more than $27 million.

*RSVP Program Profile*.—The Beginning Alcohol and Addictions Basic Education Studies (BABES) program has been operating successfully for many years in districts throughout the Portage County, Wisconsin RSVP service area. Each year, hundreds of second graders in the various districts learn from their puppet friends (via the RSVP volunteers) about complex issues like peer pressure, good decision-making, and asking for help.

In 2009, over 600 second graders participated in the program. The intermediate outcome states that teachers in the second grade classes will observe children using phrases from the presentations and reminding others about the lessons they have learned. In 2009, the target was exceeded as 21 teachers returned surveys and 90 percent (19) reported they observed children using phrases from the BABES presentations. Teacher comments included: (1) "They have brought up coping, decision-making, peer pressure and self image when we are reading other stories. They have made a connection from these lessons to what is going on in their world." (2) "One student came in from recess and said someone was peer pressuring her to do something on the playground. It was great hearing the term used!"

The end outcome states that students in second grade classes who complete the BABES program will show an increase in knowledge about alcohol and drug use and abuse and seeking help as measured on a pre/post test. In 2009, the target was exceeded as 74 percent (20 of 27 classes participating in BABES in 2009) of classes improved their scores on the post test by at least 10 percent.

While the program is successful because volunteers are willing to present the lessons, the coordination of the program is also an important piece. The RSVP Intergenerational Coordinator provides annual volunteer training, ensures volunteers have all the materials they need, works with the schools to schedule the program, ensures the pre and post tests are completed and returned and analyzes and reports the date collected to all the stakeholders.

*Senior Companion Program*.—15,200 Senior Companions serving in 194 projects provided 12.2 million hours of service helping 68,200 frail, homebound clients in need of assistance in order to remain living independently. Senior Companion Program services prevented premature and costly institutionalization at an annual savings well over $200 million. The national average cost for 1 year in a nursing home is $72,270; the assisted living facility yearly average cost is $37,572. One Senior Companion volunteer assists 2–6 homebound clients for the annual investment of $4,800.

—Senior Companions offered essential respite to nearly 9,000 primary caregivers who struggle to remain in the regular workforce while caring for their loved one.
—The Family Caregiver Alliance reports that families with long-term care responsibilities miss an average of 7.5 workdays each year.
—The MetLife Caregiving Cost Study of July 2006 reports the estimated cost to employers of full-time employed intense caregivers at a total of $17.1 billion in lost productivity annually as well as absenteeism, workday interruptions, costs due to crisis in care, supervision costs associated with caregiver employees, costs with unpaid leave and reducing hours from full-time to part-time.
—Clients have significant, long-term mental health benefits and reduced rates of depression saving $50–$75 a month in medication.
—Cost of stress management therapy for one caregiver ($125 per session) vs. respite provided by volunteer (4 hours of respite care = $10.60 plus mileage average cost of $3).
—Cost for a home health aide after a client's release from the hospital is $21 per hour as compared to $2.65 per hour for a Senior Companion volunteer (at no cost to clients).

*Senior Companion Program Profile*.—Julia, an 80 year old woman who is blind was faced with having to leave her home in Rochester, NY due to her inability to see and complete the tasks of daily living needed to stay independent. While she had home health aide service to help her bathe, dress and clean her apartment, her family wasn't able to be with her during the day and evening due to their work schedules and their own family commitments.

Julia was given two Senior Companion (SC) volunteers. One came each day mid-morning after the home health aide left and stayed until early afternoon. The SC kept Julia company, escorted her to the bathroom when needed, fixed lunch and ensured she was okay daily. The second SC came about 5 p.m. each evening. She fixed dinner, visited, cleaned up after dinner and helped Julia get ready and into bed each evening.

Between these two volunteers Julia was able to stay living at home an additional 5+ years. At an average cost of $70,000 annually for long term care compared to the cost of her SC services at approximately $4,800 annually per companion, a savings of over $300,000 was saved.

It has been stated that baby boomer and senior volunteers represent our Nation's single and fastest growing resource. During this unprecedented economic crisis facing our Nation, the number of baby boomer and senior volunteers should be greatly expanded and mobilized as solutions to the problems facing our local communities. NSCA's 2012 budget request will provide the opportunity for thousands more older adults to serve in their communities and enhance the lives of those most in need, including children with special needs, the frail and isolated elderly striving to maintain independence, and expanding the services of local non-profit agencies.

The 2010 national value of one hour of volunteer service was estimated at $21.36.

Senior Corps volunteers' 98.2 million service hours in 2010 = $2.1 billion savings.

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## Prepared Statement of the National Technical Institute for the Deaf

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2012 budget request for NTID, one of eight colleges of RIT, in Rochester, New York. Created by Congress by Public Law 89–36 in 1965, we provide university technical and professional education for students who are deaf and hard-of-hearing, leading to successful careers in high-demand fields for a sub-population of individuals historically facing high rates of unemployment and under-employment. We also provide baccalaureate and graduate level education for hearing students in professions serving deaf and hard-of-hearing individuals. As of fall 2010, NTID served a total of 1,521 students from across the Nation, including 1,263 deaf and hard-of-hearing undergraduate students and 147 hearing undergraduate students. NTID students live, study and socialize with more than 15,000 hearing students on the RIT campus.

NTID has fulfilled its mission with distinction for 43 years.

*Budget Request*

As shown below, NTID's fiscal year 2012 budget request was $64,677,000 in Operations and $2,000,000 in Construction, as part of a plan that would provide NTID with a total of $10,000,000 in Construction over the next 5 years to fund needed capital projects. The NTID request is a total of $66,677,000; the President's request is $63,037,000 in Operations and $2,000,000 in Construction, for a total of $65,037,000.

FISCAL YEAR 2012 BUDGET REQUEST STATUS

| | Operations | Construction | Total |
|---|---|---|---|
| NTID Request | $64,677,000 | $2,000,000 | $66,677,000 |
| President's Request [1] | 63,037,000 | 2,000,000 | 65,037,000 |
| Difference | 1,640,000 | ..... | 1,640,000 |

[1] For fiscal years 2009, 2010 and most likely, 2011, NTID's Operations budget has been funded at $63,037,000; the President's recommended Operations budget for fiscal year 2012 would mark four consecutive years of funding at the same amount.

For the past 3 years, NTID has been able to absorb the same level of funding in Operations primarily due to two factors: (1) a self-initiated budget-reduction/revenue enhancement campaign from fiscal year 2003 through fiscal year 2007; and (2) limited RIT-mandated salary increases in recent years. However, realized savings from the campaign now have been reallocated and are no longer available. Furthermore, the limited increases from fiscal year 2009 through fiscal year 2011 mean that NTID has fallen significantly behind its salary benchmarks. RIT has mandated a 3 percent salary increase for all faculty and staff in the coming fiscal year.

While NTID certainly would benefit from a budget increase to support upcoming strategic initiatives (see below), we understand the resource challenges facing the Committee this year. While an additional $1,640,000 beyond the President's recommended Operations funding for fiscal year 2012 is needed, we are amenable to

meeting this need by shifting funds designated in the President's 2012 budget from Construction to Operations. This would ensure NTID stays within the total allocation proposed in the President's 2012 budget of $65,037,000, and will allow us to better meet our Operations needs. In the meantime, we will continue to seek non-Federal funding to support immediate construction/renovation needs while continuing to communicate about critical long-term construction needs.

*Enrollment*

In fiscal year 2011 (fall 2010), we attracted the largest enrollment in our 43-year history. Truly a national program, NTID has enrolled students from all 50 States. Our current enrollment is 1,521. Over the last 5 years our enrollment has increased 22 percent (271 students). For fiscal year 2012, NTID anticipates maintaining this record high enrollment level. Our enrollment history over the last 5 years is shown below:

## NTID ENROLLMENTS: FIVE-YEAR HISTORY

| Fiscal Year | Deaf/Hard-of-Hearing Students | | | | Hearing Students | | | Grand total |
|---|---|---|---|---|---|---|---|---|
| | Undergrad | Grad RIT | MSSE | Subtotal | Interpreting Program | MSSE | Subtotal | |
| 2007 | 1,017 | 47 | 31 | 1,095 | 130 | 25 | 155 | 1,250 |
| 2008 | 1,103 | 51 | 31 | 1,185 | 130 | 28 | 158 | 1,353 |
| 2009 | 1,212 | 48 | 24 | 1,284 | 135 | 31 | 166 | 1,450 |
| 2010 | 1,237 | 38 | 32 | 1,307 | 138 | 29 | 167 | 1,474 |
| 2011 | 1,263 | 40 | 29 | 1,332 | 147 | 42 | 189 | 1,521 |

*Student Accomplishments*

For our graduates, over the past 5 years, an average of 93 percent have been placed in jobs commensurate with the level of their education (using the Bureau of Labor Statistics methodology). Of our fiscal year 2009 graduates (the most recent class for which numbers are available), 59 percent were employed in business and industry, 21 percent in education/nonprofits, and 20 percent in Government.

Graduation from NTID has a demonstrably positive effect on students' earnings over a lifetime, and results in a noteworthy reduction in dependence on Supplemental Security Income (SSI), Social Security Disability Insurance (SSDI) and public assistance programs. In fiscal year 2007, NTID, the Social Security Administration, and Cornell University examined approximately 13,000 deaf and hard-of-hearing individuals who applied and attended NTID over our entire history. We learned that graduating from NTID has significant economic benefits. By age 50, deaf and hard-of-hearing baccalaureate graduates earned on average $6,021 more per year than those with associate degrees, who in turn earned $3,996 more per year on average than those who withdrew before graduation. Students who withdrew earned $4,329 more than those not admitted. Students who withdrew experienced twice the rate of unemployment as graduates.

The same studies showed 78 percent of these individuals were receiving SSI benefits at age 19, but when they were 50 years old, only 1 percent of graduates drew these benefits, while on average 19 percent of individuals who withdrew or were not admitted continued to participate in the SSI program. Graduates also accessed SSDI, an unemployment benefit, at far lesser rates than students who withdrew; by age 50, 34 percent of non-graduates were receiving SSDI, while 22 percent of baccalaureate graduates and 27 percent of associate graduates were receiving them. Considering the reduced dependency on these Federal income support programs, the Federal investment in NTID returns significant societal dividends.

NTID clearly makes a significant, positive difference in earnings, and in lives.

*Strategic Initiatives Beginning Fiscal Year 2011*

In 2010, NTID completed Strategic Decisions 2020, a strategic plan based on our founding mission statement. This statement sets forth our institutional responsibility to work with students to develop their academic, career and life-long learning skills as future contributors in a rapidly changing world. It also recognizes our role as a special resource for preparing individuals who are deaf and hard-of-hearing, for conducting applied research in areas critical to the advancement of individuals who are deaf and hard-of-hearing, and for disseminating our collective and cumulative expertise.

Strategic Decisions 2020 establishes key initiatives responding to future challenges and shaping future opportunities. These initiatives, which began implementation in fiscal year 2011, include:

—Pursuing enrollment targets and admissions and programming strategies that will result in increasing numbers of our graduates achieving baccalaureate degrees and higher, while maintaining focus and commitment to quality associate-level degree programs leading directly to the workplace;

—Improving services to under-prepared students through working with regional partners to implement intensive summer academic preparation programs in selected high-growth, ethnically diverse areas of the country. Through this initiative, NTID will identify those students demonstrating promise for success in career-focused degree-level programs and beyond, and provide consultation to others regarding postsecondary educational alternatives;

—Expanding NTID's role as a National Resource Center of Excellence regarding the education of deaf and hard-of-hearing students in senior high school (grades 10, 11 and 12) and at the postsecondary level. Components of this role as a National Resource Center of Excellence will include:

—*Center for Excellence in STEM Education*.—NTID currently is working to develop an externally funded Center of Excellence on STEM Education for Deaf and Hard-of-Hearing Students. This is an example of making our expertise available nationally and enhancing deaf and hard-of-hearing students' access to STEM fields.

—*NTID Research Centers*.—NTID will organize research resources into Research Centers focused on the following strategic areas of research: Teaching and Learning; Communication; Technology, Access, and Support Services; and Employment and Adaptability to Social Changes and the Global Workplace.

—*Outreach Programs*.—Extending outreach activities to junior and senior high school students who are deaf and hard-of-hearing, many of who represent AALANA populations, to expand their horizons regarding a college education. We also support other colleges and universities serving students who are deaf

and hard-of-hearing, as well as post-college adults who are deaf and hard-of-hearing.

—Enhancing efforts to become a recognized national leader in the exploration, adaptation, testing, and implementation of new technologies to enhance access to, and support of, learning by deaf and hard-of-hearing individuals.

*NTID Academic Programs*

NTID offers high quality, career-focused associate degree programs preparing students for specific well-paying technical careers. NTID also is expanding the number of its transfer associate degree programs, currently numbering seven, to better serve the higher achieving segment of our student population seeking bachelor's and master's degrees in an increasingly demanding marketplace. These transfer programs provide seamless transition to baccalaureate studies in the other colleges of RIT. In support of those deaf and hard-of-hearing students enrolled in the other RIT colleges, NTID provides a range of access services (including interpreting, real-time speech-to-text captioning, and note-taking) as well as tutoring services. One of NTID's greatest strengths is our outstanding track record of assisting high-potential students to gain admission to, and graduate from, the other colleges of RIT at rates comparable to their hearing peers.

A cooperative education (co-op) component is an integral part of academic programming at NTID and prepares students for success in the job market. A co-op gives students the opportunity to experience a real-life job situation and focus their career choice. Students develop technical skills and enhance vital personal skills such as teamwork and communication, which will make them better candidates for full-time employment after graduation. Over 250 students each year participate in 10-week co-op experiences that augment their academic studies, refine their social skills, and prepare them for the competitive working world.

*Summary*

It is extremely important that our funding be provided at the full level requested by the President as we continue our mission to prepare deaf and hard-of-hearing people to enter the workplace and society. We ask only that the funds provided by the President for Construction be moved into Operations.

Our alumni have demonstrated that they can achieve independence, contribute to society, and find sustainable employment as a result of NTID. Research shows that NTID graduates over their lifetimes are employed at much higher rates, earn substantially more (therefore paying significantly more in taxes), and participate at a much lower rate in SSI, SSDI, and public assistance programs than those who withdraw or who apply but do not attend NTID.

We are hopeful that the members of the Committee will agree that NTID, with its long history of successful stewardship of Federal funds and outstanding educational record of service with people who are deaf and hard-of-hearing, remains deserving of your support and confidence.

FISCAL YEAR 2012 NTID BUDGET REQUEST

FISCAL YEAR 2012 NTID BUDGET STATUS

| | Operations | Construction | Total |
|---|---|---|---|
| NTID fiscal year 2011 funding | $65,437,000 | $240,000 | $65,677,000 |
| NTID original request | 64,677,000 | 2,000,000 | 66,677,000 |
| NTID updated request [1] | 65,437,000 | 1,240,000 | 66,677,000 |

[1] Note: Our updated request keeps within the limits of our original request; however, it moves money from our Construction request to maintain our Operations funding at the 2011 level.

*Context*

Enrollment is the highest in NTID history with 1,521 students, a 22 percent increase over the past 5 years.

In an effort to maximize non-Federal revenues, NTID increased tuition by 5 percent for fiscal year 2012. From fiscal year 2006-fiscal year 2012, student tuition has increased by 40 percent.

Support for NTID is an investment with significant returns in the form of increased employment and reduced dependence on Federal SSI and SSDI payments for our students. NTID's employment rate in 2010 was 89 percent in spite of a challenging job market and averages to be 93 percent over the past 5 years.

Prior to fiscal year 2011, NTID had received $63,037,000 in Operations for 2009 and 2010 and was slated to receive that sum again in 2011. NTID was able to accommodate level funding in the past through a combination of additional non-Fed-

eral revenues and targeted fiscal control strategies with minimal impact on services and programs for students. However, the $65,437,000 that NTID received in Operations for fiscal year 2011 was crucial in order to offset record student enrollment and use of access services, prevent enrollment caps, and avoid the elimination of outreach programs, equipment purchases, and matching endowments.

NTID's updated budget request for fiscal year 2012 maintains Operations funding at the fiscal year 2011 level, to support our increased enrollment, increased provision of services, and upcoming strategic initiatives. It contains $1,240,000 requested for Construction to begin major renovations to a building designed 30 years ago that houses 3 major NTID programs.

*Possible actions if less than fiscal year 2011 operations funding received*

*Limit admission of new students for Fall 2012*.—NTID has never limited the number of qualified students who can enroll—to do so would mean denying deaf and hard-of-hearing students the opportunity to receive a state-of-the-art technical education with the unparalleled access services found at NTID.

*Hiring freeze and possible staff furloughs*.—83 percent of NTID's resources support salaries/wages—NTID would have to reduce expenditures with a hiring freeze and possible furlough of staff, leaving positions vacant while serving more students than ever before.

*Substantial reduction or elimination of summer outreach programs*.—This would affect deaf and hard-of-hearing pre-college youth, especially young women and African-American and Latino-American youth, by eliminating programs that encourage them to continue on to college, especially in the STEM fields.

*Substantial reduction or elimination of equipment purchases*.—NTID's mission is to prepare deaf and hard-of-hearing students for technical and professional careers in fields characterized by cutting-edge technologies. Without the most technologically updated equipment available, the education of our students will be impaired significantly.

*Substantial reduction or elimination of matching endowment funds*.—NTID would be unable to fulfill its commitment to match endowment donations to the Institute, decreasing the level of scholarship support for students.

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## PREPARED STATEMENT OF NEMOURS

Nemours thanks Chairman Harkin, Ranking Member Shelby and members of the Subcommittee for the opportunity to submit written testimony on the fiscal year 2012 Labor, Health and Human Services, Education and Related Agencies Appropriations bill. Nemours, one of the Nation's leading child health systems, is dedicated to improving children's health and well-being by offering a spectrum of clinical treatment, research, advocacy, educational health, and prevention services extending to families in the communities it serves.

*About Nemours*

Nemours has developed a model of care that integrates clinical preventive and treatment services for children with population-based prevention initiatives. No other health system in the Nation has made the same level of investment in community-based prevention programs, policies and practices to reach all children in the community, not just those who cross our doors. Nemours Health and Prevention Services (NHPS) has developed a comprehensive, multi-sector obesity prevention initiative to reach all children in Delaware. To achieve the greatest impact, NHPS considers the many places where children and families spend their time: schools, child care, healthcare settings, community centers and neighborhoods. The goal is to reinforce consistent messages through policy and practice changes in each setting to help children make healthy food and lifestyle choices and to stay physically active.

In school settings, NHPS works with district-level teams of administrators, teachers, counselors, school nurses, parents and students to encourage wellness policies and provide training and educational tools that support policy and environmental changes to encourage healthier eating and more physical activity on school campuses. In the child care setting, Nemours worked with government leaders to help Delaware become a frontrunner for policies that support healthy eating and physical activity. NHPS provides training and educational tools to help child care providers promote healthy behaviors for young children.

In the primary care setting, Nemours convened pediatric primary care providers from across the State to participate in a learning collaborative focused on improving office-based weight management and health promotion skills. Practitioners learned about new interventions and received tools for use in the office setting, as well as take-home materials for families. In the community, NHPS works with youth-serv-

ing organizations to promote healthy eating and physical activity and to develop champions who will model the behavior and help spread the message. We also work to create an environment that promotes healthy lifestyles.

*Community-based Prevention*

As an integrated health system that is very engaged with the community, Nemours sees first-hand the impact of chronic disease on our Nation's children. We treat obese young children at our clinics, and we know that unhealthy habits that contribute to obesity are starting at a very young age. In fact, nationally, over 24 percent of children ages 2–5 are already overweight or obese. Much of what influences their health is outside the realm of the healthcare system, which is why we have made and will continue to make significant investments in community-based prevention. We believe that investing in clinical and community-based prevention is an important way to ensure that children grow up to be healthy adults. We are supportive of the Prevention and Public Health Fund and urge the Committee to utilize the resources provided from this Fund to support the integration of clinical and community-based prevention and to evaluate the outcomes associated with those investments. In particular, we are supportive of Community Transformation Grants.

Community Transformation Grants draw upon the best of what we know works: strong coalitions, multi-sector, public-private partnerships, evidence-based approaches, and evaluation. In Delaware, Nemours has successfully used this combination of approaches to stem the rising childhood obesity curve between 2006 and 2008. These grants allow us to build upon this foundation and spread what works to other communities. The purpose of the grants is to support the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence-base of effective prevention programming. In short, these grants would help us in our efforts to help children grow up healthy. If we are serious about the commitment to improving health, then we need to transform the places where children live, learn and play, which is exactly what these grants are designed to accomplish. We urge the Committee to provide $221.06 million for Community Transformation Grants in fiscal year 2012, which is the level requested by the President.

*Children's Hospital Graduate Medical Education*

Another important priority for Nemours is the healthcare workforce, particularly the pediatric workforce. Children's hospitals care for large numbers of children with complex health conditions. In order to achieve high quality clinical care and outcomes, these specialty hospitals need to have well-trained residents and physicians. The Children's Hospital Graduate Medical Education program (CHGME) provides support for graduate medical education to freestanding children's hospitals that train resident physicians. The CHGME program was created to correct an unintended inequity in the GME financing system, which is tied to the number of Medicare beneficiaries being treated at a hospital. Freestanding children's hospitals generally do not provide care to Medicare-eligible patients, and were therefore largely left out of the GME financing system. The CHGME program has addressed this issue.

CHGME supports 55 freestanding children's hospitals that train approximately 40 percent of all pediatricians, 43 percent of all pediatric specialists, and many pediatric researchers and physicians who require pediatric training. In 2009, CHGME supported the training of 5,439 pediatric resident physicians. This is a very important contribution to training our pediatric workforce, which continues to experience shortages, particularly in pediatric specialty care. A 2009 survey by the National Association of Children's Hospitals and Related Institutions (NACHRI) found that national shortages contribute to vacancies in children's hospitals that commonly last 12 months or longer for a number of pediatric specialties. These vacancies often result in longer wait times for children to see pediatric specialists.

At the Alfred I. duPont Hospital for Children, over 300 residents are trained each year. Under the supervision of physicians, these residents provide care for inpatients and also provide primary and specialty care in outpatient settings, including clinics. In 2010, CHGME covered approximately 54 percent of the cost of the Nemours residency program.

Unfortunately, the President's budget proposes to eliminate funding for this critical program. We urge Congress to reject this short-sighted cut and to continue to provide support for training the next generation of pediatricians, pediatric specialists and pediatric researchers. Nemours urges the Subcommittee to provide $317.5

million for CHGME in fiscal year 2012, the same amount that was provided in fiscal year 2010.

*Conclusion*

Nemours appreciates the opportunity to submit written testimony. As an integrated child health system, we have prioritized investments in clinical and community-based prevention and our workforce because we believe that in the long-run these investments will bend the health curve and the cost curve. We recognize that the Nation's fiscal situation requires a close examination of the programs and priorities that the Federal Government funds. As you make these critical funding decisions, we hope that prevention and the healthcare workforce will remain priorities of the Subcommittee in fiscal year 2012.

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PREPARED STATEMENT OF THE NEPHCURE FOUNDATION

Nephrotic syndrome (NS) is a collection of signs and symptoms caused by diseases that attack the kidney's filtering system. These diseases include focal segmental glomerulosclerosis (FSGS), Minimal Change Disease (MCD) and Membranous Nephropathy (MN). When affected, the kidney filters leak protein from the blood into the urine and often cause kidney failure which requires dialysis or kidney transplantation. According to a Harvard University report, 73,000 people in the United States have lost their kidneys as a result of FSGS. Unfortunately, the causes of FSGS and other filter diseases are very poorly understood.

FSGS is the second leading cause of NS and is especially difficult to treat. There is no known cure for FSGS and current treatments are difficult for patients to endure. These treatments include the use of steroids and other dangerous substances which lower the immune system and contribute to severe bacterial infections, high blood pressure and other problems in patients, particularly child patients. In addition, children with NS often experience growth retardation and heart disease. Finally, NS caused by FSGS, MCD or MN is idiopathic and can often reoccur, even after a kidney transplant.

FSGS disproportionately affects minority populations and is five times more prevalent in the African American community. In a groundbreaking study funded by NIH, researchers found that FSGS is associated with two APOL1 gene variants. These variants are common in African Americans but not in European Americans, and it is thought that these variants developed as an evolutionary response to African sleeping sickness.

FSGS also has a large social impact on the United States. FSGS leads to end-stage renal disease (ESRD) which is one of the most costly chronic diseases to manage. In 2007, the Medicare program alone spent $24 billion, 6 percent of its entire budget, on ESRD. In 2005, FSGS accounted for 12 percent of ESRD cases in the United States, at an annual cost of $3 billion. It is estimated that there are currently approximately 20,000 Americans living with ESRD due to FSGS.

Research on FSGS could achieve tremendous savings in Federal healthcare costs and reduce health status disparities—both critical and appropriate themes of the current administration. For this reason, and on behalf of the thousands of families that are significantly affected by this disease, we recommend the following:

—$35 billion for the National Institutes of Health (NIH) and a corresponding increase to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
—Continue to support the Nephrotic Syndrome Rare Disease Clinical Research Network at the Office of Rare Diseases Research (ORDR).
—Support continued expansion of the FSGS/NS research portfolio at NIDDK and the National Institute on Minority Health and Health Disparities (NIMHD) by funding more research proposals for glomerular disease.
—Support awareness activities through the Centers for Disease Control and Prevention Chronic Kidney Disease Program.

*Encourage FSGS/NS Research at NIH*

There is no known cause or cure for FSGS and scientists tell us that much more research needs to be done on the basic science behind FSGS/NS. More research could lead to fewer patients undergoing ESRD and tremendous savings in healthcare costs in the United States.

With collaboration from other Institutes and Centers, ORDR established the Rare Disease Clinical Research Network. This network provided an opportunity for the NephCure Foundation, the University of Michigan, and other university research health centers to come together to form the Nephrotic Syndrome Study Network (NEPTUNE). NEPTUNE is a relatively new collaboration and has tremendous po-

tential to make significant advancements in NS and FSGS research because it pools resources and develops a database of NS patients who are interested in participating in clinical trials. The addition of Federal resources, as well as NIH coordination of this important initiative, is crucial to ensuring the best possible outcomes for RDCRN and NEPTUNE.

The NephCure Foundation is also grateful to the NIDDK for issuing a program announcement (PA) that serves to initiate grant proposals on glomerular disease. This PA was issued in March of 2007 and utilizes utilize the R01 mechanism to award funding to glomerular disease researchers. In February, 2010 the PA was re-released and is now scheduled to expire in 2013. We ask the subcommittee to encourage NIDDK to continue to issue glomerular disease PAs.

Due to the disproportionate burden of FSGS on minority populations, the NephCure Foundation feels that it is appropriate for NIMHD to develop an interest in this research. However, NIMHD has not supported any research on FSGS. We ask the Subcommittee to encourage ORDR, NIDDK, and NIMHD to collaborate on research that studies the incidence and cause of this disease among minority populations. We also ask the Subcommittee to urge NIDDK and the NIMHD undertake culturally appropriate efforts aimed at educating minority populations about glomerular disease.

*Raise Glomerular Disease Awareness at CDC*

When glomerular disease strikes, the resulting NS causes a loss of protein in the urine and edema. The edema often manifests itself as puffy eyelids, a symptom that many parents and physicians mistake as allergies. With experts projecting a substantial increase in nephrotic syndrome in the coming years, there is a clear need to educate pediatricians and family physicians about glomerular disease and its symptoms.

It would be of great benefit for CDC to begin raising public awareness of the glomerular diseases in an attempt to diagnose patients earlier.

We ask the Subcommittee to encourage CDC to establish a glomerular disease education and awareness program aimed at both the general public and healthcare providers.

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PREPARED STATEMENT OF NEUROFIBROMATOSIS, INC.

Thank you for the opportunity to submit testimony to the Subcommittee on the importance of continued funding at the National Institutes of Health (NIH) for Neurofibromatosis (NF), a terrible genetic disorder closely linked to many common diseases widespread among the American population.

On behalf of Neurofibromatosis, Inc., a national coalition of NF advocacy groups, I speak on behalf of the 100,000 Americans who suffer from NF as well as approximately 175 million Americans who suffer from diseases and conditions linked to NF such as cancer, brain tumors, heart disease, memory loss and learning disabilities. Thanks in large measure to this Subcommittee's strong and enduring support, scientists have made enormous progress since the discovery of the NF1 gene in 1990 resulting in clinical trials now being undertaken at NIH with broad implications for the general population.

*What is Neurofibromatosis (NF)?*

NF is a genetic disorder involving the uncontrolled growth of tumors along the nervous system which can result in terrible disfigurement, deformity, deafness, blindness, brain tumors, cancer, and even death. NF can also cause other abnormalities such as unsightly benign tumors across the entire body and bone deformities. In addition, approximately one-half of children with NF suffer from learning disabilities. While not all NF patients suffer from the most severe symptoms, all NF patients and their families live with the uncertainty of not knowing whether they will be seriously affected because NF is a highly variable and progressive disease.

NF is not rare. It is the most common neurological disorder caused by a single gene and three times more common than Muscular Dystrophy and Cystic Fibrosis combined, but it is not widely known because it has been poorly diagnosed for many years. Approximately 100,000 Americans have NF, and it appears in approximately 1 in every 2,500 births. It strikes worldwide, without regard to gender, race or ethnicity. Approximately 50 percent of new NF cases result from a spontaneous mutation in an individual's genes and 50 percent are inherited. There are three types of NF: NF1, which is more common, NF2, which primarily involves tumors causing deafness and balance problems, and schwannomatosis, the hallmark of which is severe pain. In addition, advances in NF research stand to benefit over 175 million

Americans in this generation alone because NF is directly linked to many of the most common diseases affecting the general population.

When a child is diagnosed with NF it means tumors can grow anytime, anywhere on his/her nervous system, from the day he/she is born until the day he/she dies with no way to predict when or how severely the tumors will affect his/her body—and no viable way to treat the disease outside of surgery—which often results in more tumors that grow twice as fast. That same child then has a 50 percent chance to pass the gene to his/her children. That is an overwhelming diagnosis and it bears repeating: NF is one of the most common genetic disorders in our country and has no cure and no viable treatment. But that is changing. The immediate future holds real promise.

*Link to Other Illnesses*

Researchers have determined that NF is closely linked to cancer, heart disease, learning disabilities, memory loss, brain tumors, and other disorders including deafness, blindness and orthopedic disorders, primarily because NF regulates important pathways common to these disorders such as the RAS, cAMP and PAK pathways. Research on NF therefore stands to benefit millions of Americans:

*Cancer*.—NF is closely linked to many of the most common forms of human cancer, affecting approximately 65 million Americans. In fact, NF shares these pathways with 70 percent of human cancers. Research has demonstrated that NF's tumor suppressor protein, neurofibromin, inhibits RAS, one of the major malignancy causing growth proteins involved in 30 percent of all cancer. Accordingly, advances in NF research may well lead to treatments and cures not only for NF patients, but for all those who suffer from cancer and tumor-related disorders. Similar studies have also linked epidermal growth factor receptor (EGF–R) to malignant peripheral nerve sheath tumors (MPNSTs), a form of cancer which disproportionately strikes NF patients.

*Heart disease*.—Researchers have demonstrated that mice completely lacking in NF1 have congenital heart disease that involves the endocardial cushions which form in the valves of the heart. This is because the same ras involved in cancer also causes heart valves to close. Neurofibromin, the protein produced by a normal NF1 gene, suppresses ras, thus opening up the heart valve. Promising new research has also connected NF1 to cells lining the blood vessels of the heart, with implications for other vascular disorders including hypertension, which affects approximately 50 million Americans. Researchers believe that further understanding of how an NF1 deficiency leads to heart disease may help to unravel molecular pathways involved in genetic and environmental causes of heart disease.

*Learning disabilities*.—Learning disabilities are the most common neurological complication in children with NF1. Research aimed at rescuing learning deficits in children with NF could open the door to treatments affecting 35 million Americans and 5 percent of the world's population who also suffer from learning disabilities. In NF1 the neurocognitive disabilities range includes behavior, memory and planning. Recent research has shown there are clear molecular links between autism spectrum disorder and NF1; as well as with many other cognitive disabilities. Tremendous research advances have recently led to the first clinical trials of drugs in children with NF1 learning disabilities. These trials are showing promise. In addition because of the connection with other types of cognitive disorders such as autism, researchers and clinicians are actively collaborating on research and clinical studies, pooling knowledge and resources. It is anticipated that what we learn from these studies could have an enormous impact on the significant American population living with learning difficulties and could potentially save Federal, State, and local governments, as well as school districts, billions of dollars annually in special education costs resulting from a treatment for learning disabilities.

*Memory loss*.—Researchers have also determined that NF is closely linked to memory loss and are now investigating conducting clinical trials with drugs that may not only cure NF's cognitive disorders but also result in treating memory loss as well with enormous implications for patients who suffer from Alzheimer's disease and other dementias.

*Deafness*.—NF2 accounts for approximately 5 percent of genetic forms of deafness. It is also related to other types of tumors, including schwannomas and meningiomas, as well as being a major cause of balance problems.

*Scientific Advances*

Thanks in large measure to this Subcommittee's support; scientists have made enormous progress since the discovery of the NF1 gene in 1990. Major advances in just the past few years have ushered in an exciting era of clinical and translational research in NF with broad implications for the general population.

These recent advances have included:
—Phase II and Phase III clinical trials involving new drug therapies for both cancer and cognitive disorders;
—Creation of a National Clinical and Pre-Clinical Trials Infrastructure and NF Centers;
—Successfully eliminating tumors in NF1 and NF2 mice with the same drug;
—Developing advanced mouse models showing human symptoms;
—Rescuing learning deficits and eliminating tumors in mice with the same drug;
—Determining the biochemical, molecular function of the NF genes and gene products; and
—Connecting NF to more and more diseases because of NF's impact on many body functions.

*Congressional support for NF research*

The enormous promise of NF research, and its potential to benefit over 175 million Americans who suffer from diseases and conditions linked to NF, has gained increased recognition from Congress and the NIH. This is evidenced by the fact that 12 institutes at NIH are currently supporting NF research (NCI, NHLBI, NINDS, NIDCD, NHGRI, NCRR, NIMH, NIGMS, NEI, NIA, NICHD, and OD), and NIH's total NF research portfolio has increased from $3 million in fiscal year 1990 to an estimated $24 million in fiscal year 2011. Given the potential offered by NF research for progress against a range of diseases, we are hopeful that NIH will continue to build on the successes of this program by funding this promising research and thereby continuing the enormous return on the taxpayers' investment.

We respectfully request that you include the following report language on NF research at the National Institutes of Health within your fiscal year 2012 Labor, Health and Human Services, Education Appropriations bill.

*Neurofibromatosis [NF].*—NF is an important research area for multiple NIH Institutes; therefore the Committee supports efforts to increase funding and resources toward NF research and treatment. As NF is connected to many forms of cancer in children and adults; the Committee encourages the NCI to substantially increase its NF research portfolio in pre-clinical and clinical trials by applying newly developed and existing drugs. The Committee also encourages the NCI to support NF centers, clinical trials consortia, patient databases, and biospecimen repositories. The Committee also urges additional focus from the NHLBI, given NF's involvement with hypertension and congenital heart disease. Because NF causes tumors to grow on the nerves throughout the body, the Committee urges the NINDS to continue aggressive research on nerve damage and repair which has strong implications not only for NF but for spinal cord and brain injury, learning disabilities and attention deficit disorders. In addition, the Committee continues to encourage the NICHD and NIMH to expand funding of clinical trials for NF patients in the area of learning disabilities. Children with NF1 are prone to the development of severe bone deformities, including scoliosis; the Committee encourages NIAMS to expand its NF1 research portfolio. NF2 accounts for approximately 5 percent of genetic forms of deafness; the Committee therefore encourages the NIDCD to expand its NF2 research portfolio. The Committee encourages NEI to expand its NF research portfolio to advance the cause of treating Optic gliomas, vision loss and cataracts, major clinical problems associated with NF. The Committee encourages the NHGRI to expand its NF portfolio given that NF represents an ideal model to study the genomics of cancer predisposition, learning and behavior, and bone disease translatable to personalized medicine for affected individuals.

We appreciate the Subcommittee's strong support for NF research and will continue to work with you to ensure that opportunities for major advances in NF research are aggressively pursued. Thank you.

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## PREPARED STATEMENT OF THE NURSING COMMUNITY

The Nursing Community is a forum for professional nursing organizations to collaborate on a wide spectrum of healthcare and nursing issues, including practice, education, and research. These 56 organizations are committed to promoting America's health through nursing care. Collectively, the Nursing Community represents over 850,000 Registered Nurses (RNs), Advanced Practice Registered Nurses (APRNs—including certified nurse-midwives, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists), nurse executives, nursing students, nursing faculty, and nurse researchers. Together, our organizations work collaboratively to increase funding for the Nursing Workforce Development programs (authorized under Title VIII of the Public Health Service Act [42 U.S.C. 296 et

seq.]), the National Institute of Nursing Research (NINR), and to secure authorized funding for Nurse-Managed Health Clinics so that American nurses have the support needed to provide high quality healthcare to the Nation.

Nurses are involved in every aspect of healthcare, and if the nursing workforce is not strengthened, the healthcare system will continue to suffer. Currently, RNs comprise the largest group of health professionals with approximately 3.1 million licensed providers. Nurses offer essential care to patients as well as our Nation's active duty military and veterans in a variety of settings, including hospitals, ambulatory care clinics, long-term care facilities, community or public health areas, schools, workplaces, and private homes. In addition, many nurses pursue graduate degrees to assume roles as advanced practice registered nurses who practice autonomously; become nurse faculty, nurse researchers, nurse administrators, and advanced public health nurses. Nurses also specialize in areas such as mental and women's health, pain management, hospice and palliative care, nephrology, oncology, rehabilitation, forensics, dermatology, urology, and care coordination. They are critical team members in all departments such as intensive and critical care, pediatrics, geriatrics, medical surgical, and operating rooms. RNs and APRNs hold a holistic view of health.

With the Patient Protection and Affordable Care Act [Public Law 111–148] (ACA) focus on creating a system that will increase access to quality care, emphasize prevention, and decrease cost, it is critical that a substantial investment be made in our RN and APRN workforce, in the scientific research that provides the basis for nursing practice, and in the safety-net facilities they operate.

In an article published in the July/August 2009 issue of Health Affairs, Dr. Peter Buerhaus, a noted health professions workforce analyst, and colleagues confirmed that although the economic recession has led to a temporary easing of the nursing shortage in some parts of the country, the overall shortfall in the number of nurses needed is expected to grow to 260,000 by the year 2025. Three major factors contribute to this growing demand for nursing care. First, over 275,000 practicing RNs are over the age of 60 according to the 2008 National Sample Survey of Registered Nurses. When the economy rebounds, many of these nurses will seek retirement. Second, America's population is aging. Older Americans will seek more healthcare services creating an influx of consumers and necessitate the need for quality nursing care. Finally, the ACA will expand the number of individuals seeking care by 32 million.

Furthermore, in a report released by the Institute of Medicine and Robert Wood Johnson Foundation titled, The Future of the Nursing: Leading Change, Advancing Health, clear and evidence based guidance was provided on how to shape nursing's role in healthcare delivery as the system undergoes considerable changes. The report's key messages include:

—Nurses should practice to the full extent of their education and training; scope of practice limitations should be removed.

—Nurses should achieve higher levels of education and training through an improved education system that promotes seamless academic progression.

—Nurses should be full partners with other healthcare professionals in redesigning healthcare in the United States.

—Effective workforce planning and policymaking require better data collection and an improved information infrastructure.

To achieve these goals, different levels of support will be needed for all nurses and each of the funding requests outlined below will help to meet not only the goals of the IOM report, but the larger national goals of access to high quality, cost effective care.

ADDRESSING THE DEMAND: NURSING WORKFORCE DEVELOPMENT PROGRAMS

The Nursing Workforce Development programs, authorized under Title VIII of the Public Health Service Act (42 U.S.C. 296 et seq.), helped build the supply and distribution of qualified nurses to meet our Nation's healthcare needs since 1964. Over the last 47 years, these programs addressed all aspects of supporting the workforce—education, practice, retention, and recruitment. The Title VIII programs bolster nursing education at all levels, from entry-level preparation through graduate study, and provide support for institutions that educate nurses for practice in rural and medically underserved communities. Today, the Title VIII programs are essential to ensure the demand for nursing care is met. Between fiscal year 2006 and 2009, the Title VIII programs supported over 347,000 nurses and nursing students as well as numerous academic nursing institutions, and healthcare facilities.

Results from the American Association of Colleges of Nursing's (AACN) 2010–2011 Title VIII Student Recipient Survey included responses from 1,459 students

who noted that these programs played a critical role in funding their nursing education. The survey showed that 80 percent of the students receiving Title VIII funding are attending school full-time. By supporting full-time students, the Title VIII programs are helping to ensure that students enter the workforce without delay. The programs also address the current demand for primary care providers. Nearly one-third of respondents reported that their career goal is to become a nurse practitioner. Approximately 80 percent of nurse practitioners provide primary care services throughout the United States. Additionally, the respondents identified working in rural and underserved areas as future goals, with becoming a nurse faculty member, a nurse practitioner, or a certified registered nurse anesthetist as the top three nursing positions for their career aspirations.

The Nursing Community respectfully requests $313.075 million for the Nursing Workforce Development programs authorized under Title VIII of the Public Health Service Act in fiscal year 2012 as recommended in the President's fiscal year 2012 budget proposal.

BUILDING THE SCIENCE: THE NATIONAL INSTITUTE OF NURSING RESEARCH

As one of the 27 Institutes and Centers at the National Institutes of Health (NIH), the NINR funds research that establishes the scientific basis for quality patient care. Nurse researchers make significant advances in and contributions to health prevention and care. In addition, they work collaboratively as well as part of multidisciplinary research teams with colleagues from other fields and are vital in setting the national research agenda.

The Nursing Community respectfully requests $163 million for the National Institute of Nursing Research in fiscal year 2012. Nursing research is an essential part of scientific endeavors to improve the Nation's health. Knowledge of care across the lifespan is critical to the present and future health of the Nation. Research funded at the NINR helps to integrate biology and behavior as well as design new technology and tools. At a time when healthcare needs are changing, nursing care must be firmly grounded in nursing science. The four strategic areas of emphasis for research at NINR are promoting health and preventing disease, eliminating health disparities, improving quality of life, and setting directions for end-of-life research.

The science advanced at NINR is integral to the future of the Nation's healthcare system. Through grants, research training, and interdisciplinary collaborations, NINR addresses care management of patients during illness and recovery, reduction of risks for disease and disability, promotion of healthy lifestyles, enhancement of quality of life for those with chronic illness, and care for individuals at the end of life. NINR's research fosters advances in nursing practice, improves patient care, and attracts new students to the profession.

SUPPORTING SAFETY NET FACILITIES: NURSE-MANAGED HEALTH CLINICS

The ACA amended Sec. 330 of the Public Health Service Act to provide grant eligibility to Nurse-Managed Health Clinics (NMHCs) to support operating costs and authorized up to $50 million a year for this purpose. NMHCs are defined as a nurse-practice arrangement, managed by APRNs, that provides primary care or wellness services to underserved or vulnerable populations and that is associated with a school, college, university or department of nursing, federally qualified health center, or independent nonprofit health or social services agency. Nurse-Managed Health Clinics successfully engage communities and address critical health needs for underserved populations.

The Nursing Community respectfully requests $20 million for the Nurse-Managed Health Clinics authorized under Title III of the Public Health Service Act in fiscal year 2012 as recommended in the President's fiscal year 2012 budget proposal.

NMHCs provide care to clients and patients in clinics located in places like public housing, on blighted urban streets, on Native American reservations, in rural communities, in senior citizen centers, in elementary schools, in storefronts, and even in churches. The services these clinics provide include primary care, health promotion, and disease prevention. Furthermore, NMHCs also act as important teaching and practice sites for nursing students.

The care provided in these sites directly contributes to positive health outcomes and savings in the long term. In one U.S. city alone, nurses at an NMHC see their patients almost twice as frequently as other providers, and their patients are hospitalized 30 percent less and use the emergency room 15 percent less often than those of other healthcare providers. Providing funding for these centers is a direct investment in the specific health needs of localized communities.

Without a workforce of well-educated nurses providing evidence-based care to those who need it most, including our growing aging population, the healthcare sys-

tem is not sustainable. The Nursing Community's request of $313.075 million in fiscal year 2012 for the Title VIII Nursing Workforce Development programs, $163 million for the NINR, and $20 million for NMHCs will help ensure access to quality care provided by America's nursing workforce.

MEMBERS OF THE NURSING COMMUNITY SUBMITTING THIS TESTIMONY

Academy of Medical-Surgical Nurses
American Academy of Ambulatory Care Nursing
American Academy of Nurse Practitioners
American Academy of Nursing
American Assembly for Men in Nursing
American Association of Colleges of Nursing
American Association of Critical-Care Nurses
American Association of Nurse Anesthetists
American Association of Nurse Assessment Coordinators
American College of Nurse Practitioners
American College of Nurse-Midwives
American Holistic Nurses Association
American Nephrology Nurses' Association
American Nurses Association
American Organization of Nurse Executives
American Psychiatric Nurses Association
American Society for Pain Management Nursing
American Society of PeriAnesthesia Nurses
Association of Community Health Nursing Educators
Association of periOperative Registered Nurses
Association of Rehabilitation Nurses
Association of State and Territorial Directors of Nursing
Association of Women's Health, Obstetric and Neonatal Nurses
Commissioned Officers Association
Dermatology Nurses' Association
Gerontological Advanced Practice Nurses Association
Hospice and Palliative Nurses Association
Infusion Nurses Society
International Association of Forensic Nurses
International Nurses Society on Addictions
International Society of Psychiatric Nurses
National Association of Clinical Nurse Specialists
National Association of Nurse Practitioners in Women's Health
National Association of Pediatric Nurse Practitioners
National Black Nurses Association
National Coalition of Ethnic Minority Nurse Associations
National Nursing Centers Consortium
National Organization of Nurse Practitioner Faculties
Nurses Organization of Veterans Affairs
Oncology Nursing Society
Public Health Nursing Section, American Public Health Association
Society of Urologic Nurses and Associates

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## PREPARED STATEMENT OF THE ONCOLOGY NURSING SOCIETY

### OVERVIEW

The Oncology Nursing Society (ONS) appreciates the opportunity to submit written comments for the record regarding fiscal year 2012 funding for cancer and nursing related programs. ONS, the largest professional oncology group in the United States, composed of more than 35,000 nurses and other health professionals, exists to promote excellence in oncology nursing and the provision of quality care to those individuals affected by cancer. As part of its mission, the Society honors and maintains nursing's historical and essential commitment to advocacy for the public good.

In 2010, an estimated 1.529 million Americans were diagnosed with cancer, and more than 569,490 lost their battle to this terrible disease; at the same time the national nursing shortage is expected to worsen. Overall, age is the number one risk factor for developing cancer. Approximately 77 percent of all cancers are diagnosed at age 55 and older.[1] Despite these grim statistics, significant gains in the war against cancer have been made through our Nation's investment in cancer research and its application. Research holds the key to improved cancer prevention, early detection, diagnosis, and treatment, but such breakthroughs are meaningless, unless we can deliver them to all Americans in need. Moreover, a recent survey of ONS members found that the nursing shortage is having an impact in oncology physician

[1] American Cancer Society. *Cancer Facts and Figures 2010*. http://www.cancer.org/Research/CancerFactsFigures/CancerFactsFigures/cancer-facts-and-figures-2010.

offices and hospital outpatient departments. Some respondents indicated that when a nurse leaves their practice, they are unable to hire a replacement due to the shortage—leaving them short-staffed and posing scheduling challenges for the practice and the patients. These vacancies in all care settings create significant barriers to ensuring access to quality care.

To ensure that all people with cancer have access to the comprehensive, quality care they need and deserve, ONS advocates ongoing and significant Federal funding for cancer research and application, as well as funding for programs that help ensure an adequate oncology nursing workforce to care for people with cancer. ONS stands ready to work with policymakers at the local, State, and Federal levels to advance policies and programs that will reduce and prevent suffering from cancer and sustain and strengthen the Nation's nursing workforce. We thank the Subcommittee for its consideration of our fiscal year 2012 funding request detailed below.

SECURING AND MAINTAINING AN ADEQUATE ONCOLOGY NURSING WORKFORCE

Oncology nurses are on the front lines in the provision of quality cancer care for individuals with cancer—administering chemotherapy, managing patient therapies and side-effects, working with insurance companies to ensure that patients receive the appropriate treatment, providing treatment education and counseling to patients and family members, and engaging in myriad other activities on behalf of people with cancer and their families. Cancer is a complex, multifaceted chronic disease, and people with cancer require specialty-nursing interventions at every step of the cancer experience. People with cancer are best served by nurses specialized in oncology care, who are certified in that specialty.

As the overall number of nurses is expected to decline in the coming years, we likely will experience a commensurate decrease in the number of nurses trained in the specialty of oncology. With an increasing number of people with cancer needing high-quality healthcare, coupled with an inadequate nursing workforce, our Nation could quickly face a cancer care crisis of serious proportion, with limited access to quality cancer care, particularly in traditionally underserved areas. A study in the New England Journal of Medicine found that nursing shortages in hospitals are associated with a higher risk of complications—such as urinary tract infections and pneumonia, longer hospital stays, and even patient death.[2] Without an adequate supply of nurses, there will not be enough qualified oncology nurses to provide the quality cancer care to a growing population of people in need, and patient health and well-being could suffer.

Of additional concern is that our Nation also will face a shortage of nurses available and able to conduct cancer research and clinical trials. With a shortage of cancer research nurses, progress against cancer will take longer because of scarce human resources coupled with the reality that some practices and cancer centers' resources could be funneled away from cancer research to pay for the hiring and retention of oncology nurses to provide direct patient care. Without a sufficient supply of trained, educated, and experienced oncology nurses, we are concerned that our Nation may falter in its delivery and application of the benefits from our Federal investment in research.

ONS joins our colleagues from all nursing sectors and specialties to request $313.075 million for the Health Resources and Services Administrations (HRSA) Title VIII programs in fiscal year 2012, as recommended in the President's fiscal year 2012 budget. With additional funding in fiscal year 2012, the HRSA Workforce Development Programs will have much-needed resources to address the multiple factors contributing to the nationwide nursing shortage. Advanced nursing education programs play an integral role in supporting registered nurses interested in advancing in their practice and becoming faculty. As such, these programs must be adequately funded in the coming year.

ONS strongly urges Congress to provide HRSA with this amount to ensure that the agency has the resources necessary to fund a higher rate of nursing scholarships and loan repayment applications and support other essential endeavors to sustain and boost our Nation's nursing workforce. Nurses—along with patients, family members, hospitals, and others—have joined together in calling upon Congress to provide this essential level of funding. The National Coalition for Cancer Research (NCCR), a nonprofit organization comprised of 23 national cancer organizations, and One Voice Against Cancer (OVAC), a collaboration of 39 national nonprofit organiza-

[2] Needleman J., Buerhaus P., Mattke S., Stewart M., Zelevinsky K. "Nurse-Staffing Levels and the Quality of Care in Hospitals." New England Journal of Medicine 346:, (May 30, 2002): 1715–1722.

tions, are also advocating $313.075 million in fiscal year 2012 for the Nurse Reinvestment Act. ONS and its allies have serious concerns that without full funding, the Nurse Reinvestment Act will prove an empty promise, and the current and expected nursing shortage will worsen, and people will not have access to the quality care they need and deserve.

SUSTAIN AND SEIZE CANCER RESEARCH OPPORTUNITIES

Our Nation has benefited immensely from past Federal investment in biomedical research at the National Institutes of Health (NIH). ONS has joined with the broader health community in advocating a $35 billion for NIH in fiscal year 2012. This level of investment will allow NIH to sustain and build on its research progress, while avoiding the severe disruption to advancement that could result from a minimal increase. Cancer research is producing amazing breakthroughs—leading to new therapies that translate into longer survival and improved quality of life for cancer patients. In recent years, we have seen extraordinary advances in cancer research, resulting from our national investment, which have produced effective prevention, early detection, and treatment methods for many cancers. To that end, ONS calls upon Congress to allocate $5.740 billion to the National Cancer Institute (NCI), as well as $231 million to the National Center for Minority Health and Health Disparities in fiscal year 2012 to support the battle against cancer.

The National Institute of Nursing Research (NINR) supports basic and clinical research to establish a scientific basis for the care of individuals across the life span—from management of patients during illness and recovery, to the reduction of risks for disease and disability and the promotion of healthy lifestyles. These efforts are crucial in translating scientific advances into cost-effective healthcare that does not compromise quality of care for patients. Additionally, NINR fosters collaborations with many other disciplines in areas of mutual interest, such as long-term care for older people, the special needs of women across the life span, bioethical issues associated with genetic testing and counseling, and the impact of environmental influences on risk factors for chronic illnesses, such as cancer. ONS joins with others in the nursing community and NCCR in advocating a fiscal year 2012 allocation of $163 million for NINR.

BOOST OUR NATION'S INVESTMENT IN CANCER PREVENTION, EARLY DETECTION, AND AWARENESS

Approximately two-thirds of cancer cases are preventable through lifestyle and behavioral factors and improved practice of cancer screening. Although the potential for reducing the human, economic, and social costs of cancer by focusing on prevention and early detection efforts remains great, our Nation does not invest sufficiently in these strategies. The Nation must make significant and unprecedented Federal investments today to address the burden of cancer and other chronic diseases, and to reduce the demand on the healthcare system and diminish suffering in our Nation, both for today and tomorrow.

As the Nation's leading prevention agency, the Centers for Disease Control and Prevention (CDC) plays an important role in translating and delivering, at the community level, what is learned from research. Therefore, ONS joins with our partners in the cancer community in calling on Congress to provide additional resources for the CDC to support and expand much-needed and proven effective cancer prevention, early detection, and risk reduction efforts. Specifically, ONS advocates the following fiscal year 2012 funding levels for the following CDC programs:

—$275 million for the National Breast and Cervical Cancer Early Detection Program;
—$65 million for the National Cancer Registries Program;
—$70 million for the Colorectal Cancer Prevention and Control Initiative;
—$50 million for the Comprehensive Cancer Control Initiative;
—$25 million for the Prostate Cancer Control Initiative;
—$5 million for the National Skin Cancer Prevention Education Program;
—$10 million for the Gynecologic Cancer and Education and Awareness (Johanna's Law);
—$10 million for the Ovarian Cancer Control Initiative; and
—$6 million for the Geraldine Ferraro Blood Cancer Program.

CONCLUSION

ONS maintains a strong commitment to working with Members of Congress, other nursing and oncology groups, patient organizations, and other stakeholders to ensure that the oncology nurses of today continue to practice tomorrow, and that we recruit and retain new oncology nurses to meet the unfortunate growing demand

that we will face in the coming years. By providing the fiscal year 2012 funding levels detailed above, we believe the Subcommittee will be taking the steps necessary to ensure that our nation has a sufficient nursing workforce to care for the patients of today and tomorrow and that our nation continues to make gains in our fight against cancer.

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## PREPARED STATEMENT OF THE OVARIAN CANCER NATIONAL ALLIANCE

The Ovarian Cancer National Alliance (the Alliance) appreciates the opportunity to submit comments for the record regarding the Alliance's fiscal year 2012 funding recommendations. We believe these recommendations are critical to ensure advances to help reduce and prevent suffering from ovarian cancer.

For 14 years, the Alliance has worked to increase awareness of ovarian cancer and advocate for additional Federal resources to support research that would lead to more effective diagnostics and treatments. As an umbrella organization with approximately 50 national, State and local organizations, the Alliance unites the efforts of survivors, grassroots activists, women's health advocates and healthcare professionals to bring national attention to ovarian cancer. The Ovarian Cancer National Alliance is the foremost advocate for women with ovarian cancer in the United States. To advance the interests of women with ovarian cancer, the organization advocates at a national level for increases in research funding for the development of an early detection test, improved healthcare practices and life-saving treatment protocols. The Ovarian Cancer National Alliance educates healthcare professionals and raises public awareness of the risks, signs and symptoms of ovarian cancer.

According to the American Cancer Society, in 2010, more than 22,000 American women were diagnosed with ovarian cancer and approximately 15,000 lost their lives to this terrible disease. Ovarian cancer is the fifth leading cause of cancer death in women. Currently, more than half of the women diagnosed with ovarian cancer will die within 5 years. While ovarian cancer has symptoms, there is no reliable early detection test. Most women are diagnosed in Stage III or Stage IV, when survival rates are low. If diagnosed early, more than 90 percent of women will survive for 5 years, but when diagnosed later, less than 30 percent will.

Only a few treatments have been approved by the Food and Drug Administration (FDA) for ovarian cancer treatment. These are platinum-based therapies and women needing further rounds of treatment are frequently resistant to them. More than 70 percent of ovarian cancer patients will have a recurrence at some point, underlying the need for treatments to which patients do not grow resistant.

For all of these reasons, we urgently call on Congress to appropriate funds to find solutions.

As part of this effort, the Alliance advocates for continued Federal investment in the Centers for Disease Control and Prevention's (CDC) Ovarian Cancer Control Initiative. The Alliance respectfully requests that Congress provide $10 million for the program in fiscal year 2012.

The Alliance also fully supports Congress in taking action on educating Americans about ovarian cancer through providing funding for The Gynecologic Cancer Education and Awareness Act (Johanna's Law) [Public Law 111–324]. The Alliance respectfully requests that Congress provide $10 million to implement The Gynecologic Cancer Education and Awareness Act (Johanna's Law) in fiscal year 2012.

Further, the Alliance urges Congress to continue funding the Specialized Programs of Research Excellence (SPOREs), including the five ovarian cancer sites. These programs are administered through the National Cancer Institute (NCI) of the National Institutes of Health (NIH). The Alliance respectfully requests that Congress provide $5.74 billion to the National Cancer Institute for fiscal year 2012.

### CENTERS FOR DISEASE CONTROL AND PREVENTION

### THE OVARIAN CANCER CONTROL INITIATIVE

As the statistics indicate, late detection and, therefore, poor survival are among the most urgent challenges we face in the ovarian cancer field. The CDC's cancer program, with its strong capacity in epidemiology and excellent track record in public and professional education, is well positioned to address these problems. As the Nation's leading prevention agency, the CDC plays an important role in translating and delivering at the community level what is learned from research, especially ensuring that those populations disproportionately affected by cancer receive the benefits of our Nation's investment in medical research.

Congress established the Ovarian Cancer Control Initiative at the CDC in November 1999 with bipartisan, bicameral support. Congress' directive to the agency was to develop an appropriate public health response to ovarian cancer and conduct several public health activities targeted toward reducing ovarian cancer morbidity and mortality.

The CDC's Ovarian Cancer Control Initiative conducts research about early detection, treatment and survivorship nationwide to increase understanding of ovarian cancer. Some of the Ovarian Cancer Control Initiative's notable studies include: a study of women who died of ovarian cancer within three managed care organizations to investigate end-of-life care; the Ovarian Cancer Treatment Patterns and Outcomes study, which attempted to determined how the stage of cancer, the specialty of a surgeon and the success of the surgery contributed to the survival of ovarian cancer patients diagnosed between 1997 and 2000; and a study to examine geographic access to subspecialists for treating ovarian cancer.

THE GYNECOLOGIC CANCER EDUCATION AND AWARENESS ACT (JOHANNA'S LAW)

It is critical for women and their healthcare providers to be aware of the signs, symptoms and risk factors of ovarian and other gynecologic cancers. Often, women and providers mistakenly confuse ovarian cancer signs and symptoms with those of gastrointestinal disorders or early menopause. While symptoms may seem vague—bloating, pelvic or abdominal pain, increased abdominal size and bloating and difficulty, eating or feeling full quickly, or urinary symptoms (urgency or frequency)—the underlying disease can be deadly without proper medical intervention.

In recognition of the need for awareness and education, Congress unanimously passed Johanna's Law in 2006, enacted in early 2007. This law provides for an education and awareness campaign that will increase providers' and women's awareness of all gynecologic cancers including ovarian. Johanna's Law was reauthorized in 2010.

Thanks to funding under Johanna's Law, more women are learning how to identify the signs and symptoms of gynecologic. From September 2010 to January 2011, the broadcast PSAs have been played 68,630 times, generating 154,632,815 audience impressions (the number of times they have been seen or heard), worth $7,491,846 in donated placements. Additionally, since October 2010:

—there have been 25,706 plays of the TV PSAS, worth $2,800,805 in donated airtime,
—there have been 9,701 plays of English TV spots,
—there have been 16,005 plays of Spanish TV spots,
—the PSAs have aired in the top markets, including Los Angeles, Chicago, Philadelphia, San Francisco, Boston, Dallas/Fort Worth, Atlanta, Tampa/St. Petersburg, Pittsburgh, PA, Salt Lake City, Raleigh/Durham, Green Bay, Baltimore, Tucson, Cleveland, Phoenix, Tulsa, Orlando, Hartford/New Haven, Houston, Spokane, and Seattle/Tacoma, among others, and
—English spots have aired during popular programs such *Today*, *Good Morning America*, *CBS Morning News*, *Access Hollywood*, *Cold Case*, *Real Housewives of Orange County*, *The Bachelor*, *The View*, *Dr. Oz Show*, *Ellen DeGeneres Show*, *The Doctors*, *Entertainment Tonight*, and *Late Night with David Letterman* during the hours of 8 a.m. to midnight.

With continued funding, the CDC will be able to continue to print and distribute brochures, maintain and update the web resources, develop additional educational materials such as posters for physician offices, complete continuing education materials for healthcare providers, and reach out to women beyond the original 40–60 year-old initial target group.

CDC CHRONIC DISEASE PROGRAM CONSOLIDATION

The President's budget proposal for fiscal year 2012 recommends consolidating all of the Centers for Disease Control and Prevention's (CDC) chronic disease programs that are focused on heart disease and stroke, diabetes, cancer, arthritis, nutrition, and other health-related issues into one competitive grant program. It is our understanding that the Gynecologic Cancer Education and Awareness Act (Johanna's Law) and the Ovarian Cancer Control Initiative would be included in this all-encompassing competitive grant program. These programs, with congressional support, have been able to increase understanding and raise awareness of ovarian and other women's cancers that afflict Americans.

While we support efforts to improve the efficiency of Federal programs, we oppose shifting control and funding of these programs away from Congress. Moreover, given that ovarian cancer mortality rates have remained virtually unchanged for decades and currently there is no early detection test for the disease, we feel strongly that

the CDC should maintain dedicated efforts focused on reducing ovarian cancer mortality and morbidity. As such, we recommend that Johanna's Law and the Ovarian Cancer Control Initiative remain standalone line items in the fiscal year 2012 Labor, Health and Human Services, and Education (LHHS) appropriations bill.

NATIONAL CANCER INSTITUTE

The National Cancer Institute is the chief funder of ovarian cancer research in the United States and the world. In 2009, the National Cancer Institute funded over 170 studies solely dedicated to bettering our scientific understanding of ovarian cancer. These studies investigated diverse topics such as the effect of Vitamin D on ovarian cancer prevention and treatment, whether Prolactin is a risk biomarker of ovarian cancer, and whether viruses can be converted into ovarian cancer-fighting agents. Research investigators who receive funding from the National Cancer Institute study cancer are located all across the United States. According to Families USA, every dollar in Federal research spending generates about $2 in economic activity in local economies where funded projects are located.

SPECIALIZED PROGRAMS OF RESEARCH EXCELLENCE IN THE NATIONAL INSTITUTES OF HEALTH

The Specialized Programs of Research Excellence were created by the NCI in 1992 to support translational, organ site-focused cancer research. The ovarian cancer SPOREs began in 1999. There are five currently funded Ovarian Cancer SPOREs located at the MD Anderson Cancer Center, the Fred Hutchinson Cancer Research Center, the Fox Chase Cancer Center, the Dana Farber/Harvard Cancer Center and the Mayo Clinic Cancer Center.

These SPORE programs have made outstanding strides in understanding ovarian cancer, as illustrated by their more than 300 publications as well as other notable achievements, including the development of an infrastructure between Ovarian SPORE institutions to facilitate collaborative studies on understanding, early detection and treatment of ovarian cancer.

CLINICAL TRIALS

The National Cancer Institute supports clinical research—the only way to test the safety and efficacy of potential new treatments for ovarian cancer. An example of NCI-funded clinical research is a new 5-year study addressing the lack of knowledge about causes and risk factors for ovarian cancer in African American women conducted by University Hospitals Case Medical Center and Case Western Reserve University School of Medicine. Another study funded by the National Cancer Institute compared the efficacy and safety of a dose-dense regimen of single-agent cisplatin with a standard 3-weekly schedule in first-line chemotherapy for advanced epithelial ovarian cancer. The study found that increasing dose intensity of cisplatin does not improve PFS or OS compared with standard chemotherapy.

NCI supports the Gynecology Oncology Group, a more than 50-member collaborative focusing on cancers of the female reproductive system. From 2008 until present, the GOG has published 103 articles about ovarian cancer. An important and recent finding from the GOG, the GOG 218 study, was that women with advanced cancer who received chemotherapy followed by maintenance use of Avastin increased survival time without their disease worsening compared to chemotherapy alone.

SUMMARY

The Alliance maintains a long-standing commitment to work with Congress, the administration, and other policy makers and stakeholders to improve the survival rate for women with ovarian cancer through education, public policy, research and communication. Please know we appreciate and understand that our Nation faces many challenges and Congress has limited resources to allocate; however, we are concerned that without increased funding to bolster and expand ovarian cancer education, awareness and research efforts, the nation will continue to see growing numbers of women losing their battle with this terrible disease.

On behalf of the entire ovarian cancer community—patients, family members, clinicians and researchers—we thank you for your leadership and support of Federal programs that seek to reduce and prevent suffering from ovarian cancer. We request your support for our appropriations requests for fiscal year 2012 that include $10 million for the CDC's Ovarian Cancer Control Initiative, $10 million for The Gynecologic Cancer Education and Awareness Act (Johanna's Law) and $5.74 billion to NCI.

PREPARED STATEMENT OF THE PANCREATIC CANCER ACTION NETWORK

Mr. Chairman and members of the Subcommittee: My name is Julie Fleshman and I am submitting this testimony on behalf of the Pancreatic Cancer Action Network.

Founded in 1999, the Pancreatic Cancer Action Network is a nationwide network of individuals dedicated to advancing research, supporting patients and fostering hope for the families and loved ones affected by this disease.

Pancreatic cancer continues to be one of the deadliest cancers in this country. In fact, it is the only cancer tracked by both the American Cancer Society and the National Cancer Institute (NCI) that still has a 5-year survival rate in the single digits. This is even more astounding because the overall 5-year survival rate for all cancers was 50 percent in the 1970s and is now 68 percent. Last year, pancreatic cancer struck more than 43,000 Americans and resulted in 36,800 deaths. The similarity of these statistics underscores its deadliness: indeed, most patients die within months of their diagnosis.

There is no question that we have made important progress in many forms of cancer. There is also no question that this progress has been lacking in pancreatic cancer. The fact remains that there are still no early detection tools or effective treatments. A patient diagnosed today generally hears the same words as a patient diagnosed 40 years ago, "I'm sorry, but there is not much that we can do for you. Go home and get your affairs in order." The Pancreatic Cancer Action Network believes that the time has come for bold action and has launched a new mission to double the 5-year survival rate by 2020. This is an ambitious but achievable goal.

Dismal as the picture is today, unless something is done soon, it will only get worse. A recently published study in the Journal of Clinical Oncology predicts that the number of new pancreatic cancer cases will increase by 55 percent over the next two decades.

Why has there been so little change in the mortality rate associated with pancreatic—and what can be done about it?

Progress has been slow in large part because the Federal Government's investment in pancreatic cancer research has been weak. The Pancreatic Cancer Action Network recently published a report, "Pancreatic Cancer: A trickle of Federal funding for a river of need", analyzing the investment made by the NCI into this disease. The analysis shows that pancreatic cancer is behind in nearly every important grant category funded by the Federal Government.

—Currently, research dedicated to pancreatic cancer receives a mere 2 percent of the Federal dollars distributed by the NCI. By contrast, the other four of the top five cancer killers in the United States (lung, colon, breast and prostate cancer) received 2.8 to 6.3 fold more NCI funding in 2009 than pancreatic cancer.

—The average dollar amount of basic research (R) grants in pancreatic cancer was 18 to 29 percent less than R grants for the other four top cancer killers. The R grant mechanisms are the mainstay of scientific discovery in cancer research.

—Training grant funding in pancreatic cancer decreased by 15 percent from 2008 to 2009, a decline larger than in any other leading cancer. Pancreatic cancer trainees were awarded between 2.4 and 6.5 fold less grant money in 2009 than young researchers studying the other four top cancer killers.

—American Recovery & Reinvestment Act (ARRA) funding represented a unique opportunity for the NCI to direct research monies toward the deadliest cancers, including pancreatic cancer. Unfortunately, this opportunity was missed, as pancreatic cancer research received only slightly more than 1 percent of the NCI ARRA budget.

As has been noted by this Subcommittee and others in Congress in recent years, what is lacking is a well-defined, long-term comprehensive strategic plan in place to: advance the understanding of the biology of pancreatic cancer, examine its natural history and the genetic and environmental factors that contribute to its development; expand research on ways to screen and detect pancreatic cancer in much earlier stages; and launch innovative clinical trials to test targeted therapeutics and novel agents that will extend the survival and improve the quality of life of patients.

In addition, there must be a robust and sustained commitment of resources by the NCI and its sister institutes and centers at the National Institutes of Health (NIH).

Thanks to you and your colleagues, Mr. Chairman, and under the leadership of Dr. Harold Varmus, NCI has taken some encouraging steps in the right direction.

In 2010 NCI convened an internal group to develop an action plan for pancreatic cancer research and training. NCI brought together pancreatic cancer researchers and program staff from within the Institute to form the Pancreatic Cancer Action Planning Group, charged with developing an Action Plan that summarizes the fiscal

year 2011 research and training portfolio and identifies research gaps and opportunities for collaboration within NCI and with other members of the National Cancer Program, including advocacy groups, academia, and industry. This Action Plan was developed based on discussions at a Planning Group meeting held in July 2010 and continued interactions following the meeting. While it was not the long-term comprehensive strategic plan that we would still like to see the NCI develop for pancreatic cancer, we do believe that it was a good first step.

In addition to the initiatives and activities already included in the fiscal year 2011 portfolio, the Planning Group identified several opportunities for NCI to advance pancreatic cancer research. Emphasis was placed on activities with a high likelihood of improving survival rates, which have remained low despite improvements in many other cancer types. It was recognized that given the range of research conducted within and funded by NCI, the Institute is uniquely poised to support activities and provide services that other stakeholders are unable or unwilling to do. The Planning Group identified several opportunities for collaboration with advocacy organizations and the private sector to gain momentum in pancreatic cancer research.

The Action Plan reviewed the research activities that were planned for fiscal year 2011. We look forward to hearing from the NCI about the outcome of these plans. It also identified a few potential new initiatives such as a program announcement for R01 grants focused on pancreatic cancer. We strongly believe that a program announcement would be a positive step in the right direction and would urge you to find ways to encourage NCI to implement this idea. We hope to have the opportunity to work with NCI to implement the steps outlined in the plan.

Some ideas that emerged—such as promoting interaction and increased use of existing resources—will likely involve only modest financial investment, while others, like new program announcements, will require more resources. We therefore join with our colleagues in the One Voice Against Cancer (OVAC) coalition in highlighting the important role that NCI plays in our economy and in cancer research worldwide and ask this Committee to do everything in its power to safe-guard and expand this important resource.

Mr. Chairman, research is the only hope. We ask that you strongly urge the National Cancer Institute to put in place a long-term comprehensive strategic plan for pancreatic cancer research and ensure that there is funding available to implement that plan.

Thank you.

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## PREPARED STATEMENT OF THE PHYSICIAN ASSISTANT EDUCATION ASSOCIATION

On behalf of its membership, the 156 accredited physician assistant (PA) education programs in the United States, the Physician Assistant Education Association (PAEA) is pleased to submit these comments on the fiscal year 2012 appropriations for PA education programs that are authorized through Title VII of the Public Health Service Act.

PAEA is a member of the Health Professions and Nursing Education Coalition (HPNEC) and we support the HPNEC recommendation for funding of at least $762.5 million in fiscal year 2012 for the health professions education programs authorized under Title VII and VIII of the Public Health Service Act and administered through the Health Resources and Services Administration (HRSA). HPNEC is an informal alliance of more than 60 national organizations representing schools, programs, health professionals, and students and dedicated to ensuring that the healthcare workforce is trained to meet the needs of the country's growing, aging, and diverse population.

*Need for Increased Federal Funding*

Faculty development is one of the profession's critical needs. In order to attract the best qualified to teaching, PA education programs must have the resources to train faculty in academic skills, such as curriculum development, teaching methods, and laboratory instruction. The challenges of teaching are broad and varied and include understanding different pedagogical theories, writing instructional objectives, and learning and applying educational technology. Most educators come from clinical practice and these skills are essential to transitioning to teaching. Educators are a critical element of meeting the Nation's demand for an increased supply of primary care clinicians.

Generalist training, workforce diversity, and practice in underserved areas are key priorities identified by HRSA. It is increasingly important that the health workforce better represents America's changing demographics, as well as addresses the issues of disparities in healthcare. PA programs have been successful in attracting

students from underrepresented minority groups and disadvantaged backgrounds. Studies have found that health professionals from underserved areas are three to five times more likely to return to underserved areas to provide care.

*Physician Assistant Practice*

Physician assistants (PAs) are licensed health professionals who practice medicine as members of a team with their supervising physicians. PAs exercise autonomy in medical decisionmaking and provide a broad range of medical and therapeutic services to diverse populations in rural and urban settings. In all 50 States, PAs carry out physician-delegated duties that are allowed by law and within the physician's scope of practice and the PA's training and experience. Additionally, PAs are delegated prescriptive privileges by their physician supervisors in all 50 States, the District of Columbia, and Guam. This allows PAs to practice in rural, medically underserved areas where they are often the only full-time medical provider.

*Physician Assistant Education*

There are currently 156 accredited PA education programs in the United States—a growth of 22 percent in less than 5 years; together these programs graduate nearly 6,000 PA students each year. PAs are educated as generalists in medicine; their flexibility allows them to practice in more than 60 medical and surgical specialties. More than one-third of PA program graduates practice in primary care.

The average PA education program is 27 months in length. Typically, 1 year is devoted to classroom study and approximately 15 months is devoted to clinical rotations. The typical curriculum includes 400 hours of basic sciences and nearly 600 hours of clinical medicine.

As of today, approximately 20 programs are in the pipeline at various stages of development, moving toward accredited status. The growth rate in the applicant pool is even more remarkable. In March 2006, there were a total of 7,608 applicants to PA education programs; as of March 2011, there were 16,112 applicants to PA education programs. This represents a 112 percent increase in Centralized Application Service (CASPA) applicants over the past 5 years.

The PA profession is expected to continue to grow as a result of the projected shortage of physicians and other healthcare professionals, the growing demand for professionals from an aging population, and the continuing strong PA applicant pool, which has grown by more than 10 percent each year since the year 2000. The Bureau of Labor Statistics projects a 39 percent increase in the number of PA jobs between 2008 and 2018. With its relatively short initial training time and the flexibility of generalist-trained PAs, the PA profession is well-positioned to help fill projected shortages in the numbers of healthcare professionals.

The continued growth of the profession heightens the need for additional resources to help meet the challenges of recruiting qualified faculty, shortages of preceptors and clinical sites, and increasing the diversity of faculty and program applicants.

*Title VII Funding*

Title VII funding is the only opportunity for PA programs to apply for Federal funding and plays a crucial role in developing and supporting PA education programs.

Title VII funding fills a critical need for curriculum development and faculty development. Funding enhances clinical training and education, assists PA programs with recruiting applicants from minority and disadvantaged backgrounds, and funds innovative programs that focus on educating a culturally competent workforce. Title VII funding increases the likelihood that PA students will practice in medically underserved communities with health professional shortages. The absence of this funding would result in the loss of care to patients in underserved areas.

Title VII support for PA programs has been strengthened with the enactment of the Patient Protection and Affordable Health Care Act (Public Law 111–148), which provides a 15 percent carve out in the appropriations process for PA programs. This funding will enhance capabilities to train a growing PA workforce and is likely to increase the pool for faculty positions as a result of PA programs now being eligible for faculty loan repayment. Huge loan burdens serve as barriers for physician assistant entry into academia.

Here we provide several examples of how PA programs have used Title VII funds to creatively expand care to underserved areas and populations, as well as to develop a diverse PA workforce.

—One Texas program has used its PA training grant to support the program at a distant site in an underserved area. This grant provides assistance to the program for recruiting, educating, and training PA students in the largely Hispanic

South Texas and mid-Texas/Mexico border areas and supports new faculty development.

—A Utah program has used its PA training grant to promote interprofessional teams—an area of strong emphasis in the Patient Protection and Affordable Care Act. The grant allowed the program to optimize its relationship with three service-learning partners, develop new partnerships with three service-learning sites, and create a model geriatric curriculum that includes didactic and clinical education.

—An Alabama program used its PA training grant to update and expand the current health behavior educational curriculum and HIV/STD training. They were also able to include PA students from other programs who were interested in rural, primary care medicine for a 4-week comprehensive educational program in HIV disease diagnosis and management.

—A South Carolina program has developed a model program that offers a 2-year academic fellowship for recent PA graduates with at least one year of clinical experience. To further enhance an evidence-based approach to education and practice, two specific evidence-based practice projects were embedded in the fellowship experience. Fellows direct and evaluate PA students' involvement in the "Towards No Tobacco" curriculum, aimed at fifth graders, and the PDA Patient Data experience, aimed at assessing healthcare services.

*Recommendations on fiscal year 2012 Funding*

The Physician Assistant Education Association requests the Appropriations Committee to support funding for Title VII and VIII health professions programs at a minimum of $762.5 million for fiscal year 2012. This level of funding is crucial to support the Nation's demand for primary care practitioners, particularly those who will practice in medically underserved areas and serve vulnerable populations. Additionally we encourage support for the new programs and responsibilities contained in the Patient Protection and Affordable Care Act (Public Law 111–148), including a minimum of $10 million to support PA education programs. We thank the members of the subcommittee for their support of the health professions and look forward to your continued support of solutions to the Nation's health workforce shortage. We appreciate the opportunity to present the Physician Assistant Education Association's fiscal year 2012 funding recommendation.

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## Prepared Statement of PolicyLink, The Food Trust, and The Reinvestment Fund

Chairman and distinguished Senators of the Committee, thank you for the opportunity to share our support for a Healthy Food Financing Initiative (HFFI). PolicyLink is a national research and action institute advancing economic and social equity by Lifting Up What Works®; The Food Trust is a nonprofit organization working to ensure that everyone has access to affordable, nutritious food; and The Reinvestment Fund is a Community Development Financial Institution that creates wealth and opportunity for low-wealth people and places through the promotion of socially and environmentally responsible development.

Our three organizations, along with a diverse coalition of stakeholders, which includes representatives from the grocery industry, health, civil rights, agriculture and the community development finance community, support the creation of HFFI to address the problem of "food deserts" in urban and rural areas across the Nation. This problem can be solved in many communities using a successful model that is underway in the State of Pennsylvania and is now being replicated throughout the country.

HFFI is a program worthy of investment as it promotes health, creates jobs and sparks economic development. HFFI will provide loan and grant financing to attract grocery stores and other fresh food retail to underserved urban, suburban, and rural areas, and renovate and expand existing stores so they can provide the healthy foods that communities want and need. Over time, with continued investment, HFFI could solve the problem of food deserts in urban and rural communities across the country.

For decades, low-income communities, particularly communities of color, have suffered from a lack of access to healthy, fresh food. USDA research determined that more than 23.5 million Americans are living in communities without access to high-quality, fresh food. Studies repeatedly show that residents of many low-income neighborhoods must travel long distances for healthy food, or rely on corner stores and fast food outlets offering high fat, high sugar foods. For instance, a recent multistate study found that low-income census tracts had half as many super-

markets as wealthy tracts, and four times as many smaller grocery stores. Another multistate study found that 8 percent of African Americans live in a tract with a supermarket, compared to 31 percent of whites. Nationally, low-income zip codes have 30 percent more convenience stores, which tend to lack healthy food, than middle income zip codes.

And, a nationwide analysis found there are 418 rural food desert counties where all residents live more than 10 miles from a supermarket or a supercenter—this is 20 percent of rural counties. In rural communities, inadequate transportation can be a particular challenge. In Mississippi, which has the highest obesity rate of any State, over 70 percent of food stamp eligible households travel more than 30 miles to reach a supermarket. Adults living in rural Mississippi food desert counties are 23 percent less likely to consume the recommended fruits and vegetables than those in counties that have supermarkets, controlling for age, sex, race, and education.

Controlling for population density, rural areas have fewer food retailers of any types compared to urban areas, and only 14 percent the number of chain supermarkets. For instance, in New Mexico, rural residents have access to fewer grocery stores than urban residents, pay more for comparable items, and have less selection. The same market basket of groceries costs $85 for rural residents versus $55 for urban residents.

The results of this lack of healthy food options are grim—these communities have significantly higher rates of obesity, diabetes, and other related health issues. Over the past decade, obesity rates have more than doubled in children and tripled in adolescents. In 2010, PolicyLink and The Food Trust conducted a review of more than 130 studies on the issue of access to healthy food and found a direct correlation between diet-related diseases and access. A California study found that obesity and diabetes rates were 20 percent higher for those living in the least healthy "food environments." In Indianapolis, a study found that BMI values corresponded with access to supermarkets and fast food restaurants. Researchers estimated that adding a new grocery store to a high poverty neighborhood translates into a 3 pound weight decrease.

Fortunately, changing access changes eating habits. For every additional supermarket in a census tract, produce consumption increases 32 percent for African Americans and 11 percent for whites, according to a multistate study. A survey of produce availability in New Orleans' small neighborhood stores found that for each additional meter of shelf space devoted to fresh vegetables, residents eat an additional .35 servings per day. In fact, of 14 studies that examine food access and consumption of healthy foods, all but one of them found a correlation between greater access and better eating behaviors. This is also true for food stamp recipients. Proximity to a supermarket was found to be associated with increased fruit and vegetable consumption.

The problems associated with lack of access go beyond health. Low-income communities are cut off from all the economic development benefits that come with a local grocery store: the creation of steady jobs at decent wages and the sparking of complementary retail stores and services nearby. Grocery stores operate as important economic anchors for communities, providing a vital service and bringing customers that can also support other nearby business. Securing new or improved local grocery stores can improve local economies and create jobs.

President Barack Obama's proposed fiscal year 2012 budget includes a proposal to invest $330 million, including $250 million in New Markets Tax Credits, in a national HFFI. Specifically, the initiative would provide:

—$35 million through USDA's Office of the Secretary, with additional "other funds of Rural Development and the Agricultural Marketing Service available to support the USDA's portion of the Healthy Food Financing Initiative";
—$25 million through the Treasury Department's CDFI Fund;
—$20 million through Health and Human Services; and
—$250 million through the Treasury Department's New Markets Tax Credits Program.

A Healthy Food Financing Initiative would attract investment in underserved communities by providing critical loan and grant financing. These one-time resources will help fresh food retailers overcome the higher initial barriers to entry into underserved, low-income urban and rural communities, and would also support renovation and expansion of existing stores so they can provide the healthy foods that communities want and need. The program would be flexible and comprehensive enough to support innovations in healthy food retailing and to assist retailers with different aspects of the store development and renovation process.

Grocery industry representatives find that there are obstacles to grocery store development in underserved low-income communities, but also that those obstacles can be overcome. The development process for building a new grocery store is

lengthy and complex, and retailers often find that stores in low-income communities have high start-up costs, appropriate sites are hard to find, and securing financing is difficult. Grocery operators in both urban and rural areas cite lack of access to flexible financing as one of the top barriers hindering the development of stores in underserved areas.

HFFI is modeled after the successful Pennsylvania Fresh Food Financing Initiative (FFFI), a public/private partnership launched in 2004. Using a State investment of $30 million, the program has led to:

—projects totaling more than $190 million;
—88 stores built or renovated in underserved communities in urban and rural areas across the State;
—improved access to healthy food for more than 400,000 residents;
—more than 5,000 jobs created or retained;
—increased local tax revenues; and
—much-needed additional economic development in these communities.

Stores range from full-service 70,000 square foot supermarkets to 900 square food shops; and from traditional grocery stores to farmers' markets, cooperatives, and corner stores selling healthy food. Approximately two-thirds of the projects were in rural areas and small towns with the remainder in urban areas.

HFFI is a viable, effective, and economically sustainable solution to the problem of limited access to healthy foods. It can bring triple bottomline benefits, achieving multiple goals: reducing health disparities and improving the health of families and children; creating jobs; and, stimulating local economic development in low-income communities.

HFFI would incorporate the key components that allowed the Pennsylvania program to be so effective at attracting private dollars, garnering the commitment of store operators, getting fresh food retail stores and markets successfully developed, and stimulating local economies.

The Pennsylvania FFFI has been cited as an innovative model by the U.S. Centers for Disease Control and Prevention, the National Conference of State Legislatures, Harvard's Kennedy School of Government, and the National Governors Association. There is significant momentum in many States and cities across the country to address the lack of grocery access in underserved communities. Several States and/or cities are in the process of replicating the successful Pennsylvania Fresh Food Financing Initiative Program, and many others have begun to examine the needs and opportunities in their communities. For example:

—The State of New York has launched the Healthy Food, Healthy Communities Initiative, a business financing program to encourage supermarket and other fresh food retail investment in underserved areas throughout the State that will provide loans and grants to eligible projects. New York City has launched a complementary FRESH program that will encourage supermarket development through tax and zoning incentives and a single point of access to city government for supermarket operators.
—The City of New Orleans recently launched the Fresh Food Retailer Initiative Program (FFRI) that will provide direct financial assistance to retail businesses by awarding forgivable and/or low-interest loans to grocery stores and other fresh food retailers.
—The California Endowment, NCB Capital Impact, and other community, supermarket industry, and government partners have been working to create a supermarket financing program in California that is expected to be launched in the first half of 2011.

A national Healthy Food Financing Initiative could amplify the impact in each of these States and leverage the work already underway to ensure swift implementation. Moreover, a national HFFI would insure that all State and communities could solve their food desert problems with new stores and other healthy food retail projects.

In the midst of our current economic downturn, the need for a comprehensive Federal policy to address the lack of fresh food access in low-income is critical. We urge the Committee to support full funding for a Healthy Food Financing Initiative, for the benefit of communities across the Nation. Thank you for the opportunity to share our perspectives with you today. If you should need additional information about HFFI please contact Judith Bell from PolicyLink (Judith@policylink.org), Pat Smith from The Reinvestment Fund (patricia.smith@trffund.org), or John Weidman from The Food Trust (Jweidman@thefoodtrust.org)

PREPARED STATEMENT OF THE POPULATION ASSOCIATION OF AMERICA/ASSOCIATION OF POPULATION CENTERS

*Background on the PAA/APC and Demographic Research*

The Population Association of America (PAA) is a scientific organization comprised of over 3,000 population research professionals, including demographers, sociologists, statisticians, and economists. The Association of Population Centers (APC) is a similar organization comprised of over 40 universities and research groups that foster collaborative demographic research and data sharing, translate basic population research for policy makers, and provide educational and training opportunities in population studies. Population research centers are located at public and private research institutions nationwide.

Demography is the study of populations and how or why they change. Demographers, as well as other population researchers, collect and analyze data on trends in births, deaths, and disabilities as well as racial, ethnic, and socioeconomic changes in populations. Major policy issues population researchers are studying include the demographic causes and consequences of population aging, trends in fertility, marriage, and divorce and their effects on the health and well being of children, and immigration and migration and how changes in these patterns affect the ethnic and cultural diversity of our population and the Nation's health and environment.

The NIH mission is to support research that will improve the health of our population. The health of our population is fundamentally intertwined with the demography of our population. Recognizing the connection between health and demography, the NIH supports extramural population research programs primarily through the National Institute on Aging (NIA) and the National Institute of Child Health and Human Development (NICHD).

*National Institute on Aging*

According to the Census Bureau, by 2029, all of the baby boomers (those born between 1946 and 1964) will be age 65 years and over. As a result, the population age 65–74 years will increase from 6 percent to 10 percent of the total population between 2005 and 2030. This substantial growth in the older population is driving policymakers to consider dramatic changes in Federal entitlement programs, such as Medicare and Social Security, and other budgetary changes that could affect programs serving the elderly. To inform this debate, policymakers need objective, reliable data about the antecedents and impact of changing social, demographic, economic, and health characteristics of the older population. The NIA Division of Behavioral and Social Research (BSR) is the primary source of Federal support for research on these topics.

In addition to supporting an impressive research portfolio, that includes the prestigious Centers of Demography of Aging and Roybal Centers for Applied Gerontology Programs, the NIA BSR program also supports several large, accessible data surveys. One of these surveys, the Health and Retirement Study (HRS), has become one of the seminal sources of information to assess the health and socioeconomic status of older people in the United States. Since 1992, the HRS has tracked 27,000 people, providing data on a number of issues, including the role families play in the provision of resources to needy elderly and the economic and health consequences of a spouse's death. HRS is particularly valuable because its longitudinal design allows researchers: (1) the ability to immediately study the impact of important policy changes such as Medicare Part D; and (2) the opportunity to gain insight into future health-related policy issues that may be on the horizon, such as HRS data indicating an increase in pre-retirees self-reported rates of disability. In August 2011, HRS will release genotyping data, enhancing the ability of researchers to track the onset and progression of diseases and conditions affecting the elderly.

Currently, the NIA is paying grant applications requesting less than $500,000 in direct costs through the 11th percentile, while grants seeking $500,000 or more are being paid through the 8th percentile—making it one of the lowest paylines at NIH. As research costs increase, NIA faces the prospect of funding fewer grants to sustain larger ones in its commitment base. With additional support in fiscal year 2012, the NIA BSR program could fully fund its large-scale projects, including the existing centers programs and ongoing surveys, without resorting to cost cutting measures, such as cutting sample size, while continuing to support smaller investigator initiated projects

*Eunice Kennedy Shriver National Institute on Child Health and Human Development*

Since its establishment in 1968, the Eunice Kennedy Shriver NICHD Center for Population Research has supported research on population processes and change. Today, this research is housed in the Center's Demographic and Behavioral Sciences Branch (DBSB). The Branch encompasses research in four broad areas: family and fertility, mortality and health, migration and population distribution, and population composition. In addition to funding research projects in these areas, DBSB also supports a highly regarded population research infrastructure program and a number of large database studies, including the National Longitudinal Study of Adolescent Health (Add Health), Panel Study of Income Dynamics, and National Longitundinal Study of Youth.

NIH-funded demographic research has consistently provided critical scientific knowledge on issues of greatest consequence for American families: work-family conflicts, marriage and childbearing, childcare, and family and household behavior. However, in the realm of public health, demographic research is having an even larger impact, particularly on issues regarding adolescent and minority health. Understanding the role of marriage and stable families in the health and development of children is another major focus of the NICHD DBSB. Consistently, research has shown children raised in stable family environments have positive health and development outcomes. Policymakers and community programs can use these findings to support unstable families and improve the health and well being of children.

One of the most important programs the NICHD DBSB supports is the Population Research Infrastructure Program (PRIP). Through PRIP, research is conducted at private and public research institutions nationwide. The primary goal of PRIP is "to facilitate interdisciplinary collaboration and innovation in population research, while providing essential and cost-effective resources in support of the development, conduct, and translation of population research." Population research centers supported by PRIP are focal points for the demographic research field where innovative research and training activities occur and resources, including large-scale databases, are developed and maintained for widespread use.

With additional support in fiscal year 2012, NICHD could sustain full funding to its large-scale surveys, which serve as a resource for researchers nationwide. Furthermore, the Institute could apply additional resources toward improving its funding payline, which has fallen from the 13th percentile in fiscal year 2010 to the 11th percentile in fiscal year 2011. Additional support could be used to support and stabilize essential training and career development programs necessary to prepare the next generation of researchers and to support and expand proven programs, such as PRIP.

*National Center for Health Statistics*

Located within the Centers for Disease Control (CDC), the National Center for Health Statistics (NCHS) is the Nation's principal health statistics agency, providing data on the health of the U.S. population and backing essential data collection activities. Most notably, NCHS funds and manages the National Vital Statistics System, which contracts with the States to collect birth and death certificate information. NCHS also funds a number of complex large surveys to help policy makers, public health officials, and researchers understand the population's health, influences on health, and health outcomes. These surveys include the National Health and Nutrition Examination Survey (NHANES), National Health Interview Survey (HIS), and National Survey of Family Growth. Together, NCHS programs provide credible data necessary to answer basic questions about the state of our Nation's health.

Despite recent steady funding increases, NCHS continues to feel the effects of long-term funding shortfalls, compelling the agency to undermine, eliminate, or further postpone the collection of vital health data. For example, in 2009, sample sizes in HIS and NHANES were cut, while other surveys, most notably the National Hospital Discharge Survey, were not fielded. In 2009, NCHS proposed purchasing only "core items" of vital birth and death statistics from the States (starting in 2010), effectively eliminating three-fourths of data routinely used to monitor maternal and infant health and contributing causes of death. Fortunately, Congress and the new Administration worked together to give NCHS adequate resources and avert implementation of these draconian measures. Nonetheless, the agency continues to operate in a precarious state.

The Administration recommends NCHS receive $161.9 million in fiscal year 2011; however, ultimately, the agency received $23.2 million less than the Administration requested. This reduced amount has postponed important initiatives to, for example,

re-engineer collection of the Nation's vital statistics, using standard birth and death certificate items.

PAA and APC, as members of The Friends of NCHS, support the Administration's request for fiscal year 2012, $162 million, in hopes many initiatives proposed by the Administration in fiscal year 2011 can proceed, including an effort to fully support electronic birth records in all 50 States.

*Bureau of Labor Statistics*

During these turbulent economic times, data produced by the Bureau of Labor Statistics (BLS) are particularly relevant and valued. PAA and APC members have relied historically on objective, accurate data from the BLS. In recent years, our organizations have become increasingly concerned about the state of the agency's funding.

We are pleased the Administration has requested BLS receive a total of $647 million in fiscal year 2012. According to the agency, this funding level would enable BLS, for example, to add the Contingent Work Supplement to the Current Population Survey, making more data available on changing workplace arrangements and continue its work on developing an alternative poverty measure.

*Summary of fiscal year 2012 Recommendations*

In sum, the PAA and APC support the Administration's fiscal year 2012 request for the National Institutes of Health, National Center for Health Statistics and the Bureau of Labor Statistics. With respect to the NIH, however, we support the Administration's request as a floor and encourage the Subcommittee to consider providing the NIH with funding as high as $35 billion. This amount, endorsed by the Ad Hoc Group for Medical Research, reflects not only inflation, but also the additional investment needed to sustain the new research capacity created by the American Recovery and Reinvestment Act.

Thank you for considering our requests and for supporting Federal programs that benefit the population sciences.

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## PREPARED STATEMENT OF PREVENT BLINDNESS AMERICA

### FUNDING REQUEST OVERVIEW

Prevent Blindness America appreciates the opportunity to submit written testimony for the record regarding fiscal year 2012 funding for vision and eye health related programs. As the Nation's leading nonprofit, voluntary health organization dedicated to preventing blindness and preserving sight, Prevent Blindness America maintains a long-standing commitment to working with policymakers at all levels of government, organizations and individuals in the eye care and vision loss community, and other interested stakeholders to develop, advance, and implement policies and programs that prevent blindness and preserve sight. Prevent Blindness America respectfully requests that the Subcommittee provide the following allocations in fiscal year 2012 to help promote eye health and prevent eye disease and vision loss:

—Provide at least $3.23 million to maintain vision and eye health efforts at the Centers for Disease Control and Prevention (CDC).

—Support the Maternal and Child Health Bureau's (MCHB) National Center for Children's Vision and Eye Health (Center).

—Provide additional resources for the National Eye Institute (NEI).

### INTRODUCTION AND OVERVIEW

Vision-related conditions affect people across the lifespan from childhood through elder years. Good vision is an integral component to health and well-being, affects virtually all activities of daily living, and impacts individuals physically, emotionally, socially, and financially. Loss of vision can have a devastating impact on individuals and their families. An estimated 80 million Americans have a potentially blinding eye disease, 3 million have low vision, more than 1 million are legally blind, and 200,000 are more severely visually blind. Vision impairment in children is a common condition that affects 5 to 10 percent of preschool age children. Vision disorders (including amblyopia ("lazy eye"), strabismus ("cross eye"), and refractive error are the leading cause of impaired health in childhood.

Alarmingly, while half of all blindness can be prevented through education, early detection, and treatment, the NEI reports that "the number of Americans with age-related eye disease and the vision impairment that results is expected to double

within the next three decades."[1] Among Americans age 40 and older, the four most common eye diseases causing vision impairment and blindness are age-related macular degeneration (AMD), cataract, diabetic retinopathy, and glaucoma.[2] Refractive errors are the most frequent vision problem in the United States—an estimated 150 million Americans use corrective eyewear to compensate for their refractive error.[2] Uncorrected or under-corrected refractive error can result in significant vision impairment.[2]

To curtail the increasing incidence of vision loss in America, Prevent Blindness America advocates sustained and meaningful Federal funding for programs that help promote eye health and prevent eye disease, vision loss, and blindness; needed services and increased access to vision screening; and vision and eye disease research. We thank the Subcommittee for its consideration of our specific fiscal year 2012 funding requests, which are detailed below.

VISION AND EYE HEALTH AT THE CDC: HELPING TO SAVE SIGHT AND SAVE MONEY

The CDC serves a critical national role in promoting vision and eye health. Since 2003, the CDC and Prevent Blindness America have collaborated with other partners to create a more effective public health approach to vision loss prevention and eye health promotion. The CDC works to:

—Promote eye health and prevent vision loss.
—Improve the health and lives of people living with vision loss by preventing complications, disabilities, and burden.
—Reduce vision and eye health related disparities.
—Integrate vision health with other public health strategies.

*Integrating Vision Health into Broader Disease Prevention and Health Promotion Efforts*

One of the cornerstone activities of the vision and eye health work at the CDC is its support and encouragement of efforts to better integrate State-level initiatives to address vision and eye disease by approaching vision health through other public health prevention, treatment, and research efforts. Vision loss is associated with a myriad of other serious chronic, life threatening, and disabling conditions, including diabetes, depression, unintentional injuries, and other health problems and behavioral risk factors such as tobacco use. Leveraging scarce resources and recognizing the numerous connections between eye health and other diseases, the CDC works to integrate and connect vision health initiatives to other State, local, and community health programs.

To advance State-based vision health integration, CDC funds are supporting a joint effort between the New York State Department of Health and Prevent Blindness Tri-State, focused on integrating vision-related services at the State and local level. Working together, these partners are promoting vision loss prevention strategies within the State Department of Health. One initiative resulting from this partnership has been the launch of a statewide tobacco cessation media campaign highlighting the impact of smoking on potential vision loss. Other examples include State-based programs to prevent and reduce diabetes, including efforts to educate patients and healthcare providers of the relationship between diabetes and certain eye problems, such as diabetic retinopathy and cataracts. A similar effort has recently been initiated in Texas.

The goal of these integration efforts is to ensure that vision loss and eye health promotion are incorporated into all relevant local, State, and Federal public health interventions, prevention and treatment programs, and other initiatives that impact causes of—and factors that contribute to—vision problems and blindness. By integrating efforts and coordinating approaches in this manner, Federal and State resources will be used more efficiently, eye health problems and vision loss can be reduced, and the overall health and well-being of individuals and communities will be improved.

*Identifying and Preventing Vision Problems through Community-Based Strategies*

The CDC supports private sector efforts to develop and evaluate better ways to identify and treat individuals with potential eye disease, vision loss, and other ocular conditions. Among other efforts, CDC funding is currently supporting:

—A study to assess the overall effectiveness and costs associated with implementing an adult vision and eye health history and risk assessment/referral program. This study, being conducted by Johns Hopkins University, in partner-

[1] "Vision Problems in the U.S.: Prevalence of Adult Vision Impairment and Age-Related Eye Disease in America," Prevent Blindness America and the National Eye Institute, 2008.
[2] Ibid.

ship with Prevent Blindness Ohio, is working in collaboration with the Physician's Free Clinic in Columbus, Ohio and Akron Community Health Resources to investigate the best methods for identifying patients who need eye care services and providing linkages to follow-up care.

—An initiative spearheaded by Duke University and Prevent Blindness North Carolina to evaluate the benefit of pediatric and school-based vision screening. The project identified the need to ensure proper ongoing training and education of pediatricians on vision screening. In collaboration with the American Board of Pediatrics, the project has developed maintenance of certification module to improve office-based preschool vision screening.

*Data Collection*

Understanding the breadth and depth of vision and eye health issues across the Nation is paramount to ensuring appropriate allocation of resources and effective deployment of targeted interventions. Thus, the CDC supports programs and systems that collect, evaluate, and disseminate critical vision health data.

—The CDC developed the first optional Behavioral Risk Factor Surveillance System (BRFSS)[3] vision module, which collects State-based information on access to eye care and the prevalence of eye disease and eye injury. Early in 2011, the CDC will publish a report describing visual impairment as a serious public health issue affecting more than 2.9 million Americans. Unfortunately, in part due to insufficient funding, only 19 States currently use the vision module; this lack of broad adoption precludes the CDC, Congress, and other stakeholders from having the information they need to understand and address the full scope of vision loss and eye health problems facing the Nation.

—CDC funding is supporting a joint endeavor between Duke University and Prevent Blindness America to conduct a systematic evidence review to describe the delivery systems of vision-related services and to identify new areas for policy evaluation or clinical research. This information will help identify the most at-risk populations and highlight gaps in care and service delivery to ensure that public and private resources are allocated to areas of greatest need.

To that end, Prevent Blindness America respectfully requests the Subcommittee provide a $3.23 million allocation for vision and eye health initiatives at the CDC. This level of investment will help the CDC sustain its efforts to address the growing public health threat of preventable vision loss among at-risk and underserved populations. fiscal year 2012 resources will support strengthened State-based public health integration efforts to address vision and eye health and the development of additional evidence-based public health interventions that improve eye health among the Nation's most at-risk and underserved.

INVESTING IN THE VISION OF OUR NATION'S MOST VALUABLE RESOURCE—CHILDREN

While the risk of eye disease increases after the age of 40, eye and vision problems in children are of equal concern. If left untreated, they can lead to permanent and irreversible visual loss and/or cause problems socially, academically, and developmentally. Although more than 12.1 million school-age children have some form of a vision problem, only one-third of all children receive eye care services before the age of six.[4]

In 2009, the Maternal and Child Health Bureau established the National Center for Children's Vision and Eye Health, a national vision health collaborative effort aimed at developing the public health infrastructure necessary to promote eye health and ensure access to a continuum of eye care for young children. Prevent Blindness America is requesting ongoing support for the National Center for Children's Vision and Eye Health.

With this support the Center, will continue to:

—Provide national leadership in the development of best practices and guidelines for public health infrastructure, national vision screening guidelines, and statewide strategies that ensure early detection, vision screening, and a continuum of vision and eye healthcare for children.

—Determine mechanisms for advancing State-based performance improvement systems, screening guidelines, and a mechanism for uniform data collection and reporting.

—Collaborate with States to develop and implement statewide strategies for vision screening, establish quality improvement strategies, and determine mecha-

[3] BRFSS is a State-based system of health surveys that collects information on chronic disease and injury.

[4] "Our Vision for Children's Vision: A National Call to Action for the Advancement of Children's Vision and Eye Health, Prevent Blindness America," Prevent Blindness America, 2008.

nisms for the improvement of data systems and reporting of children's vision and eye health services.

ADVANCE AND EXPAND VISION RESEARCH OPPORTUNITIES

Prevent Blindness America calls upon the Subcommittee to provide additional support for the NEI to bolster its efforts to identify the underlying causes of eye disease and vision loss, improve early detection and diagnosis of eye disease and vision loss, and advance prevention and treatment efforts. Research is critical to ensure that new treatments and interventions are developed to help reduce and eliminate vision problems and potentially blinding eye diseases facing consumers across the country. In 2009, Congress commended the NEI's leadership in basic and translational research through H. Res. 366 and S. Res. 209 (111th Congress), which recognized NEI's 40 years as the National Institutes of Health (NIH) Institute that leads the Nation's commitment to save and restore vision. The Resolutions also designated 2010–2020 as the Decade of Vision in recognition of the increasing health and economic burden of eye disease, mainly as a result of an aging population.

Through additional support, the NEI will be able to continue to grow its efforts to:

—Expand capacity for research, as demonstrated by the significant number of high-quality grant applications submitted in response to American Recovery and Reinvestment Act opportunities.

—Address unmet need, especially for programs of special promise that could reap substantial downstream benefits.

—Fund research to reduce healthcare costs, increase productivity, and ensure the continued global competitiveness of the United States.

By providing additional funding for the NEI at the NIH, essential efforts to identify the underlying causes of eye disease and vision loss, improve early detection and diagnosis of eye disease and vision loss, and advance prevention, treatment efforts and health information dissemination will be bolstered.

CONCLUSION

On behalf of Prevent Blindness America, our Board of Directors, and the millions of people at risk for vision loss and eye disease, we thank you for the opportunity to submit written testimony regarding fiscal year 2012 funding for the CDC's vision and eye health initiatives, the MCHB's National Center for Children's Vision and Eye Health, and the NEI. Please know that Prevent Blindness America stands ready to work with the Subcommittee and other Members of Congress to advance policies that will prevent blindness and preserve sight. Please feel free to contact us at any time; we are happy to be a resource to Subcommittee members and your staff. We very much appreciate the Subcommittee's attention to—and consideration of—our requests.

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## PREPARED STATEMENT OF PROLITERACY

Chairman Harkin, Ranking Member Shelby, and members of the Subcommittee, on behalf of the millions of adult learners working to improve their basic reading, writing, math, and computer skills and pursue greater economic opportunity for themselves and their families, thank you for the opportunity to provide written testimony regarding the President's fiscal year 2012 budget request for adult education and family literacy, provided for under the Workforce Investment Act, Title II. We would be pleased to testify and participate in any future hearings regarding adult literacy and basic education.

We strongly urge you to approve at the very least, the President's request of $658.3 million for Adult Basic and Literacy Education in fiscal year 2012 to better assist the one in seven adults nationally who struggle with illiteracy. At a time when millions of Americans are struggling to find work, it is essential to invest in adult learning in order to put more American families on the road to self-sufficiency and economic security.

*Background: ProLiteracy*

ProLiteracy is the world's oldest and largest organization of adult literacy and basic education programs in the United States. ProLiteracy traces its roots to two premiere adult literacy organizations: Laubach Literacy International and Literacy Volunteers of America. In 2002, these two organizations merged to create ProLiteracy.

ProLiteracy represents more than 1,000 community-based organizations and adult basic education programs in the United States, and we partner with literacy organi-

zations in 50 developing countries. In communities across the United States, these organizations use trained volunteers, teachers, and instructors to provide one-on-one tutoring, classroom instruction, and specialized classes in reading, writing, math, technology, English language skills, job-training and workforce literacy skills, GED preparation, and citizenship. Our members are located in all 50 States and in the District of Columbia. Through education, training and advocacy, ProLiteracy supports the frontline work of these organizations with regional conferences and other training events; credentialing; and the publication of materials and products used to teach adults basic literacy and English-as-a-second-language and to prepare adults for the U.S. citizenship exam and GED Tests.

*The Urgent Need to Invest in Adult Education*

In 2003, the U.S. Department of Education conducted the National Assessment of Adult Literacy (NAAL) in order to gauge the English reading and comprehension skills of individuals in the United States over the age of 16 on daily literacy tasks such as reading a newspaper article, following a printed television guide, and completing a bank deposit slip. The results indicated that 30 million adults—14 percent of this country's adult population—had below basic literacy skills; that is, their ability to read was so poor, they could not complete a job application without help or follow the directions on a medicine bottle. An additional 63 million adults read only slightly better, for a total of 93 million American adults who are considered low literate.

Because under-educated adults are more likely to be unemployed and require public assistance, the high percentage of low-literate adults is having an adverse affect on our Nation's efforts to reduce unemployment and reduce the deficit. In 2009, 14.6 percent of those without a high school diploma were unemployed compared to 9.7 percent of high school graduates; 8.6 percent of those with some college; 6.8 percent with an associate's degree; 4.6 percent with a 4-year degree or more.[1] And the trends for these adults are not encouraging. For example, while 67 percent of the service industry's jobs in 1983 required a high school diploma or less, this percentage is expected to drop to zero by 2018.[2]

In addition, we will fail to meet President Obama's goal of once again leading the world in college degree attainment unless we support more adults without college degrees to enroll in post-secondary education. To meet the President's goal, it is estimated that the United States will need to move at least 3.4 million adults with high school diplomas but no college degrees into postsecondary education.[3] Increasing the number of adults with high-school degrees or equivalents, and with the skills to succeed in college, will help us achieve this goal.

The bottom line is that a greater investment in adult education will increase employment and postsecondary enrollments, move individuals off of public assistance, and ultimately reduce the deficit.

Despite the critical role that adult education plays in reducing unemployment and increasing postsecondary attainment, the adult education system currently only has the capacity to serve approximately 2.5 million of these 93 million adults each year. Adult education has been basically flat funded for a decade, seeing only a modest overall increase from 2001–2010.[4] In fiscal year 2011, the number of individuals served will almost certainly be reduced as a result of the $32.1 million cut to Title II State grants in the final fiscal year 2011 CR. This cut comes at a time when many States are responding to drastically declining revenues by slashing budgets for education, training, and human services, including their investments in adult education.

*The Proposed Adult Basic and Literacy Education Budget*

The proposed fiscal year 2012 budget includes several significant features that we strongly support. First, the President requested $635 million for State formula grants for adult education through the Workforce Investment Act (WIA), Title II, an increase of $6.8 million compared to the 2010 appropriation. As we have discussed above, the need for increased investment in adult education is clear, and we welcome the President's call for a modest increase.

We recognize that in the current fiscal environment, the subcommittee will be reluctant to increase spending in many areas of the budget above this year's level. If an increase is not possible, it is critically important to hold spending for adult education and literacy at current levels. An additional cut to Title II funding on top

[1] http://www.bls.gov/cps/cpsaat7.pdf.
[2] http://cew.georgetown.edu/(see Figure 4.17, pg. 86).
[3] http://www.womeningovernment.org/files/onemillion__letter.pdf.
[4] http://www2.ed.gov/about/overview/budget/history/edhistory.pdf.

of the $31 million cut in fiscal year 2011 would be devastating to State adult education systems around the country, and, as we have noted, would likely increase unemployment and contribute to the deficit.

*Workforce Innovation*

The administration proposes to set aside $50.8 million from the State formula funds to support a Workforce Innovation Fund (WIF), which will also include $30 million in funding from the Rehabilitation Services and Disability Research account, and almost $298 million from the Department of Labor.

ProLiteracy applauds the administration's commitment to innovation. We urge the Subcommittee to ensure that innovation funding will benefit adults at all skill levels, particularly the millions who are estimated to possess less than basic literacy skills served by community-based organizations. We suggest, in fact, competitive priority for proposals that will address those at the lowest levels of literacy and those with significant barriers to learning.

However, we also caution that after experiencing a dramatic cut to State formula funding in fiscal year 2011, care must be taken to ensure that State formula funding is sufficient to ensure the survival of existing programs. ProLiteracy urges the Subcommittee to ensure that the WIF, if it moves forward, is funded on top of annual WIA formula funds, rather than as a carve out of existing formula funds.

*National Leadership*

The President's proposal also includes an additional $12 million for national leadership funds to the Department of Education that would be used to evaluate the impact of college bridge programs that assist adult learners in transitioning from adult basic education to postsecondary education and training, and for building greater technology infrastructure for adult learners and adult educators.

We believe these ideas reflect real needs in our field, and if these initiatives lead to new resources and better services on the ground for learners and the programs that serve them, than this could be a very positive development. Again, however, we would urge that any new programming that would not have an immediate, direct, benefit to adult learners not come at the expense of State formula funds.

*WIA Reauthorization and Use of National Leadership Funds*

The President's budget request also supports the reauthorization of WIA, and specifically calls for better alignment between Title I and Title II. We share the administration's desire for more streamlined service delivery systems that are more engaged with employers, and the promotion of innovative career pathways models—but in particular for those learners at the lowest levels of literacy.

We strongly urge, therefore, expanding funding opportunities for community-based programs that have successfully implemented strategies for delivering basic literacy instruction together with employment training so that they may document and disseminate best practices related to the integration of title I job training programs with title II adult literacy programs.

Through both reauthorization of the Workforce Investment Act and use of national leadership funding, we also recommend that the Department examine and publish successful strategies and best practices that can help adults with low literacy levels improve their overall skills and employment opportunities.

We note that learners at the lowest levels of literacy often receive literacy instruction at community-based organizations (CBOs) that utilize trained volunteers. For decades, volunteers, and other types of non-career instructors such as such as VISTA or AmeriCorps members, have been a vital component in the delivery of education services for adults with low literacy in the United States. Volunteers serve in non-instructional roles as well such as mentoring, counseling, recruiting students, and serving as teaching aides to paid instructors.

However, adult education career pathway programs are based largely on traditional career pathways programs that connect secondary and postsecondary students to further education and work in a specific industry. As a result, the limited existing research on career pathway approaches used with adult learners is largely focused on students with higher-level literacy skills.

We therefore urge the subcommittee to ensure that CBOs that utilize trained volunteers are integrated into the Department's career pathways strategies. We suggest that the Department identify and disseminate successful strategies and best practices that will assist community-based organizations that utilize adult literacy volunteers to support the Department's career pathways initiatives; and implement strategies to increase participation by community-based organizations that utilize trained volunteers in any related technical assistance efforts.

Thank you for the opportunity to present this testimony. We would be happy to respond to any questions that you may have.

## PREPARED STATEMENT OF THE PROSTATITIS FOUNDATION

We are the unpaid volunteers at the Prostatitis Foundation representing thousands of men nationwide with prostatitis. Our mission for 15 years has been to:

—Educate the public about the prevalence of prostatitis by our website www.prostatitis.org, our newsletters, and newspaper and magazine articles. It is estimated that 10 percent of all males suffer from chronic prostatitis/pelvic pain syndrome (CP/PPS) and 50 percent of men will experience (CP/PPS) during their lifetime. Symptoms can include severe pelvic pain, urinary and sexual dysfunction and infertility. The possible connection of prostatitis to prostate cancer is uncertain and not adequately researched. Prostatitis is common in young men who are at an age where they are reluctant to discuss such personal matters as pelvic pain, voiding problems and sexual dysfunction with family, friends or co-workers. The result has been an unpublicized crisis and a costly, hopeless medical condition.

—Encourage research funding. We have worked with the NIH research team personnel and research centers over three sets of multi-year clinical trial programs going back to 1996. We are now assisting with the fourth group of nationwide research centers. The Map Network is a group of researchers who have been assembled by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to include specialties besides urology to get some basic scientific research that will lead to determining a cause and cure for (CP/PPS). Everyone has too much time and expense invested to let these efforts expire without pushing to complete this search for a cause and cure for (CP/PPS). If we do not build on the efforts of the three previous accumulations of data to determine a cause and cure it will be lost and the next group will have to start at the beginning again.

We request continuing funding and direction through The National Institutes of Health (NIH) to National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) who are over seeing this Mapp Network of research centers.

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## PREPARED STATEMENT OF THE PULMONARY HYPERTENSION ASSOCIATION

Mr. Chairman, thank you for the opportunity to submit testimony on behalf of the Pulmonary Hypertension Association (PHA).

I would like to extend my sincere thanks to the Subcommittee for your past support of pulmonary hypertension (PH) programs at the National Institutes of Health, Centers for Disease Control and Prevention, and Health Resources and Services Administration. These initiatives have opened many new avenues of promising research, helped educate hundreds of physicians in how to properly diagnose PH, and raised awareness about the importance of organ donation and transplantation within the PH community.

I am honored today to represent the hundreds of thousands of Americans who are fighting a courageous battle against a devastating disease. Pulmonary hypertension is a serious and often fatal condition where the blood pressure in the lungs rises to dangerously high levels. In PH patients, the walls of the arteries that take blood from the right side of the heart to the lungs thicken and constrict. As a result, the right side of the heart has to pump harder to move blood into the lungs, causing it to enlarge and ultimately fail.

PH can occur without a known cause or be secondary to other conditions such as: collagen vascular diseases (i.e., scleroderma and lupus), blood clots, HIV, sickle cell, or liver disease. PH impacts patients of all races, genders, and ages. Preliminary data from the REVEAL Registry suggests that the ratio of women to men who develop PH is 4:1. Patients develop symptoms that include shortness of breath, fatigue, chest pain, dizziness, and fainting.

Unfortunately, these symptoms are frequently misdiagnosed, leaving patients with the false impression that they have a minor pulmonary or cardiovascular condition. By the time many patients receive an accurate diagnosis, the disease has progressed to a late stage, making it impossible to receive a necessary heart or lung transplant. PH is chronic and incurable with a poor survival rate. Fortunately, new treatments are providing a significantly improved quality of life for patients with some managing the disorder for 20 years or longer.

In 1990, when three PH patients found each other with the help of the National Organization for Rare Diseases, and founded the Pulmonary Hypertension Association, there were less than 200 diagnosed cases of this disease. It was virtually unknown among the general population and not well known in the medical community. They soon realized that this was unacceptable, and formally established PHA, which is headquartered in Silver Spring, Maryland. I am pleased to report that we

are making good progress in our fight against this deadly disease. Nine medications for the treatment of PH have been approved by the FDA in the past 16 years.

Today, PHA includes:

—More than 20,000 members and supporters.

—A network of 230+ patient support groups and an active patient-to-patient telephone helpline.

—Three research programs that, through partnerships with the National Heart, Lung and Blood Institute, American Heart Association and the American Thoracic Society, have leveraged our donors' funds to commit more than $10 million toward PH research as of 2011.

—Numerous electronic and print publications, including the first medical journal devoted to pulmonary hypertension—published quarterly and distributed to all cardiologists, pulmonologists, and rheumatologists in the United States.

—A state-of-the-art website(www.phassociation.org) dedicated to providing educational and support resources to patients, caregivers, and the public.

—A medical education website (www.phaonlineuniv.org), supported in part by the CDC, providing accredited medical education and resources to the medical community

FISCAL YEAR 2012 APPROPRIATIONS RECOMMENDATIONS

*National Heart, Lung And Blood Institute*

Less than two decades ago, a diagnosis of PH was essentially a death sentence, with only one approved treatment for the disease. Thanks to advancements made through the public and private sector, patients today are living longer and better lives with a choice of nine FDA approved medications. Recognizing that we have made tremendous progress, we are also mindful that we are a long way from where we want to be in (1) the management of PH as a treatable chronic disease, and (2) a cure.

We are grateful to the National Heart, Lung and Blood Institute for their leadership in advancing research on PH. Our Association is proud to jointly sponsor investigator training grants (K awards) with NHLBI aimed at supporting the next generation of pulmonary hypertension researchers.

Moreover, we were very pleased that NHLBI recently convened some of the community's leading scientists for a Working on Group on Lung Vascular Research. The panel produced recommendations that should guide pulmonary vascular disease research and treatment, including PH research, in coming years. Their recommendations, published in the American Journal of Respiratory and Critical Care Medicine in October, 2010 are as follows:

—Advance basic scientific research in lung vascular biology utilizing emerging technologies.

—Advance and coordinate basic and clinical knowledge of the pulmonary circulation-right heart axis through novel research efforts utilizing multidisciplinary teams.

—Define interactions between lung vascular components and circulating elements and systemic circulations by fostering novel collaborations.

—Encourage systems analysis to understand and define interactions between lung vascular genetics, epigenetics, metabolic pathways, andmolecular signaling.

—Develop strategies using appropriate animal models to improve the understanding of the lung vasculature in health and in conditions that reflect human disease.

—Enhance translational research in lung vascular disease by comparing cellular and tissue abnormalities identified in animal models to those in human specimens.

—Improve lung vascular disease molecular and clinical phenotype coupling.

—Develop in vivo imaging techniques which assess structural changes in lung vasculature, metabolic shifts, functional cell responses and right ventricular function.

—Develop research consortia that advance basic, translational, and clinical studies, allow for multi-center epidemiological study feasibility, and support junior investigators' training in lung vascularbiology and disease.

We encourage the Subcommittee to support the full implementation of these recommendations by the National Institutes of Health.

Mr. Chairman, expanding clinical research remains a top priority for patients, caregivers, and PH investigators. We are particularly interested in establishing a pulmonary hypertension research network. Such a network would link leading researchers around the United States, providing them with access to a wider pool of shared patient data. In addition, the network would provide researchers with the

opportunities to collaborate on studies and to strengthen the interconnections between basic and clinical science in the field of pulmonary hypertension research. Such a network is in the tradition of the NHLBI, which, to its credit and to the benefit of the American public, has supported numerous similar networks including the Acute Respiratory Distress Syndrome Network and the Idiopathic Pulmonary Fibrosis Clinical Research Network. We encourage the NHLBI to move forward with the establishment of a PH network in fiscal year 2012.

For fiscal year 2012, PHA joins with other voluntary patient and medical organizations in recommending an appropriation of $35 billion for the National Institutes of Health. This level of funding will ensure continued expansion of research on rare diseases like pulmonary hypertension.

*Centers For Disease Control And Prevention*

Mr. Chairman, we are grateful to the subcommittee for providing past support of PHA's Pulmonary Hypertension Awareness Campaign. We know for a fact that Americans are dying due to a lack of awareness of PH, and a lack of understanding about the many new treatment options. This unfortunate reality is particularly true among minority and underserved populations. More needs to be done to educate both the general public and healthcare providers if we are to save lives.

To that end, PHA has utilized the funding provided through the CDC to: (1) launch a successful media outreach campaign focusing on both print and online outlets; (2) expand our support programs for previously underserved patient populations; and (3) establish PHA Online University, an interactive curriculum-based website for medical professionals that targets pulmonary hypertension experts, primary care physicians, specialists in pulmonology/cardiology/rheumatology, and allied health professionals. The site is continually updated with information on early diagnosis and appropriate treatment of pulmonary hypertension. It serves as a center point for discussion among PH-treating medical professionals and offers Continuing Medical Education and CEU credits through a series of online classes.

In fiscal year 2012, we encourage the subcommittee to establish a specific program at CDC to provide ongoing support for PH education and awareness activities. This would make a tremendous difference in the fight against this devastating disease.

*"Gift Of Life" Donation Initiative at HRSA*

PHA applauds the success of the Health Resources and Services Administration's "Gift of Life" Donation Initiative. This important program is working to increase organ donation rates across the country. Unfortunately, the only "treatment" option available to many late-stage PH patients is a lung, or heart and lung, transplantation. This grim reality is why PHA established "Bonnie's Gift Project."

"Bonnie's Gift" was started in memory of Bonnie Dukart, one of PHA's most active and respected leaders. Bonnie battled with PH for almost 20 years until her death in 2001 following a double lung transplant. Prior to her death, Bonnie expressed an interest in the development of a program within PHA related to transplant information and awareness.

PHA has had a very successful partnership with HRSA's "Gift of Life" Donation Program in recent years. Collectively, we have worked to increase organ donation rates and raise awareness about the need for PH patients to "early list" on transplantation waiting lists. For fiscal year 2012, PHA recommends an appropriation of $26 million for this important program.

*Social Security Disability*

Finally Mr. Chairman, PHA would like to thank the subcommittee for its commitment to address the longstanding backlog of disability claims at the Social Security Administration. We greatly appreciate this investment as a growing number of our patients are applying for disability coverage. On a related note, the SSA recently convened an Institute of Medicine panel to recommend revisions to the disability criteria for cardiovascular diseases. The IOM worked closely with our medical experts to update the disability criteria for our patient population and we were pleased to receive their recommendations earlier this year. We encourage Congress to support this process moving forward.

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## PREPARED STATEMENT OF THE RESEARCH WORKING GROUP OF THE FEDERAL AIDS POLICY PARTNERSHIP

Chairman Harkin, Ranking Member Shelby and members of the Committee, thank you for the opportunity to provide testimony on the National Institutes of Health (NIH) budget overall and for AIDS research in fiscal year 2012. Tomorrow's

scientific and medical breakthroughs depend on your vision, leadership and commitment toward robust NIH funding over the next year. To this end, the Research Working Group (RWG) urges this Committee to support—at minimum—the President's NIH budget request and also recommends a funding target of $35 billion in fiscal year 2012 to maintain the U.S.'s position as the world leader in medical research and innovation.

Investments in health research via NIH have paid enormous dividends in the health and well-being of people in the United States and around the world. NIH funded HIV and AIDS research has supported innovative basic science for better drug therapies, evidence-based behavioral and biomedical prevention interventions and vaccines which have saved and improved the lives of millions and holds great promise for significantly reducing HIV infection rates and providing more effective treatments for those living with HIV/AIDS in the coming decade.

Despite these advances, the number of new HIV/AIDS cases continues to rise in various populations in the United States and around the world. There are over 1 million HIV-infected people in the United States, the highest number in the epidemic's 30-year history; additionally over 56,000 Americans become newly infected every year. The evolving HIV epidemic in the United States disproportionately affects the poor, sexual and racial minorities and the most disenfranchised and stigmatized members of our communities. However, with proper funding coupled with the promotion of evidence based policies, 2012 will be a time of great scientific progress in prevention science, vaccines and finding a cure for HIV as well as addressing the co-morbid illnesses that affect patients with HIV such as viral hepatitis and tuberculosis. Further, as Washington, DC is set to host the International AIDS Conference in the summer of 2012, the gains in science made by NIH funded research programs will reflect our preeminence as the world's most powerful research enterprise fighting this deadly epidemic.

Major advances over the last 2 years in HIV prevention technologies—in particular with microbicides, HIV vaccines, circumcision, antiretroviral treatment as prevention and pre exposure prophylaxis using antiretrovirals (PrEP)—demonstrate that adequately resourced NIH programs can transform our lives. Federal support for AIDS research has also led to new treatments for other diseases, including cancer, heart disease, Alzheimer's, hepatitis, osteoporosis and a wide range of autoimmune disorders. Over the years, NIH has sponsored the evaluation of a host of vaccine candidates, some of which are advancing to efficacy trials. The recent successful iPrEx and HPTN 052 trials have shown the potential of antiretroviral drugs to prevent HIV infection. Moreover increased funding will support the future testing of new microbicides and therapeutics in the pipeline via the implementation of a newly restructured, cross-cutting HIV clinical trials network which translates NIH funded scientific innovation into critical quality of life gains for those most affected with HIV.

Increased funding for NIH in fiscal year 2012 makes good bipartisan economic sense, especially in shaky times. Robust funding for NIH overall will enable research universities to pursue scientific opportunity, advance public health, and create jobs and economic growth. In every State across the country, the NIH supports research at hospitals, universities, private enterprises and medical schools. This includes the creation of jobs that will be essential to future discovery. Sustained investment is also essential to train the next generation of scientists and prepare them to make tomorrow's HIV discoveries. NIH funding puts 350,000 scientists to work at research institutions across the country. According to NIH, each of its research grants creates or sustains six to eight jobs and NIH supported research grants and technology transfers have resulted in the creation of thousands of new independent private sector companies. Strong, sustained NIH funding is a critical national priority that will foster better health and economic revitalization.

Let's not jeopardize our future. Since 2003, funding for the NIH has failed to keep up with our existing research needs—damaging the success rate of approved grants and leaving very little money to fund promising new research. The real value of the increases prior to 2003 has been precipitously reduced because of the relatively higher inflation rate for the cost of research and development activities undertaken by NIH. According to the Biomedical Research and Development Price Index—which calculates how much the NIH budget must change each year to maintain purchasing power—between fiscal year 2003 and fiscal year 2011, the cost of NIH activities according to the BRDI will have increased by 32.8 percent. By comparison, the overall budget of the NIH increased by $3.6 billion or 13.4 percent over fiscal year 2003. So in real terms, the NIH has already sustained budget decreases of close to 20 percent over the past 9 years due to inflation alone. As such, any further cuts to NIH will have the clear and devastating effects of undermining our Nation's leadership in health research and our scientists' ability to take advantage of the ex-

panding opportunities to advance healthcare. The race to find better treatments and a cure for cancer, heart disease, AIDS and other diseases, and for controlling global epidemics like AIDS, tuberculosis and malaria, all depend on a robust long term investment strategy for health research at NIH.

In conclusion, the RWG calls on Congress to continue the bipartisan Federal commitment toward combating HIV as well as other chronic and life threatening illnesses by increasing funding for NIH to $35 billion in fiscal year 2012, including funds for transfer to the Global Fund for HIV/AIDS, Tuberculosis, and Malaria. A meaningful commitment toward stemming the epidemic and securing the well being of people with HIV cannot be met without prioritizing the research investment at NIH that will lead to tomorrow's lifesaving vaccines, treatments and cures. Thank you for the opportunity to provide these comments.

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## PREPARED STATEMENT OF RESEARCH!AMERICA

Thank you for the opportunity to submit testimony regarding fiscal year 2012 appropriations for the Subcommittee on Labor, Health, and Human Services, Education and Related Agencies. Research!America is the Nation's largest 501(c)(3) alliance working to make research to improve health a higher national priority. Research!America's member organizations together represent the voices of more than 125 million Americans. Our mission is grounded in strong and consistent expression by the American public for robust funding and policies in support of health research in the public and private sector. We use evidence-based advocacy to demonstrate the benefits of research that improves public health, productivity, longevity, and prosperity while solidifying America's standing as the world's engine of innovation.

Our remarks will focus on funding for the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ)—agencies that play a pivotal role in advancing the health of Americans and fueling economic growth across our Nation. In addition to these agencies, Research!America also advocates for the National Science Foundation (NSF), which fosters basic science and discovery that also impacts the health of Americans.

Research!America appreciates the subcommittee's past support for robust research funding conducted and supported by NIH, CDC, FDA, and AHRQ. Health research is in our Nation's best short- and long-term interests. Investing in research saves lives, saves dollars, produces jobs across multiple sectors of our economy, and positions our Nation for sustained global competitiveness.

The Nation is facing a debt crisis. Our debt burden will increase if we underfund agencies that drive economic growth and the private sector innovation critical to our global competitiveness. Robust support for health research agencies is critical for solving the debt crisis, reigning in the cost of medical care, and getting the economy back on track.

NIH, CDC, AHRQ and FDA each contribute in multifaceted ways to improved health and the economic growth our Nation.

—Research funded by the National Institutes of Health at research institutions across the country provides the groundwork for new product development in the private sector, which creates jobs and pumps dollars into local economies.

—The Centers of Disease Control and Prevention engage in epidemiological and public health research that stems deadly and costly pandemics, bolsters our Nation's defenses against bioterrorism, and addresses public health threats like drug-resistant infections that increase hospital costs and threaten lives.

—Research supported by the Agency for Healthcare Research and Quality improves the efficiency and quality of healthcare in this country by reducing duplication and waste and improving healthcare outcomes;

—By ensuring the safety and efficacy of new medicines and medical devices, The Food and Drug Administration plays a pivotal role in translating health research into improved treatments for patients.

As polling commissioned by Research!America clearly demonstrates, the American public strongly supports robust investment in health and medical research. A recent poll that surveyed a mix of self-described conservatives (32 percent), liberals (32 percent) and moderates (36 percent) found that, as we emerge from the recession:

—78 percent of Americans think Federal funding for health research is important for job creation and the economy;

—61 percent say accelerating our Nation's investment in research to improve health is a priority;

—76 percent think global health R&D is important to the U.S. economy;

—84 percent think it is important that the Government plays a role in research for prevention and wellness; and
—53 percent of Americans think that spending cuts are necessary, but the United States must invest strategically to improve the health of the economy.

The poll also confirms that Americans value public/private collaboration in order to rapidly build on discoveries made in federally funded labs to bring new drugs and devices to market. Some 84 percent of Americans think it is important to invest in regulatory science, an increasingly important area of focus at FDA and NIH, to make the drug and device development process more efficient for businesses and safer for patients.

Additional findings from Research!America polling include:
—91 percent of Americans think R&D is important to their State's economy;
—83 percent agree that basic scientific research should be funded by the Federal government;
—66 percent think research to improve health is part of the solution to rising healthcare costs.

The American public knows that research not only saves lives, but money. Disease and disability pose a major economic threat to our Nation, as the aging of our population and rising obesity rates increase the prevalence of heart disease, cancer, stroke, diabetes, Parkinson's disease, Alzheimer's disease and other major illnesses. It is estimated that chronic disease alone costs the United States $1.7 trillion each year.[1] Research conducted by both the public and private sectors is a potent weapon against rising healthcare costs. For example:
—An NIH-sponsored clinical trial showed treatment with aspirin could reduce stroke in Atrial Fibrillation (AF) victims by 80 percent, resulting in a 10-year net benefit of $1.27 billion.[2]
—A breast cancer diagnostic test developed by a private company using data from the publicly funded human genome project saves an estimated $2,000 per patient by reducing the number of women who are prescribed chemotherapy.[3]
—A recent NIH-funded study shows that vaccinating healthy, employed adults (ages 18 to 50) against the flu saves as much as $31 per person.[4]

U.S. research leading to the control and eradication of global illnesses can dramatically increase global productivity, while helping to protect Americans. In addition to benefiting our troops abroad, U.S. research focused on global diseases is actually an investment in the health of Americans. International travel means that it is not a matter of if, but when, deadly global threats, such as multiple-drug resistant tuberculosis reach the United States. Every year, 60 million Americans travel to other countries and 50 million people from abroad travel to the United States.[5]

In an interconnected world, U.S. global research helps grow our economy and saves lives at home and abroad.

Both the NIH and the CDC work closely with other agencies, like the U.S. Agency for International Development (USAID) to support the development of new biomedical, diagnostic, and other global health-related technologies. Through public private partnerships (PPP), including product development partnerships (PDP), these agencies leverage expertise from academia, private sector, and others to create new tools to combat neglected diseases throughout the world. This innovative collaborative PDP model has resulted in 12 novel products that could prove transformative for global health. We urge the committee to provide continued and robust support for these programs that touch every corner of our world, save lives, and strengthen the U.S. economy.

Whether the goal is to save lives, bend the cost curve by progressively reducing the cost of treating chronic and life-threatening health conditions, or promote the kind of innovation that positions our Nation for global economic leadership now and in the future, ample funding for NIH, CDC, FDA, and AHRQ is a cost-effective investment. Research!America appreciates the difficult task facing the subcommittee and urges that you recognize the return on investment that these four Federal agencies bring to our country. Investing in these agencies is the right, and smart, choice.

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[1] Partnership to Fight Chronic Disease, Almanac of Chronic Disease, 2009.
[2] Johnston SC, Rootenberg JD, Katrak S, et. al. Effect of a US NIH programme of clinical trials on public health and costs. The Lancet 2006;367:1319–1327.
[3] Lyman, G.H. et al. Impact of a 21-gene RT–PCR assay on treatment decisions in early-stage breast cancer. Cancer. 2007; 109:1011–1118.
[4] Lee, Patrick Y. "Economic Analysis Of Influenza Vaccination And Antiviral Treatment For Healthy Working Adults." Annals of Internal Medicine 137 (2002): 225–31.
[5] ITA (International Trade Administration), Office of Travel and Tourism Industries, "Total International Travelers Volume to and from the U.S. 1995–2005," available online at http://tinet.ita.doc.gov/outreachpages/inbound.total__intl__travel__volume__1995-2005.html.

## PREPARED STATEMENT OF ROTARY INTERNATIONAL

Chairman Harkin, members of the Subcommittee, Rotary International appreciates this opportunity to submit testimony to the in support of the polio eradication activities of the U.S. Centers for Disease Control and Prevention (CDC). The Global Polio Eradication Initiative is an unprecedented model of cooperation among national governments, civil society and U.N. agencies to work together to reach the most vulnerable through a safe, cost-effective public health intervention, and one which is increasingly being combined with opportunistic, complementary interventions such as the distribution of life-saving vitamin A drops, oral rehydration therapy, zinc supplements, and even something as simple as the distribution of soap. The goal of a polio free world is within our grasp because polio eradication strategies work even in the most challenging environments and circumstances.

### PROGRESS IN THE GLOBAL PROGRAM TO ERADICATE POLIO

Thanks to this committee's leadership in appropriating funds, progress toward a polio-free world continues.

—Only 4 countries (Nigeria, India, Pakistan and Afghanistan) are polio-endemic—the lowest number in history.

—The number of polio cases has fallen from an estimated 350,000 in 1988 to less than 1300 in 2010—a more than 99 percent decline in reported cases.

—As of April 21, 2011, Uttar Pradesh (UP) in India celebrated 1 year without reporting a single case of polio. The state has traditionally been a major exporter of virus to other parts of India and the world, and has been described as one of the most difficult places to eradicate polio.

—The number of polio cases in the polio endemic countries of India and Nigeria declined by more than 90 percent in 2010 as compared to 2009. As of 2011, India has reported only 1 case; Nigeria—5 cases.

—Incidence of type 3 polio, which accounted for 70 percent of all polio cases in 2009, decreased significantly in 2010 accounting for only 8 percent of all cases.

—Bivalent oral polio vaccine, which was introduced at the end of 2009, has proven to effectively target both of the remaining strains of polio, and has been a major factor in the progress made in 2010.

—A shortfall in the funding needed for polio eradication activities in polio affected and at-risk countries continues to pose a serious threat the achievement of a polio free world.

In summary, significant operational progress was made in 2010 despite funding challenges and outbreaks which, will continue to threaten polio free countries until polio eradication is achieved. Rotary, as a spearheading partner of the GPEI, will continue to pursue aggressive progress as outlined in the Strategic Plan for 2010–12 which has already demonstrated results in terms of reducing the number of cases in 2010 and into 2011.

The ongoing support of donor countries is essential to assure the necessary human and financial resources are made available to polio-endemic countries to take advantage of the window of opportunity to forever rid the world of polio. Access to children is needed, particularly in conflict-affected areas such as Afghanistan and its shared border with Pakistan. Polio-free countries must maintain high levels of routine polio immunization and surveillance. The continued leadership of the United States is essential to ensure we meet these challenges.

### THE ROLE OF ROTARY INTERNATIONAL

Rotary International, a global association of more than 32,000 Rotary clubs in more than 170 countries with a membership of over 1.2 million business and professional leaders (more than 365,000 of which are in the United States), has been committed to battling polio since 1985. Rotary International has contributed more than US$1 billion toward a polio free world—representing the largest contribution by an international service organization to a public health initiative ever. Rotary also leads the United States Coalition for the Eradication of Polio, a group of committed child health advocates that includes the March of Dimes Foundation, the American Academy of Pediatrics, the Task Force for Global Health, the United Nations Foundation, and the U.S. Fund for UNICEF. These organizations join us in thanking you for your staunch support of the Polio Eradication Initiative.

### THE ROLE OF THE U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

Rotary commends CDC for its leadership in the global polio eradication effort, and greatly appreciates the Subcommittee's support of CDC's polio eradication activities. The investment in this global effort has helped to make the United States the leader

among donor nations in the drive to eradicate this crippling disease. Due to congressional support, in fiscal year 2010 and fiscal year 2011 CDC was able to:

—Support the international assignment of more than 358 long- and short-term epidemiologists, virologists, and technical officers to assist the World Health Organization and polio-endemic countries to implement polio eradication strategies while on temporary duty travel from Atlanta, and 31 technical staff on direct 2-year assignments to WHO and UNICEF to assist polio-endemic and polio-reinfected countries.

—Perform the lead technical monitoring role for the Global Polio Eradication Initiative (GPEI) Strategic Plan 2010–2012 released in May 2010. On a quarterly basis, beginning in Q4, 2010, CDC provided a detailed epidemiologic report and risk assessment on the progress toward achieving the goals outlined in the Strategic Plan to the Independent Monitoring Board (IMB) for policy and decision-making.

—Provide $53.4 million in fiscal year 2010 to UNICEF for approximately 292 million doses of polio vaccine and $7.3 million for operational costs for NIDs in all polio-endemic countries and other high-risk countries in Asia, the Middle East and Africa. Most of these NIDs would not take place without the assurance of CDC's support.

—Collaborate with WHO, UNICEF, Rotary International, U.N. Foundation and the Bill and Melinda Gates Foundation to facilitate World Bank financing through its buy-down mechanism for the purchase of OPV. In 2010, this mechanism provided $14.1 million to Nigeria and $37.3 million to Pakistan. For 2011, Nigeria has been approved for $60 million, 1-year credit and Pakistan is eligible for a $41 million, 1-year credit.

—Provide $30.9 million in fiscal year 2010 to WHO for surveillance, technical staff and NIDs' operational costs, primarily in Africa. As successful NIDs take place, surveillance is critical to determine where polio cases continue to occur. Effective surveillance can save resources by eliminating the need for extensive immunization campaigns if it is determined that polio circulation is limited to a specific locale.

—Train virologists from around the world in advanced poliovirus research and public health laboratory support. CDC's Atlanta laboratories are a global reference center and training facility.

—Provide, as the leading specialize polio reference lab in the world, the largest volume of operational (poliovirus isolation) and technologically sophisticated (genetic sequencing of polio viruses) lab support to the 145 laboratories of the global polio laboratory network.

—Provide scientific and technical expertise to WHO on research issues regarding: (1) laboratory containment of wild poliovirus stocks following polio eradication, and (2) when and how to stop or modify polio vaccination following global certification of polio eradication.

—Provide critical support for post-polio-eradication planning through research, new product development, strategy formulation and policy development.

—Train and deploy public health professionals to improve AFP surveillance and to help plan, implement, and evaluate vaccination campaigns, communications, etc. through CDC's Stop Transmission of Polio (STOP) program. Since 1999, more than 1,000 STOP team members have participated in 3-month assignments in 60 countries, providing 262 person-years of support at the national and State levels. In 2010, the STOP program deployed 185 professionals to 69 countries.

—Launch a customized N (national)-STOP initiative in March 2011 in collaboration with the Pakistan Ministry of Health, WHO and the USAID Mission in Islamabad. Sixteen national epidemiologists from CDC's Field Epidemiology Training Program (FETP) were trained and deployed to the highest risk districts for circulation of wild polio virus in an effort to help improve the quality of disease surveillance and immunization activities there and to strengthen routine immunization systems.

—Deploy E (enhanced)-STOP initiative teams to Nigeria, S. Sudan, Angola, Chad, and DRC. Those serving in E–STOP are assigned to support efforts in strategic areas, are more experienced, and serve for a longer durations. As part of E–STOP in 2010, 28 professionals were deployed to Nigeria, 35 to South Sudan, 7 to Angola, 5 to Chad, and 5 to DRC. This initiative was facilitated by an expanding partnership with the Organization of Islamic Conference (OIC) facilitating outreach to Muslim states and the Pan American Health Organization facilitating Brazilian and Southern Cone support for Angola. With available funding, CDC plans to expand the number of participants in E–STOP in 2011.

—Support global polio eradication by participating in technical advisory groups, EPI manager and other key meetings. The CDC also published 14 updates on progress toward polio eradication in the Morbidity and Mortality Weekly Report (MMWR) and other peer-reviewed journals.

FISCAL YEAR 2012 BUDGET REQUEST

For fiscal year 2012, we respectfully request that this subcommittee include $112 million for the targeted polio eradication efforts of the Centers for Disease Control and Prevention, the same level included in the President's fiscal year 2012 request. The funds we are seeking will allow CDC to continue intense supplementary immunization activities in Asia and to improve the quality of immunization campaigns in Africa to interrupt transmission of polio in these regions as quickly as possible. These funds will also help maintain certification standard surveillance. This will ensure that we protect the substantial investment we have made to protect the children of the world from this crippling disease by supporting the necessary eradication activities to eliminate polio in its final strongholds—in South Asia and sub-Saharan Africa.

The United States' commitment to polio eradication has stimulated other countries to increase their support. Other countries that have followed America's lead and made special grants for the global Polio Eradication Initiative include the United Kingdom ($900.03 million), Japan ($418.65 million), Germany ($390.94 million), and Canada ($289.53 million). Since 2002, the members of the G8 have committed to provide sufficient resources to eradicate polio. G8 member states, many of which were already leading donors to the Polio Eradication Initiative, have encouraged other donors to provide support, and have emphasized the importance of polio eradication when meeting with leaders of polio-endemic countries. As a result, the base of donor nations that have contributed to the Global Polio Eradication Initiative has expanded to include Spain, Sweden, Saudi Arabia, and even contributions from United Arab Emirates, Kuwait, Hungary, and Turkey.

Endemic nations are also providing funds to support polio eradication activities. It is noteworthy that India has provided US$692 million in funding for polio eradication activities there since 2003 and Nigeria provided approximately US$61.75 million, and Pakistan has provided US$50 million.

BENEFITS OF POLIO ERADICATION

Since 1988, over 5 million people who would otherwise have been paralyzed will be walking because they have been immunized against polio. Tens of thousands of public health workers have been trained to manage massive immunization programs and investigate cases of acute flaccid paralysis. Cold chain, transport and communications systems for immunization have been strengthened. The global network of 145 laboratories and trained personnel established for polio eradication also tracks measles, rubella, yellow fever, meningitis, and other deadly infectious diseases and will do so long after polio is eradicated. NIDs for polio have also been used to distribute essential vitamin A, thereby saving the lives of over 1.25 million children since 1988.

A study published in the November 2010 issue of the journal Vaccine estimates that the global polio eradication initiative to eradicate polio could provide net benefits of at least $40–50 billion if transmission of wild polio viruses is stopped within the next 5 years. Polio eradication is a cost-effective public health investment, as its benefits accrue forever. On the other hand, more than 10 million children will be paralyzed in the next 40 years if the world fails to capitalize on the more than $8 billion already invested in eradication. Success will ensure that the significant investment made by the United States, Rotary International, and many other countries and entities, is protected in perpetuity.

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PREPARED STATEMENT OF THE RYAN WHITE MEDICAL PROVIDERS COALITION

*Introduction*

I am James Raper, a nurse practioner and Director of the 1917 HIV/AIDS Outpatient Clinic at the University of Alabama at Birmingham. I am submitting written testimony on behalf of the Ryan White Medical Providers Coalition.

Thank you for the opportunity to discuss the important HIV/AIDS care conducted at Ryan White Part C funded programs nationwide. Specifically, the Ryan White Medical Provider Coalition, the HIV Medicine Association, the CAEAR Coalition, and the American Academy of HIV Medicine estimate that approximately $407 million is needed to provide the standard of care for all Part C program patients. (This

estimate is based on the current cost of care and the number of patients that Part C clinics serve.) Because these are exceptionally challenging economic times, we request $272 million for Ryan White Part C programs in fiscal year 2012, the amount that Congress authorized for Part C programs in its 2009 reauthorization of the Ryan White Program.

The Ryan White Medical Providers Coalition was formed in 2006 to be a voice for medical providers across the Nation delivering quality care to their patients through Part C of the Ryan White program. We represent every kind of program, from small and rural to large urban sites in every region in the country. We speak for those who often cannot speak for themselves and we advocate for a full range of primary care services for these patients. Sufficient funding for Part C is essential to providing appropriate care for individuals living with HIV/AIDS.

Part C of the Ryan White Program funds comprehensive Early Intervention Services (EIS) for HIV care and treatment, that are directly responsible for the dramatic decreases in AIDS-related mortality and morbidity over the last decade. The Centers for Disease Control and Prevention estimate that there are more than 1.1 million persons living with HIV/AIDS, and approximately 240,000, or almost 1 in 4, of these individuals received services from Part C medical providers—a dramatic 30 percent increase in patients in less than 10 years.

*The Cost of Care Is Reasonable; The Reimbursement for Care Isn't*

On average it costs $3,501 per person per year to provide the comprehensive outpatient care and treatment available at Part C funded programs (excluding medication costs), including lab work, STD/TB/Hepatitis screening, ob/gyn care, dental care, mental health and substance abuse treatment, and case management. Part C funding covers only a small percentage of the total cost of this comprehensive care, with some programs receiving $450 (12 percent of the total cost) or less per patient per year to cover the cost of care.

*Part C Programs Save Both Lives and Money*

Investing in Part C services improves lives and saves money. In the United States, nearly 50 percent of persons living with HIV/AIDS who are aware of their status are not in continuing care. Early and reliable access to HIV care and treatment both helps patients with HIV live relatively healthy and productive lives and is more cost effective. One study from my Part C Clinic at the University of Alabama at Birmingham found that patients treated at the later stages of HIV disease required 2.6 times more healthcare dollars than those receiving earlier treatment meeting Federal HIV treatment guidelines.

*Patient Loads Are Increasing at an Unsustainable Rate*

Patient loads have been increasing at Part C clinics nationwide, despite the fact that there has not been significant new Federal funding, and in most cases, State and/or local funding has been cut. A steady increase in patients has occurred on account of higher diagnosis rates and declining insurance coverage resulting in part from the economic downturn. The CDC reports that the number of HIV/AIDS cases increased by 15 percent from 2004 to 2007 in 34 States.[1]

For example, at a clinic in Greensboro, North Carolina, the number of patients has more than doubled from 321 patients in 2002 to more than 800 in 2009. The clinic continues to deliver care in the same space with the same staffing as in 2002 despite the 250 percent increase in patients. In Sonoma County, California, funding became so scarce that the Part C clinic there closed its doors, and had to patch together new medical homes in other locations for 350 patients. In New York, when St. Vincent's Hospital in New York City closed, including the HIV/AIDS clinic, a Part C clinic at St. Luke's-Roosevelt Hospital had to absorb almost the entire St. Vincent's clinic, approximately 1,000 patients, over the course of just a few days.

Our patients struggle in times of plenty, and during this economic downturn they have relied on Part C programs more than ever. While these programs have been under-funded for years, State and local economic pressures are creating a crisis in our communities. Clinics are discontinuing primary care and other critical medical services, such as laboratory monitoring; suffering eviction from their clinic locations; operating only 4 days per week; and laying off staff just to get by. Years of nearly flat funding combined with large increases in the patient population and the recent economic crisis are negatively impacting the ability of Part C providers to serve their patients.

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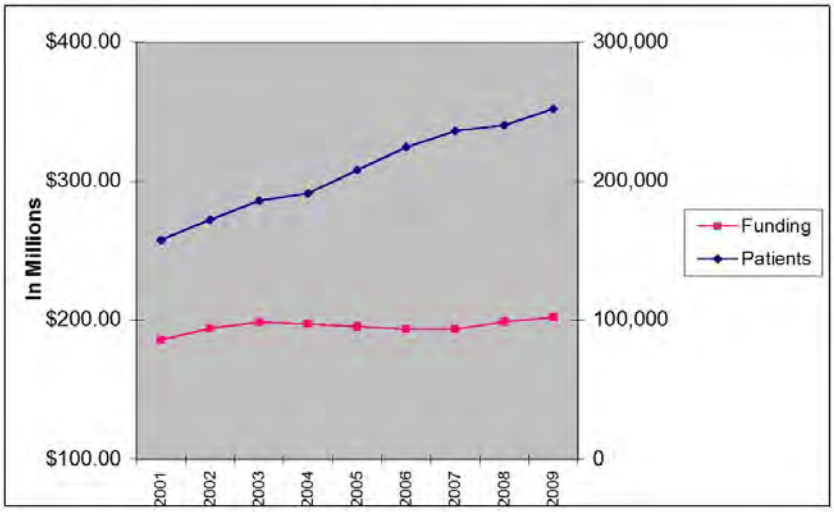
[1] Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report, 2007. Vol. 19. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2009:5. www.cdc.gov/hiv/topics/surveillance/resources/reports/.

The following graph demonstrates the growing disparity between funding for Part C and the increasing patient population. I refer to this gap between funding and patients as the "Triangle of Misery" because it represents both the thousands of patients who deserve more than we can offer and the Part C programs nationwide that are struggling to serve them with shrinking resources.

THE TRIANGLE OF MISERY

**2001 to 2009: Part C Patients Increased by 59%, While Funding Only Increased by 8.6%**




*Conclusion*

These are challenging economic times, and we recognize the severe fiscal constraints Congress faces in allocating limited Federal dollars. The significant financial and patient pressures that we face in our clinics at home propel us to make this funding request for fiscal year 2012 funding of Ryan White Part C programs. This funding would help to support medical providers nationwide in delivering appropriate and effective HIV/AIDS care to their patients. As the survey below of Part C providers nationwside shows, this Federal support is urgently needed.

Thank you for your time and consideration of our request. If you have any questions, please do not hesitate to contact me at the 1917 HIV/AIDS Outpatient Clinic, University of Alabama at Birmingham, Birmingham, Alabama 35294–2050, e-mail at jimraper@uab.edu.

RWMPC SURVEY: BUDGETARY CONSTRAINTS CONTINUE TO DRIVE CUTBACKS IN HIV CARE

In January 2011, the Ryan White Medical Providers Coalition, which represents Ryan White Part C programs nationwide that provide comprehensive HIV medical care and treatment, asked members to indicate their top three concerns as well as their frontline experiences providing HIV care and treatment in the current, constrained economic environement. The results of the brief survey included:

—The top three concerns (in order of importance):
  —Funding cuts/shortfalls
  —Sustaining the Ryan White Program and Part C programs and preparing for health reform
  —Clinic management issues, including:
    —HIV medical workforce recruitment and retention
    —Access to medications for patients (including the amount of work that clinics are doing to secure this access now that the ADAP crisis has worsened)
    —Increasing patient loads and the fact that clinics are reaching the limits of what they can do within their current financial and workforce resources.
—For those who are worried about funding cuts and shortfalls, 57 percent are worried about cuts to Federal funds.

—More than 56 percent of respondents have made cuts or changes to their programs because of funding cuts or shortfalls (both state and Federal).
—The types of cuts or changes that have been made include:
—More than 32 percent of clinics have either reduced or cut the services they provide.
—21.5 percent have either frozen their hiring or laid off staff
—13.5 percent have reduced coverage for lab monitoring

These survey results indicate the need to support and increase the investment in Part C programs, a valuable, effective and cost efficient resource that provides medical homes to tens of thousands of persons with HIV nationwide. Unless Part C programs receive additional funding, more services and infrastructure will be lost during this critical time period before the implementation of healthcare reform in 2014. Loss of such resources and infrastructure would reduce the availability of quality HIV care and treatment at just the time when the National HIV/AIDS Strategy is hoping to increase access to these life-saving services.

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## PREPARED STATEMENT OF THE SCLERODERMA FOUNDATION

### FISCAL YEAR 2012 APPROPRIATIONS RECOMMENDATIONS

Funding for the National Institutes of Health (NIH) at a level of $35 million.

An increase for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) concurrent with the overall increase to NIH.

Committee recommendation encouraging the Centers for Disease Control and Prevention to partner with the Scleroderma Foundation in promoting increased awareness of scleroderma among the general public and healthcare providers.

Mr. Chairman, I am Cynthia Cervantes, I am 12 and in the ninth grade. I live in Southern California and in October 2006 I was diagnosed with scleroderma. Scleroderma means "hard skin" which is literally what scleroderma does and, in my case, also causes my internal organs to stiffen and contract. This is called diffuse scleroderma. It is a relatively rare disorder effecting only about 300,000 Americans.

About 2 years ago I began to experience sudden episodes of weakness, my body would ache and my vision was worsening, some days it was so bad I could barely get myself out of bed. I was taken to see a doctor after my feet became so swollen that calcium began to ooze out. It took the doctors (period of time) to figure out exactly what was wrong with me, because of how rare scleroderma is.

There is no known cause for scleroderma, which affects three times as many women as men. Generally, women are diagnosed between the ages of 25 and 55, but some kids, like me, are affected earlier in life. There is no cure for scleroderma, but it is often treated with skin softening agents, anti-inflammatory medication, and exposure to heat. Sometimes a feeding tube must be used with a scleroderma patient because their internal organs contract to a point where they have extreme difficulty digesting food.

The Scleroderma Foundation has been very helpful to me and my family. They have provided us with materials to educate my teachers and others about my disease. Also, the support groups the foundation helps organize are very helpful because they help show me that I can live a normal, healthy life, and how to approach those who are curious about why I wear gloves, even in hot weather. It really means a lot to me to be able to interact with other people in the same situation as me because it helps me feel less alone.

Mr. Chairman, because the causes of scleroderma are currently unknown and the disease is so rare, and we have a great deal to learn about it in order to be able to effectively treat it. I would like to ask you to please significantly increase funding for the National Institute of Health so treatments can be found for other people like me who suffer from scleroderma. It would also be helpful to start a program at the Centers for Disease Control and Prevention to educate the public and physicians about scleroderma.

### OVERVIEW OF THE SCLERODERMA FOUNDATION

The Scleroderma Foundation is a nonprofit organization based in Danvers, Massachusetts with a three-fold mission: support, education, and research. The Foundation provides support for people living with scleroderma and their families through programs such as peer counseling, doctor referrals, and educational information, along with a toll-free telephone helpline for patients.

The Foundation also provides education about the disease to patients, families, the medical community, and the general public through a variety of awareness programs at both the local and national levels. Over $1 million in peer-reviewed re-

search grants are awarded annually to institutes and universities to stimulate progress in the search for a cause and cure for scleroderma.

WHO GETS SCLERODERMA?

There are many clues that define the susceptibility to develop scleroderma. A genetic basis for the disease has been suggested by the fact that it is more common among patients whose family members have other autoimmune diseases (such as lupus). In rare cases, scleroderma runs in families, although for the vast majority of patients there is no other family member affected. Some Native Americans and African Americans suffer a more severe form of the disease Caucasians. Women between the ages of 25–55 are more likely to develop scleroderma.

CAUSES OF SCLERODERMA

The cause of scleroderma is unknown. However, we do understand a great deal about the biological processes involved. In localized scleroderma, the underlying problem is the overproduction of collagen (scar tissue) in the involved areas of skin. In systemic sclerosis, there are three processes at work: blood vessel abnormalities, fibrosis (which is overproduction of collagen) and immune system dysfunction, or autoimmunity.

RESEARCH

Unfortunately, support for scleroderma research at the National Institutes of Health over the past several years has been flat funded at $19 million since fiscal year 2009, and is again estimated at $19 million for fiscal year 2012. This absence of increase is extremely frustrating to our patients who recognize biomedical research as their best hope for a better quality of life. It is also of great concern to our researchers who have promising ideas they would like to explore if resources were available.

TYPES OF SCLERODERMA

There are two main forms of scleroderma: systemic (systemic sclerosis, SSc) that usually affects the internal organs or internal systems of the body as well as the skin, and localized that affects a local area of skin either in patches (morphea) or in a line down an arm or leg (linear scleroderma), or as a line down the forehead (scleroderma en coup de sabre). It is very unusual for localized scleroderma to develop into the systemic form.

*Systemic Sclerosis (SSc)*

There are two major types of systemic sclerosis or SSc: limited cutaneous SSc and diffuse cutaneous SSc. In limited SSc, skin thickening only involves the hands and forearms, lower legs and feet. In diffuse cutaneous disease, the hands, forearms, the upper arms, thighs, or trunk are affected.

People with the diffuse form of SSc are at risk of developing pulmonary fibrosis (scar tissue in the lungs that interferes with breathing, also called interstitial lung disease), kidney disease, and bowel disease. The risk of extensive gut involvement, with slowing of the movement or motility of the stomach and bowel, is higher in those with diffuse rather than limited SSc. Symptoms include feeling bloated after eating, diarrhea or alternating diarrhea and constipation.

Pulmonary Hypertension (PH) is high blood pressure in the blood vessels of the lungs. It is totally independent of the usual blood pressure that is taken in the arm. This tends to develop in patients with limited SSc after several years of disease. The most common symptom is shortness of breath on exertion. However, several tests need to be done to determine if PH is the real culprit. There are now many medications to treat PH.

*Localized Scleroderma*

*Morphea*

Morphea consists of patches of thickened skin that can vary from half an inch to 6 inches or more in diameter. The patches can be lighter or darker than the surrounding skin and thus tend to stand out. Morphea, as well as the other forms of localized scleroderma, does not affect internal organs.

*Linear scleroderma*

Linear scleroderma consists of a line of thickened skin down an arm or leg on one side. The fatty layer under the skin can be lost, so the affected limb is thinner than

the other one. In growing children, the affected arm or leg can be shorter than the other.

*Scleroderma en coup de sabre*

Scleroderma en coup de sabre is a form of linear scleroderma in which the line of skin thickening occurs on the forehead or elsewhere on the face. In growing children, both linear scleroderma and en coup de sabre can result in distortion of the growing limb or lack of symmetry of both sides of the face.

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PREPARED STATEMENT OF SENIOR SERVICE AMERICA, INC.

We urge the subcommittee to restore funding for the Senior Community Service Employment Program (SCSEP), currently administered by the Department of Labor, to no less than $600 million for fiscal year 2012. would return funding for this proven and unique Federal employment and training program to pre-ARRA levels.

SCSEP is the only Federal program targeted at assisting low income workers over the age of 55 either regain employment or provide minimum wage employment through community service in communities across the Nation. A restoration of funding for SCSEP to $600 million would provide community service employment to an additional 24,000 unemployed and low-income older workers and at least 7 million lost staffing hours in participants' community service to local government agencies and nonprofit organizations meeting basic human needs.

We estimate that the public return on investment is more than double its appropriations level. The value of the community service by SCSEP participants would exceed $900 million. In addition to the value of the this service, SCSEP produces savings to the Federal Government by helping many thousands of vulnerable older adults to avoid becoming totally dependent on government transfer payments, including Medicaid, Supplemental Security Income, and early receipt of Social Security benefits.

*SCSEP's severe cut in fiscal year 2011 will have devastating impact on older workers and communities.*—Restoring funding in fiscal year 2012 would lessen the impact of the 45 percent reduction in SCSEP as a result of the fiscal year 2011 yearlong Continuing Resolution, The cut of $375 million from fiscal year 2010 is larger than the WIA core funding cut. As a result, during the year starting July 1, 2011, nearly 50,000 fewer jobless older adults will be employed and almost 35 million staff hours will be lost by over 30,000 local agencies and programs throughout the 50 States. Using tables from the Independent Sector, the value of these lost SCSEP community service hours exceeds $740 million.

SCSEP currently supports a wide range of community services and local government programs. For example, in 2011 over 1,100 public libraries (at least one in every State, most in rural areas) employed at least one SCSEP participant in a variety of library-related assignments. About one-fourth of all SCSEP community service hours are performed in service to other older adults, such as senior centers, nutrition, Meals on Wheels, and adult day care centers.

*SCSEP is a unique Federal workforce development program.*—According to a January 2011 GAO report on multiple employment and training programs, SCSEP is one of only three Federal workforce development programs that do not overlap with any other program. Since 1998, it is the only Federal program targeted to assist older adults return to the workforce and serves almost twice the number of adults 55 and over who receive training under WIA. Previous research by GAO and others have documented that WIA has consistently underserved older jobseekers.

Older adults, especially those eligible for SCSEP, continue to suffer in the current economy. Older workers have been described as the "new unemployables" in a recent report by Rutgers University. The current jobless rate for all older workers continues to be lower than the rate for all workers, but in 2010 the unemployment rate of older adults 55–74 years of age eligible for SCSEP was 23 percent, more than three times the national average for all adult workers. Among displaced workers 55 and older, the reemployment rate was only 38 percent, the lowest of any age group, with those from lower income households and with less than a college education faring the worst. Finally, the average duration of unemployment among adults 55 and over continued to increase in April 2011 to 53.6 weeks, with more than half of all older jobseekers out of work for 27 or more weeks, also an increase from the prior month. (More information is available from AARP and Senior Service America websites.)

The job market is not likely to improve significantly for most of these low-income and disadvantaged older job seekers in the foreseeable future. Too many will remain out of work and be forced to sustain themselves by becoming totally reliant on gov-

ernment transfers such as Medicaid, Supplemental Security Income, and early receipt of Social Security income benefits. Many will be highly unlikely to return to the labor force. Restoring SCSEP appropriations to pre-ARRA levels is a wise investment in a program of demonstrated effectiveness operated by a network of proven performers.

*DOL's SCSEP grantee network consistently achieves its performance measures.*—According to official statistics, in PY2009 the aggregate performance of the 18 national grantees and 56 State and territorial grantees achieved 98 percent or more of each of the common performance measures established for the program by DOL. For example, the grantee network achieved a 46.2 percent Entered Employment Rate (compared to the goal of 47 percent established by DOL); 70 percent Retention (68 percent goal); and $6,900 6 month earnings ($6,229 goal). For comparison, the Entered Employment Rate achieved was 48.1 percent in PY2008 and 52.4 percent in PY2007.

In addition, ratings by SCSEP participants and participating host agencies using the American Customer Satisfaction Index have been consistently higher for SCSEP than for WIA. In PY2009, participants gave SCSEP an ACSI score of 82.7 and host agencies gave a score of 81.3. Additional information from these independent national surveys:

*SCSEP Participants (number of respondents=24,358)*

ACSI score of 82.7 (about the same as prior year's score)

Nearly 92 percent of respondents reported that, compared to the time before they entered SCSEP, their physical health is the same or better, 73 percent reported that their outlook on life is a little more positive or much more positive.

Participants were in moderate to strong agreement (7.9 on a scale of 1 to 10) with the statement that their community service wages have made a substantial improvement in their quality of life.

*SCSEP Host Agencies (number of respondents=10,567)*

ACSI score of 81.3 (nearly identical to prior year's score)

75 percent indicated that participation in SCSEP increased their ability to provide services to the community either "somewhat" or "significantly."

The impact of the fiscal year 2011 cuts to SCSEP will be felt in every State. For example:

Impact on Iowa: Loss of nearly $5 million in SCSEP funding and over $7 million in services.

During fiscal year 2010, about 490 local programs in 153 Iowa towns and cities hosted at least one SCSEP participant, including: 171 local and State government agencies; 71 programs serving older adults, including at least 20 senior centers; 36 schools and post-secondary institutions; 31 workforce development offices; 24 public libraries and 11 museums; and 10 community action agencies.

| | Current fiscal year 2010 appropriations | Final fiscal year 2011 funding level | Impact |
|---|---|---|---|
| Funding Allocation for Iowa (all SCSEP grantees) | $10.5 million | $5.6 million | −$4.9 million |
| Number of Participants in Paid Community Service Employment in Iowa | 1,520 persons | 880 persons | −640 persons |
| Number of SCSEP Hours Serving Iowa Communities | 944,700 hours | 507,700 hours | −437,000 hours |
| Value of SCSEP Hours Serving Iowa Communities @$16.77/hour (www.independentsector.org/volunteer__time) | $15.8 million | $8.5 million | −$7.3 million |

The U.S. Department of Labor awards SCSEP funding for Iowa to the AARP Foundation, Experience Works, Senior Service America, Inc., and the Iowa Dept. on Aging. Local agencies in Iowa that operate SCSEP are Community Action Agency of Siouxland, Generations Area Agency on Aging, Hawkeye Area Community Action Program, and West Central Community Action.

Impact on Alabama: A loss of $6.4 million in SCSEP funding and $10 million in services.

During fiscal year 2010, more than 600 local government and nonprofit programs hosted at least one SCSEP participant, including:

—Nearly 300 local government agencies and programs, including 35 libraries and 31 senior centers, and

—More than 220 nonprofit organizations, including the American Red Cross, Boys and Girls Clubs, and Chambers of Commerce.

Starting July 1, 2011, the fiscal year 2011 cut in SCSEP funding will mean over 800 fewer job opportunities and 568,000 fewer community service hours to Alabama

agencies (valued at least $10 million, according to tables provided by the Independent Sector).

| | Current fiscal year 2010 appropriations | Final fiscal year 2011 funding level | Impact |
|---|---|---|---|
| Funding Allocation for Alabama (all SCSEP grantees) | $14.5 million | $8.1 million | −$6.4 million |
| Number of Participants in Paid Community Service Employment in Alabama | 2,090 persons | 1,280 persons | −810 persons |
| Number of SCSEP Hours Serving Alabama Communities | 1,302,000 hrs. | 734,000 hrs. | −568,000 hrs. |
| Value of SCSEP Hours Serving Iowa Communities @$17.70/hour (www.independentsector.org/volunteer__time) | $23 million | $13 million | −$10 million |

The U.S. Department of Labor provides SCSEP funding to the Alabama Department of Senior Services, Easter Seals, and Senior Service America, Inc.

The following local government agencies in Alabama receive SCSEP funding: Alabama-Tombigbee Regional Commission, East Alabama Regional Planning and Development Commission, Jefferson County Commission, Middle Alabama Area Agency on Aging, North-central Alabama Regional Council of Governments, Northwest Alabama Council of Local Governments, South Central Alabama Development Commission, Southeast Alabama Regional Planning and Development Commission, Top of Alabama Regional Council of Governments, and West Alabama Regional Commission.

*Summary*

We recognize that these are challenging times for the Subcommittee and difficult funding decisions must be made. A partial restoration of SCSEP funding to $600 million will ensure that an additional 24,000 of the hardest to reemploy, low income older workers will be able to provide an additional 7 million hours in service to communities across the Nation, with a return on investment double the appropriations provided to SCSEP. Thank you for considering this funding request.

*About Senior Service America, Inc.*

Senior Service America, Inc. (SSAI) has been awarded a national SCSEP grant from DOL since 1968, including competitive grants in 2003 and 2006. As the third largest national grantee, SSAI operates SCSEP exclusively through subgrants to 81 local organizations that serve 430 counties in 16 States. Its diverse network of subgrantees includes 25 area agencies on aging, 11 community action agencies, 10 regional councils of government, 13 workforce development agencies, eight faith-based organizations, two community colleges, and one local United Way.

For more information, please visit www.seniorserviceamerica.org. or contact Tony Sarmiento, Executive Director, at 301–578–8469, tsarmiento@ssa-i.org,

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## Prepared Statement of the Sickle Cell Disease Association of America

Mr. Chairman and distinguished Members of the Subcommittee, my name is Sonja L. Banks. I was recently elected President and Chief Operating Officer of the Sickle Cell Disease Association of America, Inc (SCDAA). Since 1971, SCDAA has served as the Nation's only volunteer organization working full time on a national level to resolve issues surrounding sickle cell disease. We have grown to approximately 55 community-based member organizations focused on serving the needs of individuals with Sickle Cell Disease or Sickle Cell Trait, their families, and over 300 communities nationwide and in Canada.

On behalf of the organization, I am honored to submit this testimony to your Subcommittee as a public witness in conjunction with your consideration of fiscal year 2012 Appropriations legislation.

SCDAA respectfully urges the Subcommittee to support President Obama's continuation of funding for the Sickle Cell Anemia Demonstration Program, and the Registry and Surveillance System for Hemoglobinopathy and Hemoglobinopathy Program Initiative. We also urge the Subcommittee to restore funding to the Sickle Cell Disease and Newborn Screening Program, a crucial program to fulfilling Secretary Kathleen Sebelius' charge to the Department of Health and Human Services (HHS) to make SCD a priority area of focus.

SCD is an inherited blood disorder that is a major problem in the United States. An estimated 72,000 Americans live with the disease. More than 2.5 million Americans have the Sickle Cell Trait (SCT), including 1 in 12 African Americans. The average life span of an adult with SCD is only 45 years.

Common complications include early childhood death from infection, stroke in young children and adults, infection of the lungs similar to pneumonia, pulmonary hypertension, chronic damage to organs such as the kidney resulting in chronic kidney failure, and frequent severe painful episodes. These unpredictable, intermittent, devastating pain events can begin as early as six months of age and can span a lifetime, impacting school and work attendance.

As the Nation addresses issues associated with healthcare reform, a real and rare opportunity exists to support, a population in dire need of treatment and care through innovative research and improved care.

First, we respectfully request that the Subcommittee provide $4,740,000 for the Sickle Cell Anemia Demonstration Program and Data Coordination Center. In fiscal year 2011, the Program received an appropriation of $4,750,000, and for fiscal year 2012 the President's budget recommends $4,740,000. Funding this national program will improve the lives of SCD patients through disease management programs to help them live longer, healthier lives while supporting research toward a comprehensive cure and providing community education about this disease and its treatment options.

Second, we respectfully request that the Subcommittee include $20,165,000 for the Public Health Approach to Blood Disorders Program. The President's fiscal year 2012 budget request consolidates existing budget sub-lines into one line called "Public Health Approach to Blood Disorders." As part of this coordinated effort, a Hemoglobinopathy Data Center will operate surveillance and registry program entitled RuSH (Registry and Surveillance System for Hemoglobinopathies) in seven States for 2 years.

The RuSH health data systems will provide researchers, policy makers, and the public with imperative information about SCD and SCD-related diseases that is currently unavailable. The lack of this type of data system for Sickle-Cell-related diseases limits the research and treatment communities' ability to fully understand the impact of the disease and to develop healthcare planning at the local, State, and national levels. Additionally, funding also will support a multi-agency collaboration to form an HHS Hemoglobinopathy Program Initiative to offer more effective care and lower societal and medical costs for individuals affected by blood disorders such as SCD.

Finally, we respectfully request that the Subcommittee restore $3,774,000 for the Sickle Cell Disease and Newborn Screening Program (SCD–NBS). Unfortunately, the President has proposed to eliminate this program in fiscal year 2012. On the other hand, Secretary Sebelius has launched an SCD initiative aimed at increasing access to and improving care. We believe that continuing the SCD–NBS program is critical to the initiative's goal, and invaluable to families and individuals suffering from this debilitating disease.

The SCD–NBS Program provides a continuity of medical services, education and counseling from birth to adulthood for persons afflicted with Sickle Cell Disease and Sickle Cell Trait. Since 2002, the project has supported a National Coordinating and Evaluation Center and 17 community-based demonstration sites across the country. Because of changes in the eligibility requirements for demonstration sites due next month, we also ask that report language be included in the fiscal year 2012 Subcommittee bill to direct the Program's funding to community-based or faith-based organizations involved with Sickle Cell Disease.

Thank you for considering these requests. We look forward to working with the Senate Appropriations Subcommittee on Labor, Health, and Education to fund these three critical programs that will help African Americans and other historically underserved children and families with Sickle Cell Disease live longer and healthier lives.

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## Prepared Statement of the Society for Maternal-Fetal Medicine

Mr. Chairman and Members of the Committee: The Society for Maternal-Fetal Medicine is pleased to have the opportunity to submit testimony on behalf of the fiscal year 2012 budget for the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). We urge the Committee, as you move forward with your deliberations on the fiscal year 2012 budget for the National Institutes of Health (NIH), to keep in mind the enormous lost opportunities that the NIH, and in particular the NICHD, will experience if the level of funding is not sustained.

Established in 1977, the Society for Maternal-Fetal Medicine (SMFM) is dedicated to improving maternal and child outcomes; and raising the standards of prevention, diagnosis, and treatment of maternal and fetal disease.

Maternal-fetal medicine specialists, also known as MFM specialists, perinatologists, and high-risk pregnancy physicians, are highly trained obstetrician/gynecologists with advanced expertise in obstetric, medical, and surgical complications of pregnancy and their effects on the mother and fetus.

The most common medical illnesses managed by MFM's include hypertension, diabetes, seizure disorders, autoimmune diseases, and blood clotting disorders. We also provide care for women who are at increased risk for preterm birth, including multiple gestations, women with cervical insufficiency who may require a surgery to prevent preterm birth, and women with placental problems such as bleeding from premature separation. In addition, MFM specialists are often responsible for the management of preterm labor, premature rupture of membranes, and other complications during labor that have the potential to impact newborn and long-term infant outcomes.

The special problems faced by these mothers may lead to death, short-term or in some cases life-long problems for their babies. For example:

—*Pre-term birth (birth before the fetus is at 37 weeks' gestation)*.—Over half a million children are born preterm each year. Preterm infants are at high risk for a variety of disorders, including mental retardation, cerebral palsy, and vision impairment. These infants are also at risk for long-term health issues, including cardiovascular disease (heart attack, stroke, and high blood pressure) and diabetes. The annual cost to society (medical, educational, and lost productivity) of preterm birth is at least $26 billion (in 2005 dollars).

—*Hypertension*.—High blood pressure during pregnancy endangers the health of both the mother and the baby and is increasingly common as women delay pregnancy until they are older, and as they are more frequently overweight. Chronic hypertension complicating pregnancy is associated with a risk of fetal growth restriction and a risk of preterm birth. Hypertension in pregnancy is also the second leading cause of maternal death in the United States.

—*Diabetes*.—The hormonal changes of pregnancy often bring about a diabetic state (gestational diabetes) in predisposed women or can seriously worsen pre-existing diabetes. Whether diabetes mellitus existed before conception or gestational diabetes develops during pregnancy, maternal glucose intolerance can have significant medical consequences. Poorly controlled diabetes is associated with miscarriage, congenital malformations, abnormal fetal growth, stillbirth, obstructed labor, increased cesarean delivery, and neonatal complications.

NICHD's commitment to basic, clinical and translational research has lead to new ways to treat and improve the health of pregnant women and infants. One of the most successful approaches for testing research questions is the NICHD Maternal-Fetal Medicine Units (MFMU) Network which allows researchers from across the country to coordinate clinical studies to improve maternal, fetal and neonatal health. The studies to date have not only identified new therapies and evaluated technologies used in maternal fetal medicine, but also have helped to abolish practices that are not useful.

—Researchers supported through the MFMU were responsible for the groundbreaking finding related to preterm birth and progesterone. Following a series of studies in the 1970s and 1980s, a national clinical trial showed that progesterone treatment resulted in a substantial reduction in the rate of preterm delivery among women who had a previous preterm birth, reduced the risk of newborn complications, and was effective in both African American and Non-African American women. This preventive therapy has been translated into practice. The drug was widely available through compounding pharmacies at a cost of $15–$30 per injection or $300 for a 20 week treatment course. However, in February 2011 the FDA granted KV Pharmaceutical orphan status for its drug named Makena, a manufactured version of the identical compound drug. After which, KV Pharmaceutical increased the price of the drug to $1,500 per injection, and later reduced it to $690 per injection. (SMFM is actively engaged in efforts to ensure that this medication is accessible and affordable to every pregnant woman who is at risk for recurrent preterm birth.)

—Until recently, there was no evidence to show whether treating the mild form of gestational diabetes benefited or posed risks for mothers and infants. A recent Network study found women who were treated for mild gestational diabetes were half as likely to have an unusually large baby, and their babies were half as likely to experience shoulder dystocia, an emergency condition in which the baby's shoulder becomes lodged inside the mother's body during birth. Treated women in the study also had fewer caesarean deliveries. In addition, they had fewer problems with hypertension and preeclampsia, a life-threatening complication of pregnancy that can lead to maternal seizures and death. Research supported by the MFMU provided the first conclusive evidence that

treating pregnant women who have even the mildest form of gestational diabetes can reduce the risk of common birth complications among infants, as well as blood pressure disorders among mothers. These findings will change clinical practice.

—Recent research conducted by the network found that antenatal magnesium sulfate, when administered to women at risk of delivering preterm, reduces the risk of cerebral palsy in surviving preterm infants by 45 percent. This finding has been translated into clinical practice.

Cerebral palsy refers to a group of neurological disorders affecting control of movement and posture and which limit activity. The brain may be injured or develop abnormally during pregnancy, birth or in early childhood. The causes of cerebral palsy are not well understood. Both economically and emotionally, the burden of cerebral palsy is enormous. The Centers for Disease Control and Prevention (CDC) estimates the lifetime costs including direct medical, direct non-medical, and indirect for all people born with cerebral palsy in 2000 to be $11.5 billion (in 2003 dollars).

Research that disproves a current therapy or treatment can also provide valuable guidance to clinicians and their patients.

—Translational research in the 1990s found that the use of corticosteroids in pregnancies at risk of preterm birth improved the outcomes for infants born preterm, reducing rates of breathing problems, bleeding into the brain, and problems with the intestines. However, NICHD sponsored research that evaluated the use of repeated doses of corticosteroids found that repeated doses resulted in smaller birth weights and head circumstances. Researchers also found a concerning increase in cerebral palsy in children who were exposed to four or more courses of corticosteroids. This study, along with an NIH Consensus Development Conference to pull together all available data, stopped the routine use of repeated courses of antenatal corticosteroids.

NICHD is at the forefront of several novel and important research areas, but there are still many areas about maternal health, pregnancy, fetal well-being, labor and delivery and the developing child that are not close to being understood. The challenges of the NICHD to investigate these problems remain. For example:

—*Preterm Birth and Stillbirth*.—Preterm birth and stillbirth represent two of the most important complications of pregnancy. Prevention of preterm birth and stillbirth depends on identifying women at risk and understanding the mechanisms of disease. It is imperative that NICHD take advantage of high throughput technologies to understand the causes of preterm birth and stillbirth and support genomics, proteomics, and metabolomics studies focusing on prediction and prevention of preterm birth and stillbirth, as well as the use of existing biobanks. The promise of these new technologies is that a better understanding of the biologic processes involved in pregnancy and pregnancy complications will lead to improved prediction, prevention, and treatment strategies that will improve maternal and infant health.

—*Severe, Early Adverse Pregnancy Outcomes*.—Women with severe, early adverse pregnancy outcome, such as multiple losses, demises, and severe preeclampsia, are at increased risk for long-term chronic health problems, including hypertension, stroke, diabetes, and obesity. Studies have shown that women who have had preeclampsia are more likely to develop chronic hypertension, to die from cardiovascular disease and to require cardiac surgery later in life. In addition, approximately 50 percent of women with gestational diabetes will develop diabetes later in life. Studies to identify women at risk for long term morbidity, and to develop strategies to prevent long term adverse outcomes in these women are urgently needed.

—*Maternal Fetal Medicine Units Network*.—Vigorous support of the MFMU Network is needed so that therapies and preventive strategies that have significant impact on the health of mothers and their babies will not be delayed. Until new options are created for identifying those at risk and developing cause specific interventions, preterm birth will remain one of the most pressing problems in obstetrics.

SMFM applauds NICHD efforts to move forward with the development of a scientific vision process for the Institute that will set an ambitious agenda and inspire the Institute, the research community, and its many partners to achieve critical scientific goals and meet pressing public health needs.

Mr. Chairman, we understand the budgetary constraints that are facing the Congress, but as providers of care for women with high-risk pregnancies we have seen emerging technologies that have provided greater opportunity to evaluate and treat the complicated problems involving the mother and fetus. Without a sustained investment in the critical medical research being conducted by the National Institutes

of Health, and the National Institute of Child Health and Human Development in particular, the health of pregnant women and their babies will be at risk and NICHD's mission of promoting healthy development throughout the lifespan will be hindered.

*Recommendation*

The Society for Maternal-Fetal Medicine joins with the Ad Hoc Group for Medical Research in urging the Committee to provide an appropriation of $35 billion in fiscal year 2012 for the National Institutes of Health.

The Society joins with the Friends of the National Institute of Child Health and Human Development in support of a fiscal year 2012 budget of $1.352 billion for the National Institute of Child Health and Human Development.

Thank you for the opportunity to submit our concerns to the Committee.

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## PREPARED STATEMENT OF THE SOCIETY FOR NEUROSCIENCE

*Introduction*

Mr. Chairman and Members of the Subcommittee, my name is Susan Amara, Ph.D. I am the Thomas Detre Professor of Neuroscience and Chair of the Department of Neurobiology as well as Co-Director of the Center for Neuroscience at the University of Pittsburgh and President of the Society for Neuroscience. My major research efforts have been focused on the structure, physiology, and pharmacology of a group of proteins in the brain that are the primary targets for addictive drugs including cocaine and amphetamines, for the class of therapeutic antidepressants, known as reuptake inhibitors, and for methylphenidate, which is used to treat attention deficit hyperactivity disorders.

On behalf of the more than 41,000 members of the Society for Neuroscience (SfN) and myself, I would like to thank you for your past support of neuroscience research at the National Institutes of Health (NIH). Over the past century, researchers have made tremendous progress in understanding cell biology, physiology, and chemistry of the brain. Research funded by NIH has made it possible to make advances in brain development, imaging, genomics, circuit function, computational neuroscience, neural engineering and many other disciplines. In this testimony, I will highlight how these advances have benefited taxpayers and why we should continue to strengthen this investment, even as the Nation makes difficult budget choices.

*Fiscal Year 2012 Budget Request*

The Society respectfully requests that Congress provide a fiscal year 2012 appropriation in the amount of $35 billion for NIH. This level of funding will enable the field to serve the long-term needs of the Nation by continuing to improve health for the benefit of the American people and the world, advance science, and promote America's near-term and long-range economic strength. This level will build on the research activities supported under prior year appropriations, enabling neuroscience-related NIH institutions to aggressively fund strategic plans that will significantly advance the understanding of the brain and the nervous system. In so doing, these investments will contribute to economic growth in hundreds of communities nationwide, as more than 83 percent of NIH funding is distributed to more than 3,000 institutions in communities in every State. Moreover, it will help preserve and expand America's role as leader in biomedical research, which fosters a wide range of private enterprises in the pharmaceutical, biotechnology, medical device, hospitality industries as well as many others.

SfN hopes that such an appropriation will be the first step on the path to providing a consistent and reliable long-term investment in the NIH and in particular the field neuroscience. This will ensure that there is not a dramatic drop in research activity or a loss of jobs, and serve as an inducement to keeping our young researchers in the training pipeline.

*What is the Society for Neuroscience*

SfN is a nonprofit membership organization of basic scientists and physicians who study the brain and nervous system. The SfN mission is to:

—Advance the understanding of the brain and the nervous system by bringing together scientists of diverse backgrounds, by facilitating the integration of research directed at all levels of biological organization, and by encouraging translational research and the application of new scientific knowledge to develop improved disease treatments and cures.

—Provide professional development activities, information and educational resources for neuroscientists at all stages of their careers, including undergradu-

ates, graduates, and postdoctoral fellows, and increase participation of scientists from a diversity of cultural and ethnic backgrounds.

—Promote public information and general education about the nature of scientific discovery and the results and implications of the latest neuroscience research. Support active and continuing discussions on ethical issues relating to the conduct and outcomes of neuroscience research.

—Inform legislators and other policymakers about new scientific knowledge and recent developments in neuroscience research and their implications for public policy, societal benefit, and continued scientific progress.

*What is Neuroscience?*

Neuroscience is the study of the nervous system. It advances the understanding of human function on every level: movement, thought, emotion, behavior, and much more. Neuroscientists use tools ranging from computers to special dyes to examine molecules, nerve cells, networks, brain system, and behavior. From these studies, they learn how the nervous system develops and functions normally and what goes wrong in neurological and psychiatric disorders.

Neuroscience is now a unified field that integrates biology, chemistry, and physics with studies of structure, physiology, and behavior, including human emotional and cognitive functions. Neuroscience research includes genes and other molecules that are the basis for the nervous system, individual neurons, and ensembles of neurons that make up systems and behavior. Through their research, neuroscientists work to demonstrate normal functions of the brain and determine how the nervous system develops, matures, and maintains itself through life. They seek to prevent or cure many devastating neurological and psychiatric disorders.

As the committee works to set funding levels for critical research initiatives for fiscal year 2012 and beyond we need to do more than establish a budget that is "workable" in the context of the current fiscal situation. We ask you to help establish a national commitment to advance the understanding of the brain and the nervous system—an effort that has the potential to transform the lives of thousands of people living with brain-based diseases and disorders. Help us to fulfill our commitment to overcoming the most difficult obstacles impeding progress, and to identifying critical new directions in basic neuroscience.

*Brain Research and Discoveries*

The power of basic science unlocks the mysteries of the human body by exploring the structure and function of molecules, genes, cells, systems, and complex behaviors. Every day, neuroscientists are advancing scientific knowledge and medical innovation by expanding our knowledge of the basic makeup of the human brain. In doing so, researchers exploit these findings and identify new applications that foster scientific discovery which can lead to new and ground-breaking medical treatments. Basic research funded by the National Institutes of Health continues to be essential to ensuring discoveries that will inspire scientific pursuit and medical progress for future generations. The funds provided in the past have helped neuroscientists make tremendous strides in diagnosing and treating neurological and psychiatric disorders. Due to federally funded research, scientists and healthcare providers now have a much better understanding of how the brain functions.

As we look ahead to the long-term trajectory for NIH funding, steady, sustainable growth is essential to maintaining a continuous research pipeline that spans from basic science to clinical outcomes. Without a long-term sustainable plan for investing in research, dramatic swings in the funding cycle have a stifling, often irreversible impact on progress, shutting down laboratories, driving away talented young investigators and disillusioning students who have just discovered a passion for biomedical research. As support declines, gaps emerge between levels of funding and the need for scientific advance. There are two kinds of gap—the ones you see and the ones you don't. In times of limited resources, it is easier to deal strategically with the gaps you know. For example, with an aging population it makes sense to maintain support for research on Alzheimer's and other chronic neurodegenerative diseases. But it's the gaps we are unaware of that I also worry about. We know from past experience that it is not always clear where the next critical breakthrough or innovative approach will come from—progress in science depends on imaginative curiosity-driven research that makes leaps in ways no one could have anticipated. Where would neuroscience and cell biology be without a rainbow of fluorescent proteins from jellyfish, which are now illuminating neurological diseases and disorders? Where would cutting edge work in systems neuroscience be today without research on channel rhodopsins from algae, which now hold promise for novel, noninvasive treatments for brain disorders? When resources are limited, balancing support for high-risk high-payoff ideas with disease-driven translational research presents a

huge challenge—it is easy to see why the latter is important, yet ultimately both kinds of research have the potential to contribute to the development of life changing therapies and cures for different diseases. More than ever is it important to support and fund research at many levels from the most basic to translational. The following are just two of the many basic research success stories in neuroscience research emerging now thanks to strong historic investment in NIH and other research agencies:

*Nicotine Addiction*

Although tobacco has been used legally for hundreds of years, nicotine addiction takes effect through pathways similar to those involving cocaine and heroin. During addiction, drugs activate brain areas that are typically involved in the motivation for other pleasurable rewards such as eating or drinking. These addictions leave the body with a strong chemical dependence that is very hard to get over. In fact, almost 80 percent of smokers who try to quit fail within their first year. The lack of a reliable cessation technique has profound consequences. Tobacco-related illnesses kill as many as 440,000 Americans every year, and thus the human and economic costs of nicotine addiction are staggering. One out of every five U.S. deaths is related to smoking.

Past Federal funding has enabled scientists to understand the mechanisms of nicotine addiction, enabling them develop successful treatments for smoking cessation. The discoveries that lead to these findings started back in the 1970's, when scientists identified the substance in the brain that nicotine acted on to transmit its pleasurable effects. They found that nicotine was hijacking a receptor, a protein used by the brain to transmit information. This receptor, called the nicotinic acetylcholine receptor, regulates the release of another key transmitter, dopamine, which in turn acts within reward circuits of the brain to mediate both the positive sensations and eventual addiction triggered by nicotine consumption. This knowledge has been the basis for the development of several therapeutic strategies for smoking cessation: nicotine replacement, drugs that target nicotine receptors, as well as drugs that prevent the reuptake of dopamine have all been shown to increase the long-term odds of quitting by several fold.

More recently, using mice genetically modified to have their nicotinic acetylcholine receptors contain one specific type of subunit, scientists determined that some kinds of receptor subunits are more sensitive to nicotine than others, and because each subunit is generated from its own gene, this discovery indicated that genetics can influence how vulnerable a person is to nicotine addiction. Further research to spot genetic risk factors and to generate genetically tailored treatment options is ongoing. Other studies are also testing whether a vaccine that blocks nicotine's effects can help discourage the habit. Since people who are able to quit smoking immediately lower their risk for certain cancers, heart disease and stroke, reliable and successful treatments are clearly needed. Today's continued research funding can make it possible for these emerging therapies to ultimately help people overcome the challenges of nicotine addiction.

*Brain-machine interface*

The brain is in constant communication with the body in order to perform every minute motion from scratching an itch to walking. Paralysis occurs when the link between the brain and a part of the body is severed, and eliminates the control of movement and the perception of feeling in that area. Almost 2 percent of the U.S. population is affected by some sort of paralysis resulting from stroke, spinal cord or brain injury as well as many other causes. Previous research has focused on understanding the mechanisms by which the brain controls a movement. Research during which scientists were able to record the electrical communication of almost 50 nerve cells at once showed that multiple brain cells work together to direct complex behaviors. However, in order to use this information to restore motor function, scientists needed a way to translate the signals that neurons give into a language that an artificial device could understand and convert to movement.

Basic science research in mice lead to the discovery that thinking of a motion activated nerve cells in the same way that actually making the movement would. Further studies showed that a monkey could learn to control the activity of a neuron, indicating that people could learn to control brain signals necessary for the operation of robotic devices. Thanks to these successes, brain-controlled prosthetics are being tested for human use. Surgical implants in the brain can guide a machine to perform various motor tasks such as picking up a glass of water. These advances, while small, are a huge improvement for people suffering from paralysis. Scientists hope to eventually broaden the abilities of such devises to include thought-controlled speech and more. Further research is also needed to develop non-invasive interfaces

for human-machine communication, which would reduce the risk of infection and tissue damage. Understanding how neurons control movement has had and will continue to have profound implications for victims of paralysis.

A common theme of both these examples of basic research success stories is that they required the efforts of basic science researchers discovering new knowledge, of physician scientists capable adapting those discoveries into better treatments for their patients and of companies willing to build on all of this knowledge to develop new medications and devices.

*The future of American science*

Finally, as the subcommittee considers this year's funding levels and in future years, I hope that the members will consider that significant advancements in the biomedical sciences often come from younger investigators who bring new insights and approaches to bear on old or intractable problems. Without sustained investment, I fear that flat or falling funding will begin to take a toll on the imagination, energy and resilience of younger investigators and I wonder about the impact of these events on the next generation. America's scientific enterprise—and its global leadership—has been built over generations, but without sustained investment, we could lose that leadership quickly, and it will be difficult to rebuild. When we undermine a research enterprise—whether a single lab or a national infrastructure built through decades of Federal funding—it is a loss to us all and difficult to recover. In the United States—traditionally a pacesetter for strong investment—threatened cuts in science funding jeopardize a global training system that fosters and encourages scientific creativity, flexibility, and enterprise. As a young girl interested in science, I was inspired by the idea that the United States was a place where anyone with imagination, drive, and a passion for research could come, learn, and potentially do something great. Without funding, that culture of entrepreneurship and curiosity—driven research could be hindered for decades.

*Conclusion*

We live at a time of extraordinary opportunity in neuroscience. When I read an exciting research article, I get a sense of awe and pride at the extraordinary progress in our field. A myriad of questions once impossible to consider are now within reach as a consequence of new technologies, an ever-expanding knowledge base, and a willingness to embrace many disciplines.

As a result of NIH investments, the field of neuroscience research holds great potential for making great progress to understand basic biological principles and for addressing the numerous neurological and psychiatric illnesses that strike more than 100 million Americans annually. And we have entered an era in which knowledge of nerve cell function has brought us to the threshold of a more profound understanding of behavior and of the mysteries of the human mind. However, continued progress can only be accomplished by a consistent and reliable funding source.

An NIH appropriation of $35 billion for fiscal year 2012 and sustained reliable growth is required to take the research to the next level in order to improve the health of Americans and to maintain American leadership in science worldwide. As a field we look forward to realizing that goal. Thank you for this opportunity to testify.

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PREPARED STATEMENT OF THE SOCIETY FOR WOMEN'S HEALTH RESEARCH

The Society for Women's health Research (SWHR) and the Women's Health Research Coalition (WHRC), is pleased to have the opportunity to submit the following testimony in support of ongoing Federal funding for biomedical research—specifically sex differences and total women's health research—within the Department of Health and Human Services (HHS) at the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the Agency for Healthcare and Research Quality (AHRQ).

SWHR and WHRC believe that sustained funding for biomedical and women's health research programs conducted and supported across the Federal agencies is absolutely essential if the United States is going to meet the health needs of women and men. A well-designed and appropriately funded Federal research agenda does more than avoid dangerous and expensive "trial and error" medicine for patients—it advances the Nation's research capability, continues growth in a sector with proven return on investment, and takes a proactive approach to maintaining America's position as world-wide leader in medical research, education, and development.

SWHR and WHRC believe that sustained funding for biomedical and women's health research programs conducted and supported across the Federal agencies is

absolutely essential if the United States is to meet the health needs of women, and men, and advance the nation's research capability.

As President Obama stated in his State of the Union Address, investment in biomedical research "will strengthen our security, protect our planet, and create countless new jobs for our people". Proper investment in health research will save valuable dollars that are currently wasted on inappropriate treatments and procedures. Further, SWHR and WHRC want targeted research into sex differences that will help in determining targeted treatments that will help women and men to receive quality appropriate care.

*National Institutes of Health*

Past Congressional investment for the NIH positioned the United States as the world's leader in biomedical research and has provided a direct and significant impact on women's health research and the careers of women scientists over the last decade. In recent years, that investment has declined along with America's place as the Number 1 in biomedical research. These two facts are interrelated. Cutting NIH funding threatens scientific advancement, substantially delays cures becoming available in the United States, and puts the innovative research practices and reputation that America is known for in jeopardy.

When faced with budget cuts, NIH is left with no other option but to reduce the number of grants it is able to fund. The number of new grants funded by NIH had dropped steadily with declining budgets, growing at a percent less than that of inflation since fiscal year 2003. Cuts to investments in biomedical research also negatively impact the economy. A shrinking pool of available grants has a significant impact on scientists who depend upon NIH support to cover both salaries and laboratory expenses to conduct high quality biomedical research, putting both medical advancement and job creation at risk. More than 83 percent of NIH funding is spent in communities across the Nation, creating jobs at more than 3,000 universities, medical schools, teaching hospitals, and other research institutions in every State.

Reducing the number of grants available to researchers further decreases publishing of new findings and decreases the number of scientists gaining experience in research, both reducing a scientist's likelihood of achieving tenure in a university setting. New and less established researchers are forced to consider other careers, or take positions outside the United States, and results in the loss of the skilled bench scientists and researchers so desperately needed to sustain America's cutting edge in biomedical research.

While the U.S. deficit requires careful consideration of all funding and investments, cutting relatively small discretionary funding within the NIH budget will not make a substantial impact on the deficit, but will drastically hamper the ability of the United States to remain the global leader in biomedical research. SWHR and WHRC recommend that Congress set, at a minimum, a budget that matches the administration's request for a $1 billion increase for NIH for fiscal year 2012.

*Study of Sex Differences*

It has only been within the past decade that scientists have begun to uncover the significant biological and physiological differences between women and men and its impact health and medicine. Sex-based biology, the study of biological and physiological differences between women and men, has revolutionized the way that the scientific community views the sexes. Sex differences play an important role in disease susceptibility, prevalence, time of onset and severity and are evident in cancer, obesity, heart disease, immune dysfunction, mental health disorders, and many other illnesses. Medications can have different effects in woman and men, based on sex specific differences in absorption, distribution, metabolism and elimination. It is imperative that research addressing these important differences be supported and encouraged.

SWHR recommends that NIH, with the funds provided, report sex/gender differences in all research findings. Further, NIH should seek to expand its inclusion of women in basic, clinical and medical research to Phase I, II, and III studies. By currently only mandating sufficient female subjects in Phase III, researchers often miss out on the chance to look for variability by sex in the early phases of research, where scientists look at treatment safety and determine safe and effective dose levels for new medications. By mandating that sex differences research occur in earlier phases of clinical research studies, the NIH can continue to serve as a role model for industry research, as well as other nations. Only by gaining more information on how therapies work in women will medicine be able to advance toward more targeted and effective treatments for all patients, women and men alike.

*Office of Research on Women's Health*

The NIH's Office of Research on Women's Health (ORWH) serves as the focal point for coordinating women's health and sex differences research at NIH, advising the NIH Director on matters relating to research on women's health and sex differences research, strengthening and enhancing research related to diseases, disorders, and conditions that affect women; working to ensure that women are appropriately represented in research studies supported by NIH; and developing opportunities for and support of recruitment, retention, re-entry and advancement of women in biomedical careers. In September 2010, ORWH celebrated its 20th anniversary and unveiled a new strategic plan for women's health and sex difference research, Moving Into The Future With Dimensions and Strategies: A Vision For 2020 For Women's Health Research.

*BIRCWH and SCOR*

The Building Interdisciplinary Research Careers in Women's Health (BIRCWH) and Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCOR) are two ORWH programs that benefit the health of both women and men through sex and gender research, interdisciplinary scientific collaboration, and provide tremendously important support for young investigators in a mentored environment.

The BIRCWH program, created in 2000, is an innovative, trans-NIH career development program that provides protected research time for junior faculty by pairing them with senior investigators in an interdisciplinary mentored environment. Each BIRCWH receives approximately $500,000 a year, most from the ORWH budget. To date, 407 scholars have been trained in 41 centers, and 80 percent of those scholars are female. The BIRCWH centers have produced over 1,300 publications, 750 abstracts, 200 NIH grants and 85 awards from industry and institutional sources.

SCORs, established in 2003, are designed to increase innovative, interdisciplinary research focusing on sex differences and major medical problems that affect women through centers that facilitate basic, clinical, and translational research. Each SCOR program results in unique research and in 2010, resulted in over 150 published journal articles, 214 abstracts and presentations and 44 other publications.

Additionally, ORWH has created several additional programs to advance the science of sex differences research and research into women's health. The Advancing Novel Science in Women's Health Research (ANSWHR) program, created in 2007, promotes innovative new concepts and interdisciplinary research in women's health research and sex/gender differences. The Research Enhancement Awards Program (REAP) supports meritorious research on women's health that otherwise would have missed the IC pay line.

In addition to its funding of research on women's health and sex differences research, ORWH has established several methods for dissemination information about women's health and sex differences research. ORWH created the Women's Health Resources web portal in collaboration (http://www.womenshealthresources.nlm.nih.gov) with that National Library of Medicine, to serve as a resource for researchers and consumers on the latest topics in women's health and uses social media to connect the public to health awareness campaigns.

To allow ORWH's programs and research grants to continue make their impact on research and the public, Congress must direct that NIH continue its support of ORWH and provide it with $1 million budget increase, bringing its fiscal year 2012 total to $43.9 million.

*Health and Human Services' Office of Women's Health*

The HHS Office of Women's Health (OWH) is the Government's champion and focal point for women's health issues. It works to redress inequities in research, healthcare services, and education that have historically placed the health of women at risk. Without OWH's actions, the task of translating research into practice would be only more difficult and delayed.

Under HHS, the agencies currently with offices, advisors or coordinators for women's health or women's health research include the Food and Drug Administration, Centers for Disease Control and Prevention, Agency for Healthcare Quality and Research, Indian Health Service, Substance Abuse and Mental Health Services Administration, Health Resources and Services Administration, and Centers for Medicare and Medicaid Services. It is imperative that these offices are funded at levels which are adequate for them to perform their assigned missions, and are sustainable so as to support needed changes in the long term. We ask that the committee report reflect Congress's support for these Federal women's health offices, and recommend that they are appropriately funded on a permanent basis to ensure that these programs can continue and be strengthened in the coming fiscal year.

It is only through consistent funding that the OWH will be able to achieve its goals. The budgets for theses offices have been flat-lined in recent years, which results in effectively a net decrease due to inflation. Considering the impact of women's health programs from OWH on the public, we urge Congress to provide an increase of $1 million for the HHS OWH, a total $34.7 million requested for fiscal year 2012.

*Centers for Disease Control and Prevention*

SWHR supports the national and international work of the CDC, especially the work of CDC's Office of Women's Health (OWH). While SWHR is delighted that the CDC's OWH is now codified in statue, we are concerned that proposed cuts to the CDC budget by the administration will significantly jeopardize programs that benefit women, leaving them with even fewer options for sound clinical information. Research and clinical medicine are still catching up from decades of a male-centric focus, and when diseases strike women, there remains a paucity of basic knowledge on how diseases affect female biology, a lack of drugs that have been adequately tested in women, and now even fewer options for information through the many educational outreach programs of the CDC.

The OWH within CDC is fundamental to promoting and improving the health, safety, and quality of life of women across their lifespan. The office led the CDC in the collaboration and development of text4baby, which sends free text messages on health and pregnancy issues, to pregnant women and new moms. In the year since its launch, over 135,000 subscribers have signed up for the service and millions of text messages have been sent. More than 300 outreach partners, including national, State, business, academic, nonprofit, and other groups, help to promote the service.

With its small budget, the OWH actively participated with others in CDC, HHS, and the State Department in the early development of the Global Health Initiative, and routinely collaborates with other agencies to advance the knowledge and research into women's health issues. This year, OWH worked closely with HHS OWH on the development of the Action Agenda on Women's Health: Beyond 2010 and with NIH on the development of the research conference on Advances in Uterine Leiomyoma. SWHR and WHRC recommend that Congress provide the CDC OWH with a 1.06 percent increase for fiscal year 2012, bringing their total to $478,000.

*Agency for Healthcare and Research Quality*

The Agency for Healthcare Research and Quality's work serves as a catalyst for change by promoting the results of research findings and incorporating those findings into improvements in the delivery and financing of healthcare. Through AHRQ's research projects, lives have been saved. For example, it was AHRQ who first discovered that women treated in emergency rooms are less likely to receive life-saving medication for a heart attack. AHRQ funded the development of two software tools, now standard features on hospital electrocardiograph machines, which have improved diagnostic accuracy and dramatically increased the timely use of "clot-dissolving" medications in women having heart attacks. As efforts to improve the quality of care, not just the quantity of care, progress, findings such as these coming out of AHRQ reveal where relatively modest investments can offer significant improvement to women's health outcomes, as well as a better return on investment for scarce healthcare dollars.

While AHRQ has made great strides in women's health research, its budget has been dismally funded for years, though targeted funding increases in recent years for dedicated projects, including funds from the American Recovery and Reinvestment Act (ARRA), moved AHRQ in the right direction. ARRA funds more than doubled AHRQ's investment in patient-centered research relevant to women. AHRQ is now supporting studies that examining comparative effectiveness in diabetes and breast cancer prevention in women, and comprehensive care for adults with serious mental illness.

With the ARRA funds, total investment in women's health increased from $52 million to $109 million, however, more core and sustained funding is needed to help AHRQ continue doing the research that helps patients and doctors make better medical decisions. Lack of investment in AHRQ will hinder advancements that will improve medical decisionmaking of doctors and patients and will result in improved health outcomes. Any decreased level of funding seriously jeopardizes the research and quality improvement programs that Congress mandates from AHRQ.

SWHR and WHRC recommend Congress fund AHRQ at $405 million for fiscal year 2012, an increase 2 percent over 2010 enacted levels. This investment ensures that adequate resources are available for high priority research, including women's healthcare, sex- and gender-based analyses, and health disparities—valuable infor-

mation that can help to better personalize treatments, lower overall medical spending, and improve outcomes for female and male patients nationwide.

In conclusion, Mr. Chairman, we thank you and this Committee for its strong record of support for medical and health services research and its commitment to the health of the Nation through its support of peer-reviewed research. We look forward to continuing to work with you to build a healthier future for all Americans.

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## PREPARED STATEMENT OF THE SPINA BIFIDA ASSOCIATION

*Background and Overview*

On behalf of the estimated 166,000 individuals and their families who are affected by all forms of Spina Bifida—the Nation's most common, permanently disabling birth defect—Spina Bifida Association (SBA) appreciates the opportunity to submit public written testimony for the record regarding fiscal year 2012 funding for the National Spina Bifida Program and other related Spina Bifida initiatives. SBA is a national voluntary health agency, working on behalf of people with Spina Bifida and their families through education, advocacy, research and service. SBA stands ready to work with Members of Congress and other stakeholders to ensure our Nation mounts and sustains a comprehensive effort to reduce and prevent suffering from Spina Bifida.

Spina Bifida, a neural tube defect (NTD), occurs when the spinal cord fails to close properly within the first few weeks of pregnancy and most often before the mother knows that she is pregnant. Over the course of the pregnancy—as the fetus grows—the spinal cord is exposed to the amniotic fluid, which increasingly becomes toxic. It is believed that the exposure of the spinal cord to the toxic amniotic fluid erodes the spine and results in Spina Bifida. There are varying forms of Spina Bifida occurring from mild—with little or no noticeable disability—to severe—with limited movement and function. In addition, within each different form of Spina Bifida the effects can vary widely. Unfortunately, the most severe form of Spina Bifida occurs in 96 percent of children born with this birth defect.

The result of this NTD is that most people with it suffer from a host of physical, psychological, and educational challenges—including paralysis, developmental delay, numerous surgeries, and living with a shunt in their skulls, which seeks to ameliorate their condition by helping to relieve cranial pressure associated with spinal fluid that does not flow properly. As we have testified previously, the good news is that after decades of poor prognoses and short life expectancy, children with Spina Bifida are now living into adulthood and increasingly into their advanced years. These gains in longevity, principally, are due to breakthroughs in research, combined with improvements generally in healthcare and treatment. However, with this extended life expectancy, our Nation and people with Spina Bifida now face new challenges, such as transitioning from pediatric to adult healthcare providers, education, job training, independent living, healthcare for secondary conditions, and aging concerns, among others. Individuals and families affected by Spina Bifida face many challenges—physical, emotional, and financial. Fortunately, with the creation of the National Spina Bifida Program in 2003, individuals and families affected by Spina Bifida now have a national resource that provides them with the support, information, and assistance they need and deserve.

As is discussed below, the daily consumption of 400 micrograms of folic acid by women of childbearing age, prior to becoming pregnant and throughout the first trimester of pregnancy, can help reduce the incidence of Spina Bifida, by up to 70 percent. The Centers for Disease Control and Prevention (CDC) calculates that there are approximately 3,000 NTD births each year, of which an estimated 1,500 are Spina Bifida, and, as such, with the aging of the Spina Bifida population and a steady number of affected births annually, the Nation must take additional steps to ensure that all individuals living with this complex birth defect can live full, healthy, and productive lives.

*Cost of Spina Bifida*

It is important to note that the lifetime costs associated with a typical case of Spina Bifida—including medical care, special education, therapy services, and loss of earnings—are as much as $1 million. The total societal cost of Spina Bifida is estimated to exceed $750 million per year, with just the Social Security Administration payments to individuals with Spina Bifida exceeding $82 million per year. Moreover, tens of millions of dollars are spent on medical care paid for by the Medicaid and Medicare programs. Efforts to reduce and prevent suffering from Spina Bifida will help to not only save money, but will also save—and improve—lives.

*Improving Quality-of-Life through the National Spina Bifida Program*

Since 2001, SBA has worked with Members of Congress and staff at the CDC to help improve our Nation's efforts to prevent Spina Bifida and diminish suffering—and enhance quality-of-life—for those currently living with this condition. With appropriate, affordable, and high-quality medical, physical, and emotional care, most people born with Spina Bifida will likely have a normal or near normal life expectancy. The CDC's National Spina Bifida Program works on two critical levels—to reduce and prevent Spina Bifida incidence and morbidity and to improve quality-of-life for those living with Spina Bifida.

The National Spina Bifida Program established the National Spina Bifida Resource Center housed at the SBA, which provides information and support to help ensure that individuals, families, and other caregivers, such as health professionals, have the most up-to-date information about effective interventions for the myriad primary and secondary conditions associated with Spina Bifida. Among many other activities, the program helps individuals with Spina Bifida and their families learn how to treat and prevent secondary health problems, such as bladder and bowel control difficulties, learning disabilities, depression, latex allergies, obesity, skin breakdown, and social and sexual issues. Children with Spina Bifida often have learning disabilities and may have difficulty with paying attention, expressing or understanding language, and grasping reading and math. All of these problems can be treated or prevented, but only if those affected by Spina Bifida—and their caregivers—are properly educated and given the skills and information they need to maintain the highest level of health and well-being possible. The National Spina Bifida Program's secondary prevention activities represent a tangible quality-of-life difference to the estimated 166,000 individuals living with all forms of Spina Bifida, with the goal being living well with Spina Bifida.

An important resource to better determine best clinical practices and the most cost effective treatments for Spina Bifida is the National Spina Bifida Registry, now in its third year. Nine sites throughout the Nation are collecting patient data, which supports the creation of quality measures and will assist in improving clinical research that will truly save lives, while also realizing a significant cost savings.

SBA understands that the Congress and the Nation face unprecedented budgetary challenges. However, the progress being made by the National Spina Bifida Program must be sustained to ensure that people with Spina Bifida—over the course of their lifespan—have the support and access to quality care they need and deserve. To that end, SBA respectfully urges the Subcommittee to Congress allocate $6.25 million (level funding) in fiscal year 2012 to the program, so it can continue and expand its current scope of work; further develop the National Spina Bifida Patient Registry; and sustain the National Spina Bifida Resource Center. Sustaining funding for the National Spina Bifida Program will help ensure that our Nation continues to mount a comprehensive effort to prevent and reduce suffering from—and the costs of—Spina Bifida.

*Preventing Spina Bifida*

While the exact cause of Spina Bifida is unknown, over the last decade, medical research has confirmed a link between a woman's folate level before pregnancy and the occurrence of Spina Bifida. Sixty-five million women of child-bearing age are at-risk of having a child born with Spina Bifida. As mentioned above, the daily consumption of 400 micrograms of folic acid prior to becoming pregnant and throughout the first trimester of pregnancy can help reduce the incidence of Spina Bifida, by up to 70 percent. There are few public health challenges that our nation can tackle and conquer by nearly three-fourths in such a straightforward fashion. However, we must still be concerned with addressing the 30 percent of Spina Bifida cases that cannot be prevented by folic acid consumption, as well as ensuring that all women of childbearing age—particularly those most at-risk for a Spina Bifida pregnancy—consume adequate amounts of folic acid prior to becoming pregnant.

Since 1968, the CDC has led the Nation in monitoring birth defects and developmental disabilities, linking these health outcomes with maternal and/or environmental factors that increase risk, and identifying effective means of reducing such risks. The good news is that progress has been made in convincing women of the importance of folic acid consumption and the need to maintain a diet rich in folic acid. This public health success should be celebrated, but still too many women of childbearing age consume inadequate daily amounts of folic acid prior to becoming pregnant, and too many pregnancies are still affected by this devastating birth defect. The Nation's public education campaign around folic acid consumption must be enhanced and broadened to reach segments of the population that have yet to heed this call—such an investment will help ensure that as many cases of Spina Bifida can be prevented as possible.

The goal is to increase awareness of the benefits of folic acid, particularly for those at elevated risk of having a baby with neural tube defects (those who have Spina Bifida themselves, or those who have already conceived a baby with Spina Bifida). With continued funding in fiscal year 2012, CDC's folic acid awareness activities could be expanded to reach the broader population in need of these public health education, health promotion, and disease prevention messages. SBA advocates that Congress provide adequate funding to CDC to allow for a targeted public health education and awareness focus on at-risk populations (e.g., Hispanic-Latino communities) and health professionals who can help disseminate information about the importance of folic acid consumption among women of childbearing age.

In addition to a $6.25 million fiscal year 2012 allocation for the National Spina Bifida Program, SBA urges the Subcommittee to provide $5.126 million for the CDC's national folic acid education and promotion efforts to support the prevention of Spina Bifida and other NTD; $26.342 million to strengthen the CDC's National Birth Defects Prevention Network; and $144 million to fund the National Center on Birth Defects and Developmental Disabilities.

*Improving Health Care for Individuals with Spina Bifida*

As you know, Agency for Health Research and Quality's (AHRQ) mission is to improve the outcomes and quality of healthcare, reduce healthcare costs, improve patient safety, decrease medical errors, and broaden access to essential health services. AHRQ's work is vital to the evaluation of new treatments, which helps ensure that individuals living with Spina Bifida continue to receive state-of-the-art care and interventions. To that end, we request a $405 million fiscal year 2012 allocation for AHRQ, to help improve quality of care and outcomes for people with Spina Bifida.

*Sustain and Seize Spina Bifida Research Opportunities*

Our Nation has benefited immensely from our past Federal investment in biomedical research at the NIH. SBA joins with other in the public health and research community in advocating that NIH receive increased funding in fiscal year 2012. This funding will support applied and basic biomedical, psychosocial, educational, and rehabilitative research to improve the understanding of the etiology, prevention, cure and treatment of Spina Bifida and its related conditions. In addition, SBA respectfully requests that the Subcommittee include the following language in the report accompanying the fiscal year 2012 L–HHS appropriations measure:

"The Committee encourages NIDDK, NICHD, and NINDS to study the causes and care of the neurogenic bladder in order to improve the quality of life of children and adults with Spina Bifida; to support research to address issues related to the treatment and management of Spina Bifida and associated secondary conditions, such as hydrocephalus; and to invest in understanding the myriad co-morbid conditions experienced by children with Spina Bifida, including those associated with both paralysis and developmental delay."

*Conclusion*

Please know that SBA stands ready to work with the Subcommittee and other Members of Congress to advance policies and programs that will reduce and prevent suffering from Spina Bifida. Again, we thank you for the opportunity to present our views regarding fiscal year 2012 funding for programs that will improve the quality-of-life for the estimated 166,000 Americans and their families living with all forms of Spina Bifida.

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## PREPARED STATEMENT OF THE AIDS INSTITUTE

The AIDS Institute, a national public policy research, advocacy, and education organization, is pleased to comment in support of critical HIV/AIDS and Hepatitis programs as part of the fiscal year 2012 Labor, Health and Human Services, Education and Related Agencies appropriation measure. We thank you for your past support of these programs and hope you will do your best to adequately fund them in the future in order to provide for and protect the public health.

### HIV/AIDS

HIV/AIDS remains one of the world's worst health pandemics in history. According to the CDC, over 617,000 people have died of AIDS in the United States and there are 56,300 new infections each year. At the end of 2007, an estimated 1.1 million people in the United States were living with HIV/AIDS. Persons of minority races and ethnicities are disproportionately affected. African Americans account for

half of the cases. HIV/AIDS disproportionately affects the poor and about 70 percent of those infected rely on publicly funded healthcare.

The vast majority of the discretionary programs supporting HIV/AIDS efforts domestically are funded through your Subcommittee. The AIDS Institute, working in coalition, has developed funding requests for each of these programs. We ask that you do your best to adequately fund them at the requested level.

We are keenly aware of budget constraints and competing interests for limited dollars, but programs that prevent and treat HIV are inherently Federal, as they help protect the public health against a highly infectious virus, which if left untreated will most likely lead to death and increased infections. Federal funding is particularly critical at this time since State and local budgets are being severely cut during the economic downturn.

*National HIV/AIDS Strategy*

President Obama released a comprehensive National HIV/AIDS Strategy (NHAS) which seeks to reduce new HIV infections, increase access to care and improving health outcomes for people living with HIV, and reduce HIV-related health disparities. The Strategy sets ambitious goals and seeks a more coordinated national response with a focus on those communities most affected and on programs that work. In order to attain the goals, additional investment will be needed and health reform must be implemented.

The budget proposed by the President requests that up to 1 percent of HHS discretionary funds appropriated for domestic HIV/AIDS activities be provided to the Office of the Assistant Secretary for Health to foster collaborations across HHS agencies and finance high priority initiatives in support of the NHAS. Such initiatives would focus on improving linkages between prevention and care, coordinating Federal resources within targeted high-risk populations, enhancing provider capacity, and monitoring key Strategy targets. The AIDS Institute supports this provision and encourages you to include it in the fiscal year 2012 appropriation measure.

*Centers for Disease Control and Prevention—HIV Prevention and Surveillance*

Fiscal year 2011—$800.4 million
Fiscal year 2012 community request—$1,325.7 million

The United Staes allocates only about 4 percent of its domestic HIV/AIDS spending on prevention. Investing in prevention today will save money tomorrow. Preventing all the new 56,000 cases in just one year would translate into an astounding $20 billion in lifetime medical costs.

The CDC is focused on carrying out several goals of the NHAS by 2015. Specifically, they are seeking to lower the annual number of new infections by 25 percent, reduce the HIV transmission rate by 30 percent, and increase from 79 to 90 the percentage of people living with HIV who know their serostatus.

While it is estimated that an increase of over $500 million would be needed to achieve the goals of the NHAS, The AIDS Institute supports an increase of at least the $57.2 million over fiscal year 2011 as the President has proposed, including $30.4 million from the Prevention and Public Health Fund. We are also supportive of a transfer of $40 million from the Chronic Disease Prevention and Public Health Promotion for HIV school health programs to achieve closer coordination of CDC's HIV prevention programs.

With this funding, the CDC would improve surveillance and use of community viral load, enhance prevention among most affected communities, integrate care and prevention, expand HIV testing and linkage to care, build capacity, develop social marketing campaigns, and improve monitoring.

*Ryan White HIV/AIDS Programs*

Fiscal year 2011—$2,336.7 million
Fiscal year 2012 community request—$2,687.0 million

The centerpiece of the Government's response to caring and treating low-income people with HIV/AIDS is the Ryan White HIV/AIDS Program, which currently serves over half a million low-income, uninsured, and underinsured people. In fiscal year 2011, almost all parts of the Program experienced funding cuts at a time of increased need and demands on the program. Consider the following:

—Caseloads are increasing. People are living longer due to lifesaving medications, there are over 56,000 new infections each year, and increased testing programs identify thousands of new people infected with HIV. With rising unemployment, people are losing their employer-sponsored health coverage.

—State and local budgets are experiencing cutbacks due to the economic downturn. A survey by the National Alliance of State and Territorial AIDS Directors

found that State funding reductions totaled more than $170 million in 29 States during fiscal year 2009.

—States are cutting and the Federal Government is proposing massive cuts to Medicaid. As the payer of last resort cuts to entitlement programs, such as Medicaid, place further pressure on the Ryan White Program.

—There are significant numbers of people in the United States who are not receiving life-saving AIDS medications. An IOM report concluded that 233,069 people in the United States who know their HIV status do not have continuous access to Highly Active Antiretroviral Therapy.

Specifically, The AIDS Institute requests the following funding levels for each part of the Program:

Part A provides medical care and vital support services for persons living with HIV/AIDS in the metropolitan areas most affected by HIV/AIDS. We request an increase of $74.2 million, for a total of $752 million.

Part B base provides essential services including diagnostic, viral load testing and viral resistance monitoring, and HIV care to all 50 States, District of Columbia, Puerto Rico, and the territories. We are requesting a $76.8 million increase, for a total of $495 million.

The AIDS Drug Assistance Program (ADAP) provides life-saving HIV drug treatment to over 200,000 people, or about one in four HIV positive people in care in the United States. The majority of whom are people of color and very poor. ADAPs are experiencing unprecedented growth and are in crisis. Over the course of 1 year, HRSA reported an increase of over 30,000 new people to the program. Because of a lack of funding, there are currently 8,100 people in 13 States on waiting lists, thousands more have been removed from the program due to lowered eligibility requirements, and drug formularies have been reduced.

According to NASTAD's recent annual ADAP monitoring report, State funding for ADAPs increased 61 percent in fiscal year 2009 to a total of $346 million, and drug company rebates grew 5 percent to $522 million. The Federal share of the overall ADAP budget has decreased to less than 50 percent.

The AIDS Institute is very appreciative of the $50 million increase to ADAP in fiscal year 2011, but it is far from what is currently required to meet the growing number of new people needing ADAP medications in the coming year. The true need is an increase of $360 million. The AIDS Institute requests that you provide an increase that is as close as possible to that amount. We note the President has requested an increase of $55 million, which would only provide medications to fewer than 4,800 people.

Part C provides early medical intervention and other supportive services to over 248,000 people at over 380 directly funded clinics. We are requesting a $66.6 million increase, for a total of $272 million.

Part D provides care to over 84,000 women, children, youth, and families living with and affected by HIV/AIDS. We are requesting a $5.8 million increase, for a total of $83.1 million.

Part F includes the AIDS Education and Training Centers (AETCs) program and the Dental Reimbursement program. We are requesting a $15.4 million increase for the AETC program, for a total of $50 million, and a $5.5 million increase for the Dental Reimbursement program, for a total of $19 million.

*National Institutes of Health—AIDS Research*

Fiscal year 2011—$3.07 billion
Fiscal year 2012 community request—$3.5 billion

The NIH conducts research to better understand HIV and its complicated mutations, discover new drug treatments, develop a vaccine and other prevention programs such as microbicides, and ultimately develop a cure. The critically important work performed by the NIH not only benefits those in the United States, but the entire world. This research has already helped in the development of many highly effective new drug treatments, prolonging the lives of millions of people. NIH also conducts the necessary behavioral research to learn how HIV can be prevented best in various affected communities. We ask the Committee to fund critical AIDS research at the community requested level of $3.5 billion.

*Comprehensive Sexuality Education*

Since the vast majority of HIV infection occurs through sex, age appropriate education on how HIV is transmitted and HIV prevention is critical. It is for this reason, The AIDS Institute is supportive of funding the Teen Pregnancy Prevention Initiative for a total of $135 million and we oppose funding of abstinence only education programs, which have proven not to be effective.

*Minority AIDS Initiative*

The AIDS Institute supports increased funding for the Minority AIDS Initiative, which is funded by numerous Federal agencies to address the disproportionate impact that HIV has on communities of color. For fiscal year 2012, we are requesting a total of $610 million.

*Policy Riders*

The AIDS Institute is opposed to using the appropriations process as a vehicle to repeal or prevent the implementation of current law or ban funding for certain activities or organizations, such as the Affordable Care Act and syringe exchange programs which are scientifically proven to be effective in the prevention of HIV and Hepatitis.

VIRAL HEPATITIS

The Institute of Medicine (IOM) report Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C outlines recommendations on how the incidence of Hepatitis B and C infections can be decreased. They include increased public awareness campaigns, heightened testing and vaccination programs, continued research, along with improved surveillance. The Administration recently announced the first ever national strategy to eliminate Viral Hepatitis.

In fiscal year 2011, Congress funded CDC's Viral Hepatitis Division at only $19.8 million. Given the huge impact that Hepatitis B and C have on the health of so many people, and the large treatment costs, and to begin to implement the IOM recommendations and the national strategy, The AIDS Institute urges the Federal Government to make a greater commitment to Hepatitis prevention. For fiscal year 2012, we request a total of $59.8 million.

The AIDS Institute asks that you give great weight to our testimony as you develop the fiscal year 2012 appropriation bill. Should you have any questions or comments, feel free to contact Carl Schmid, Deputy Executive Director, The AIDS Institute or cschmid@theaidsinstitute.org.

Thank you very much.

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## PREPARED STATEMENT OF THE ENDOCRINE SOCIETY

The Endocrine Society is pleased to submit the following testimony regarding fiscal year 2012 Federal appropriations for biomedical research, with an emphasis on appropriations for the National Institutes of Health (NIH). The Endocrine Society is the world's largest and most active professional organization of endocrinologists representing more than 14,000 members worldwide. Our organization is dedicated to promoting excellence in research, education, and clinical practice in the field of endocrinology. The Society's membership includes thousands of scientists and clinicians who receive Federal support for their research and, in turn, contribute greatly to the Nation's scientific and healthcare advances.

A half century of sustained investment by the United States Federal Government in biomedical research has dramatically advanced the health and improved the lives of the American people. The NIH specifically has had a significant impact on the United State's global preeminence in research and fostered the development of a biomedical research enterprise that is unrivaled throughout the world. As the world's largest supporter of biomedical research, the NIH competitively awards extramural grants and supports in-house research. However, with the continued decline in real dollars allocated to biomedical research each year by the Federal Government, the opportunities to discover life-changing cures and treatments have already begun to decrease.

Biomedical research funds allocated by the Federal government support both basic and translational research, ensuring that the discoveries made in the laboratory become realistic treatment options for patients suffering from debilitating and life-threatening diseases. Diabetes is a devastating condition that affects an increasingly large number of Americans and requires a large proportion of the Nation's healthcare spending. Almost 26 million people (8.3 percent of the U.S. population) have diabetes, and the estimated cost of diabetes was $174 billion in 2007.[1]

No new diabetes medications would have been developed without federally supported basic and clinical research. The discovery of insulin and the collaborative research effort of basic and clinical scientists eventually led to the approval of a new class of medications for diabetes, essentially the first new treatments of diabetes in

[1] Centers for Disease Control and Prevention. National Diabetes Fact Sheet, 2011.

the past 80 years. Without the continued support of both basic and clinical research in diabetes, these medications would have never been developed. Now, with this broadened portfolio of treatments, it is possible to help most people with diabetes achieve optimal blood sugar control.

Beyond the multitude of health benefits that result from NIH-funded research, national and local economies benefit from the dollars that flow out of NIH into the communities. Researchers in all 50 States and 90 percent of congressional districts receive funding from NIH, and these funds stimulate local economies through salaries and purchase of equipment, laboratory supplies, and vendor services. For instance, for each dollar of taxpayer investment, UCLA generates almost $15 in economic activity, resulting in a $9.3 billion impact on the Los Angeles region. The estimated economic impact of Baylor on the surrounding community in Houston is more than $358 million, generating more than 3,300 jobs.[2] The governors of 25 States acknowledged the economic impact that NIH-funded research has on their States in an April 2010 letter to House and Senate Budget Committee members. The letter states,

"During a time of recession, investment in biomedical research makes sense because it leads to cures and treatments for debilitating diseases while at the same time generating significant economic activity for local communities throughout the country."

The Endocrine Society remains deeply concerned about the future of biomedical research in the United States without sustained support from the Federal Government. The Society strongly supports the continued increase in Federal funding for biomedical research in order to provide the additional resources needed to enable American scientists to address the burgeoning scientific opportunities and new health challenges that continue to confront us. The Endocrine Society recommends that NIH receive at least $35 billion in fiscal year 2012 to ensure the steady and sustainable growth necessary to continue building on the advances made by scientists and physicians during the past decade.

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## PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES

On behalf of The Humane Society of the United States (HSUS) and the Humane Society Legislative Fund (HSLF), and our joint membership of over 11 million supporters nationwide, we appreciate the opportunity to provide testimony on our top NIH funding priorities for the Senate Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittee in fiscal year 2012.

### BREEDING OF CHIMPANZEES FOR RESEARCH

The HSUS requests that no Federal funding be appropriated for the breeding of chimpanzees for laboratory research. The basis of our request is as follows:

—The National Center for Research Resources (NCRR) of the National Institutes of Health (NIH), responsible for the oversight and maintenance of federally owned and supported chimpanzees, placed a moratorium on breeding federally owned and supported chimpanzees in 1995, primarily due to the excessive costs of lifetime care of chimpanzees in laboratory settings. NCRR extended the moratorium indefinitely in 2007. As a result, none of the 500 federally owned chimpanzees should have given birth or sired infants since 1995.

—There is evidence, however, that at least one laboratory has used millions of Federal dollars in recent years to support breeding of government owned chimpanzees. There are major financial implications to the Federal Government and taxpayers if this breeding continues. Therefore, we seek to simply reinforce NIH policy and ensure that no laboratory can use funding provided by NIH or any other HHS agency for breeding of government-owned or supported chimpanzees.

—According to records provided by the New Iberia Research Center (NIRC) and the National Institutes of Health 123 infants were born to a federally owned mother and/or federally owned father at NIRC between 2000 and 2009.

—The cost of maintaining chimpanzees in laboratories is exorbitant, up to $67 per day per chimpanzee; over $1,000,000 per chimpanzee over an individual's approximately 60-year lifetime. Breeding of additional chimpanzees into laboratories will only perpetuate and increase the burdens on the government in supporting and managing the chimpanzee research colony.

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[2] Federation of American Societies for Experimental Biology. NIH Advocacy Slides: California, Texas.

—The U.S. currently has a surplus of chimpanzees available for use in research due to overzealous breeding for HIV research and subsequent findings that they are a poor HIV model.[1]

—Expansion of the chimpanzee population in laboratories only creates more concerns than presently exist about their quality of care—an issue of great public concern.

*Background and history*

Beginning in 1995, the National Research Council (NRC) confirmed a chimpanzee surplus and recommended a moratorium on breeding of federally owned or supported chimpanzees,[1] which includes nearly all of the approximately 1,000 chimpanzees available for research in the United States. On May 22, 2007 the NCRR of NIH indefinitely extended its moratorium on breeding federally-owned and supported chimpanzees. Further, it has also been noted that "a huge number" of chimpanzees are not being used in active research protocols and are therefore "just sitting there."[2] If no breeding is allowed, it is projected that the government will have almost no financial responsibility for the chimpanzees it owns within 30 years due to the age of the population—any breeding today will extend this financial burden to 60 years.

There is no justification for breeding of additional chimpanzees for research; therefore lack of Federal funding for breeding will ensure that no breeding of federally owned or supported chimpanzees for research will occur in fiscal year 2012.

*Concerns regarding chimpanzee care in laboratories*

A nine month undercover investigation by The HSUS at University of Louisiana at Lafayette New Iberia Research Center (NIRC)—the largest chimpanzee laboratory in the world—revealed some chimpanzees living in barren, isolated conditions and documented over 100 alleged violations of the Animal Welfare Act at the facility regarding conditions for and treatment of chimpanzees. The U.S. Department of Agriculture (USDA) and NIH's Office of Laboratory Animal Welfare (OLAW) launched formal investigations into the facility and NIRC paid an $18,000 stipulation for violations of the Animal Welfare Act.

Aside from the HSUS investigation, inspections conducted by the USDA demonstrate that basic chimpanzee standards are often not being met. Inspection reports for other federally funded chimpanzee facilities have reported violations of the Animal Welfare Act in recent years, including the death of a chimpanzee during improper transport, housing of chimpanzees in less than minimal space requirements, inadequate environmental enhancement, and/or general disrepair of facilities. These problems add further argument against the breeding of even more chimpanzees into this system.

*Chimpanzees have often been a poor model for human health research*

The scientific community recognizes that chimpanzees are poor models for HIV because chimpanzees do not develop AIDS even after being infected with HIV. Similarly, chimpanzees do not model the course of the human hepatitis C virus yet they continue to be used for this research, adding to the millions of dollars already spent without a sign of a promising vaccine. According to the chimpanzee genome, some of the greatest differences between chimpanzees and humans relate to the immune system,[3] calling into question the validity of infectious disease research using chimpanzees.

*Ethical and public concerns about chimpanzee research*

Chimpanzee research raises serious ethical issues, particularly because of their extremely close similarities to humans in terms of intelligence and emotions. Americans are clearly concerned about these issues: 90 percent believe it is unacceptable to confine chimpanzees individually in government-approved cages (as we documented during our investigation at NIRC); 71 percent believe that chimpanzees who have been in the laboratory for over 10 years should be sent to sanctuary for retire-

[1] NRC (National Research Council) (1997) Chimpanzees in research: strategies for their ethical care, management and use. National Academies Press: Washington, D.C.

[2] Cohen, J. (2007) Biomedical Research: The Endangered Lab Chimp. Science. 315:450–452.

[3] The Chimpanzee Sequencing and Analysis Consortium/Mikkelsen, TS, et al.,(1 September 2005) Initial sequence of the chimpanzee genome and comparison with the human genome, Nature 437, 69–87.

ment[4]; and 54 percent believe that it is unacceptable for chimpanzees to "undergo research which causes them to suffer for human benefit."[5]

We respectfully request the following bill or committee report language:

"No funds made available in this Act, or any prior Act, may be used for "The Committee directs that no funds provided in this Act be used to support the breeding of federally owned or federally supported chimpanzees for research."

We appreciate the opportunity to share our views for the Labor, Health and Human Services, Education and Related Agencies Appropriations Act for Fiscal Year 2012. We hope the Committee will be able to accommodate this modest request that will save the government a substantial sum of money, benefit chimpanzees, and allay some concerns of the public at large. Thank you for your consideration.

HIGH THROUGHPUT SCREENING, TOXICITY PATHWAY PROFILING, AND BIOLOGICAL INTERPRETATION OF FINDINGS—NATIONAL INSTITUTES OF HEALTH—OFFICE OF THE DIRECTOR

In 2007, the National Research Council published its report titled "Toxicity Testing in the 21st Century: A Vision and a Strategy." This report catalyzed collaborative efforts across the research community to focus on developing new, advanced molecular screening methods for use in assessing potential adverse health effects of environmental agents. It is widely recognized that the rapid emergence of omics technologies and other advanced technologies offers great promise to transform toxicology from a discipline largely based on observational outcomes from animal tests as the basis for safety determinations to a discipline that uses knowledge of biological pathways and molecular modes of action to predict hazards and potential risks.

In 2008, NIH, NIEHS and EPA signed a memorandum of understanding[6] to collaborate with each other to identify and/or develop high throughput screening assays that investigate "toxicity pathways" that contribute to a variety of adverse health outcomes (e.g., from acute oral toxicity to long-term effects like cancer). In addition, the MOU recognized the necessity for these Federal research organizations to work with "acknowledged experts in different disciplines in the international scientific community." Much progress has been made, including FDA joining the MOU, but there is still a significant amount of research, development and translational science needed to bring this vision forward to where it can be used with confidence for safety determinations by regulatory programs in the government and product stewardship programs in the private sector. In particular, there is a growing need to support research to develop the key science-based interpretation tools which will accelerate using 21st century approaches for predictive risk analysis. We believe the Office of the Director at NIH can play a leadership role for the entire U.S. Government by funding both extramural and intramural research.

We respectfully request the following committee report language, which is supported by The HSUS, HSLF, Procter & Gamble, and the American Chemistry Council.

"The Committee supports the implementation of the National Research Council's report "Toxicity Testing in the 21st Century: A Vision and a Strategy" to create a new paradigm for chemical risk assessment based on the incorporation of advanced molecular biological and computational methods in lieu of animal toxicity tests within integrated evaluation strategies, and urges the National Institutes of Health to play a leading role by funding a coordinated, long-term program of relevant intramural and extramural research. Current activities at the NIH Chemical Genomics Center, National Institute of Environmental Health Sciences, the Environmental Protection Agency and the Food and Drug Administration show considerable potential and the NIH Director should explore opportunities to augment this effort by identifying additional resources that could be directed to priority research projects. The Director shall report on the NIH funding of and progress on these activities to the Committee commencing September 30, 2012 and annually thereafter."

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[4] 2006 poll conducted by the Humane Research Council for Project Release & Restitution for Chimpanzees in laboratories.

[5] 2001 poll conducted by Zogby International for the Chimpanzee Collaboratory.

[6] http://www.genome.gov/pages/newsroom/currentnewsreleases/ntpncgcepamou121307finalv2.pdf.

PREPARED STATEMENT OF THE UNIVERSITY OF VIRGINIA MEDICAL CENTER

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to submit testimony on behalf of the University of Virginia Medical Center. As members of this committee you have jurisdiction for funding the agencies responsible for the delivery of healthcare in the United States. As a healthcare provider in Virginia and a representative of a major institution responsible for training the healthcare providers of tomorrow, I want to use this opportunity to discuss the vital importance of Federal funding for Graduate Medical Education (GME) in the United States. I urge you to support an increase in the number of appropriately trained physicians in the United States while protecting the integrity and structure of the GME program.

*Overview of the University of Virginia Health System*

The University of Virginia Health System is an academic medical center composed of the Hospital and its satellite facilities and programs, the School of Medicine, School of Nursing, other allied health programs, and faculty physicians. The University of Virginia Health System plays a critical role in the Nation's healthcare structure as well as the healthcare structure of Virginia. We have multiple key missions: training the next generation of healthcare workers, caring for the sickest patients and the underserved who have nowhere to turn, providing innovative treatments with state-of-the-art technology, and performing medical research. Our key missions are what distinguish us from regular community hospitals.

The University of Virginia Medical Center and its Graduate Medical Education training programs provide an essential bridge for medical school graduates to become well-trained practicing physicians. At the University of Virginia Medical Center, we continuously provide an environment of excellence in which our trainees gain the necessary experience to practice in their specialties in a setting that emphasizes quality and patient safety.

Our training programs have been recognized by the Accreditation Council for Graduate Medical Education for their compliance in meeting the necessary training standards and for their innovative educational techniques. We currently sponsor 68 accredited core specialty and subspecialty training programs. All of our programs are fully accredited, and many have been awarded the maximum accreditation cycle length.

Our programs are well positioned to meet the growing national workforce shortages in primary care (Family Medicine, Internal Medicine including General Medicine, Obstetrics and Gynecology, Pediatrics, and General Surgery), as well as in those specialties where workforce shortages have been identified in the Commonwealth of Virginia (Emergency Medicine, Child and Adolescent Psychiatry).

We have excellent training programs that are well-suited to train physicians who will care for our aging population, including Geriatrics, Palliative and Hospice Medicine, Orthopedic Surgery (including Reconstructive Spine), Endocrinology (Diabetes, Obesity, and Osteoporosis), Cardiology and Cardiothoracic Surgery, Oncology, and Neurology (Alzheimer's Disease).

*Funding of Graduate Medical Education*

Training of future physicians is a core mission that distinguishes academic medical centers and teaching hospitals like the University of Virginia Medical Center from other healthcare institutions. Congress has recognized the critical role that teaching hospitals play in the training of America's physicians; however, this key endeavor is very expensive. Consequently, Congress has agreed that teaching hospitals should be paid for their increased patient care expenses as well as for their costs associated with GME training programs. This is accomplished through two mechanisms: Direct Graduate Medical Education (DGME) payments and the Indirect Medical Education (IME) adjustment.

The Direct Graduate Medical Education payment (DGME) is a Medicare payment intended to reimburse teaching hospitals directly for resident stipends, the costs of teaching by attending physicians, the expenses incurred with educational classrooms and the administrative costs of the residency program office. Medicare DGME payments are based upon the number of residents and the number of Medicare beneficiaries in the hospital (i.e., it does not cover the entire cost of teaching to the institution.) Currently UVa Medical Center is reimbursed under DGME for approximately 38 percent of the cost of training each resident.

The Indirect Medical Education adjustment (IME) was created in 1983 by Congress. "This adjustment is provided in light of doubts . . . about the ability of the DRG case classification system to account fully for factors such as severity of illness of patients requiring the specialized services and treatment programs provided by teaching institutions and the additional costs associated with the teaching of

residents . . . . The adjustment for indirect medical education costs is only a proxy to account for a number of factors which may legitimately increase costs in teaching hospitals." (House Ways and Means Committee Report, No. 98–25, March 4, 1983 and Senate Finance Committee Report, No. 98–23, March 11, 1983).

The IME adjustment is based on a complex formula that was empirically determined to be related to the ratio of residents to beds (IRB). The hospital's IME payment is determined by its individual intern/resident-to-bed ratio in a formula established under the Medicare statute. For every Medicare case paid, a teaching hospital receives an additional IME payment, calculated as a percentage add-on to the basic price per case. In 1983, payments added 11.59 percent to each DRG amount for every 10 percent increase in the IRB. The IME adjustment as originally calculated, in conjunction with DGME payments, more satisfactorily reimbursed teaching hospitals for the cost of training the next generation of doctors. However, the Balanced Budget Act of 1997 (BBA) caused the IME adjustment to substantially decline. Over time, Congress has periodically reduced the adjustment—by 30 percent since 1997—to the current 5.5 percent adjustment.

According to the American Association of Medical Colleges (AAMC), the Medicare program annually provides about $3 billion in DGME payments and $6 billion in IME payments to nearly 1,100 teaching hospitals. While these payments represent less than 2 percent of total Medicare payments, for teaching hospitals they are extremely important in supporting the mission of training physicians. These payments provide the backbone for our Nation's healthcare system, and they ultimately contribute to better patient care by providing the support necessary for excellent training programs.

The BBA also capped the number of resident slots that Medicare will support. It limited the number of allopathic and osteopathic resident physicians who may be counted for purpose of calculating IME and DGME reimbursement to the number that the teaching hospital reported on its 1996 Medicare cost report. This cap is preventing academic medical centers and teaching hospitals from expanding the number of residents and fellows even while the Nation continues to suffer a physician shortage. At a time when we should be producing more physicians, especially in the key areas mentioned previously, this outdated rule is thwarting our efforts.

The University of Virginia Medical Center trains more than 750 residents and fellows each year. It is significantly over its Medicare limit or cap for training slots. For purposes of Direct Graduate Medical Education, the University of Virginia's cap is 538 residents, and it is 121 positions over its cap; for purposes of Indirect Graduate Medical Education, the University of Virginia's cap is 508 residents, and it is 131 positions over its cap. The cost of training a resident is approximately $100,000 per year, thus, the University of Virginia Medical Center is spending about $12,100,000 per year on resident positions over the cap.

Graduate Medical Education training helps ensure that healthcare delivery in the United States continues to be the highest quality. The additional costs incurred at teaching hospitals for the training of tomorrow's doctors are real and should be reimbursed at a level commensurate with the expense. Without specific appropriate reimbursement from Medicare, teaching hospitals will run deficit budgets and be forced to cut the very programs that differentiate them and allow them to provide the best and most innovative care.

*Challenges Facing Graduate Medical Education*

Recently, the National Commission on Fiscal Responsibility and Reform recommended reducing the IME adjustment from 5.5 percent to 2.2 percent annually, which represents an approximate two-thirds cut in the IME payment. The potential loss of approximately two-thirds support from the Federal Government would severely compromise the ability of the University of Virginia Medical Center, and other academic medical centers, to fund this crucial educational mission. The estimated impact of this reduction on the University of Virginia Medical Center is approximately $26,700,000 per year.

Although we recognize the importance of a balanced Federal budget and the need to control healthcare spending, reducing the funds available for training future physicians will lead to a severe lack of access to healthcare in the near future. This will occur at the very time that hospitals are being asked to expand access to care.

For example, the Patient Protection and Affordable Care Act (i.e., the healthcare reform law) will provide health insurance coverage to 32 million more Americans; however, health insurance does not guarantee timely access to care. There must be a well trained workforce to care for the additional patients to ensure that implementation of the new healthcare reform law is successful. Unfortunately, the United States is already experiencing a shortage of physicians. As healthcare reform is fully implemented and the population of the United States continues to age, the shortage

of physicians is expected to worsen. By 2020 the demand for physicians will significantly outweigh the supply. According to the AAMC's Center for Workforce Studies, by 2020 there will be a shortage of 45,000 primary care physicians, and a shortage of 46,000 surgeons and medical specialists.

Only 700 Medicare-funded training slots were awarded during the most recent reallocation authorized by the healthcare reform law. Most teaching hospitals, including the University of Virginia, did not receive any additional Medicare-funded residency slots. Unless the cap is increased or lifted, it is expected that there will be more medical school graduates than residency positions in the near future. Indeed, in its April GME e-letter (http://www.ama-assn.org/resources/doc/med-ed-products/gmee-04-2011.pdf) the American Medical Association stated that we may have already reached the point where U.S. medical school graduates are not able to find a residency position because there are now more graduates than available GME slots.

Specifically, the University of Virginia School of Medicine, along with dozens of medical schools nationally, has increased class size to meet the needs of the impending workforce shortages. However, medical students looking to join a residency program have begun to face a significant bottleneck after graduation. While institutions like the University of Virginia are graduating exceptional medical students, the University of Virginia Medical Center can only accept a finite number Medicare-funded residency positions due to the cap. Thus, the shortage of open residency positions for medical students creates another barrier to the supply of well-trained physicians.

To address the severe doctor shortage crisis facing the United States and to ensure that there is a well-trained healthcare workforce to successfully care and treat the increasing number of patients in the future, it is critical that Congress support Graduate Medical Education by increasing the number of resident slots available for medical students, and continue to invest in Graduate Medical Education. I respectfully request that this committee do everything within its jurisdiction to achieve these important goals.

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## PREPARED STATEMENT OF THE TRI-COUNCIL FOR NURSING

The Tri-Council for Nursing, comprised of the American Association of Colleges of Nursing, the American Nurses Association, the American Organization of Nurse Executives, and the National League for Nursing, respectfully request $313.075 for the Nursing Workforce Development programs authorized under Title VIII of the Public Health Service Act (42 U.S.C. 296 et seq.) in fiscal year 2012. This is the amount requested in the recommended funding levels for the President's fiscal year 2012 budget.

The Tri-Council is a long-standing nursing alliance focused on leadership and excellence in the nursing profession. This marks the 13th year of the nurse and nurse faculty shortages which have eroded the ability of the nursing profession to provide the highest quality of care that all patients rightfully desire and morally deserve. As the Nation looks toward restructuring the healthcare system by focusing on expanding access, decreasing cost, and improving quality, a significant investment must be made in strengthening the nursing workforce, a profession which The U.S. Bureau of Labor Statistics expects a 22 percent growth in employment through 2018.

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## PREPARED STATEMENT OF THE UNITED NEGRO COLLEGE FUND

Mr. Chairman and distinguished Members of the subcommittee, I am Dr. Michael L. Lomax, President and CEO of UNCF—the United Negro College Fund. I want to thank you for allowing me to submit funding recommendations and priorities relevant to the fiscal year 12 Labor-HHS-Education Appropriations bill.

Statistically, HBCUs graduate a preponderant share of all black Americans receiving postsecondary degrees. While comprising only 3 percent of the Nation's 4,197 institutions of higher learning, the 106 HBCUs are responsible for producing approximately 25 percent of all bachelor's degrees, 10 percent of all master's degrees and 26 percent of all first professional degrees earned by African Americans annually.

UNCF institutions are a critical component and significant subset of the larger community of HBCUs. Specifically, UNCF is the national fundraising and advocacy representative for 38 private historically black colleges and universities. There are more than 350,000 persons who are counted as alumni of UNCF member colleges and universities. Our alumni include persons such as Rev. Dr. Martin Luther King, Jr., Brown University President Dr. Ruth Simmons, three former surgeon generals,

numerous current Members of Congress and a host of noted authors, poets, attorneys, professors and philanthropists.

UNCF—the Nation's oldest and most successful minority higher education assistance organization—fulfills its primary goal by increasing opportunities for access to higher education. During its 66-year existence, UNCF has raised more than $3 billion to support its historically black college and university member institutions and administered nearly 400 programs, including scholarships, mentoring programs, summer enrichment, study abroad, curriculum, faculty, and leadership development. Today, UNCF supports more than 65,000 students at over 900 colleges and universities across the country.

We recognize that working with the Administration and Congress will continue to be particularly challenging in a budget-constrained environment where more diverse students with unique academic and familial circumstances are dependent upon need-based aid. The face of our Nation is changing and nowhere is the change more evident than in education. Compared with the last century, we are increasingly changing with more of us being born in other nations, speaking other languages and carrying different cultures. Minority

populations are growing more quickly than the U.S. population as a whole. In keeping with this, UNCF continues to endorse the following policies and positions as the focal point of its legislative agenda for fiscal year 2012. These recommendations continue a basic commitment to enrolling, nurturing, and graduating students, some of whom lack the social, educational, and financial advantages of other college bound populations. This agenda reflects what is needed to level the playing field for both UNCF member schools and students as we continue to pursue educational excellence.

The following fiscal year 2012 programs are of particular relevance and importance to UNCF.

*Title III, Part B, Strengthening Historically Black Colleges and Universities—$267 million (Section 323)*

Because of its flexibility, this program is the fundamental source of institutional assistance for HBCUs and is used to support strategic planning initiatives, academic enhancements, administrative and fiscal management, student services, physical plant improvements, and general institutional development.

The current level of funding to Title III, Part B must be maintained in order to continue to enhance and sustain the quality of HBCUs, and to meet the national challenges associated with global competitiveness, job creation and changing demographics. For fiscal year 2012, UNCF requests $267 million to support Section 323.

*Title III, Part D, HBCU Capital Financing Program—a minimum of $20.58 million, plus increase the statutory cap to at least $1.7 billion. Bill language is needed to make funding available to institutions that have a need but fall into a category that has exhausted resources within the current cap of $1.1 billion.*

Funded through Title III, Part D of the Higher Education Act, the HBCU Capital Financing Program is intended to provide low-interest capital financing loans to historically disadvantaged institutions throughout the HBCU community. In light of economic hardships and challenges confronting several of our member institutions, UNCF has worked with national stakeholders, officials at the Department of Education, and Congressional leadership to propose a comprehensive revision of the capital financing provisions.

For fiscal year 2012, UNCF requests at least $20.58 million to allow the Secretary to support the administration of additional loans through the Capital Financing Program. Further, we request the assistance of Federal leaders in working with the HBCU Capital Financing Board to ensure that recommendations made to Congress will promote increased participation within the program among all eligible institutions.

*The Hawkins Centers of Excellence Program—$40 million*

Under this budget proposal, the Administration proposes giving grants to minority-serving institutions to prepare teachers by providing extensive training, creating a system for tracking program graduates and raising exit standards. The Centers are named after the recently deceased Augustus F. Hawkins in honor of his historic leadership as a champion for expanding education as well as job opportunity.

For fiscal year 2012, UNCF requests $40 million to implement the Hawkins Centers of Excellence Program. This program would help expand the pool of effective minority teachers thus working to close the achievement gap for minority students.

*Pell Grants Program—$5,550 (current maximum reward)*

This program assists so many deserving students in getting into college. As college costs increase, the amount of jobs available to solely high school graduates is rapidly decreasing. It is imperative to preserve the maximum award of $5,550 and continue to fund Pell at the appropriate level. The budget would call for a cut of $100 billion in Pell grants over 10 years, paid for by eliminating the "Two Pell" benefits and the in-school interest subsidy for graduate and professional student loans.

For fiscal year 2012, UNCF requests the current maximum awards of $5,550 to continue the support of the Pell Grants Program. Maintaining the maximum Pell award is critical to ensure that the growing pool of first generation and low income college students are provided much needed financial support to access higher education and minimize the burden of costly education loans.

UNCF and our member schools have, among them, many years of experience in making the dream of a college education a reality for low-income students and the colleges they attend. My staff and I, as well as the presidents of our member schools, stand ready to continue to work closely with your committee to formulate and craft a plan that will work for all the young people who are seek and deserve college education.

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PREPARED STATEMENT OF THE UNITED NETWORK FOR ORGAN SHARING

Highlighting the urgent need to address the ever-growing waiting list for organs for transplantation and the number of people that die every day just waiting for an organ, by strengthening programs at HRSA, the National Institutes of Health and within the Office of the Secretary.

Mr. Chairman and Members of the Subcommittee, thank you for giving the United Network for Organ Sharing (UNOS) the opportunity to provide testimony as the Subcommittee begins to consider funding priorities for fiscal year 2012. My name is Mary Ellison and I am the Acting Executive Director of UNOS, the organization with the Federal contract to coordinate the Nation's organ transplant system, providing vital services to meet the needs of men, women and children awaiting lifesaving organ transplants. Based in Richmond, Virginia, UNOS is a private, nonprofit membership organization. UNOS members encompass every transplant hospital, tissue matching laboratory and organ procurement organization in the United States, as well as voluntary health and professional societies, ethicists, transplant patients and organ donor advocates.

Transplantation has saved and enhanced the lives of more than 450,000 people in the United States. It is the leading form of treatment for many forms of end-stage organ failure. With this success, however, has come increasing demand for donated organs. Living donation (transplanting all or part of an organ from a living person) has increased dramatically in the last few years, helping increase the number of transplants performed. In addition, UNOS has enacted a number of policies to encourage more efficient use of available organs, such as "splitting" livers from deceased donors to allow two recipients to be transplanted. The only long-term solution to the organ shortage, however, is for more people to agree to become organ donors. UNOS works closely with medical professionals to increase their understanding and support of the organ donation process.

Mr. Chairman, as you know the primary Federal agency with jurisdiction over organ transplantation issues is the Health Resources Services Administration. However, as we will describe below, the Office of the Secretary and NIH also have important roles to play to help people in need of an organ transplant.

*Health Resources Services Administration*

Even with advances in the use of living liver donors, the increase in the demand for organs needed for transplantation will continue to exceed the number available. The need to increase the rate of organ donation is critical. On April 11, 2011 there were 110,676 men, women and children on the national transplantation waiting list. Last year an average of 74 patients were transplanted each day; however a daily average of 18 patients died because the organ they needed did not become available in time to save them. HRSA's Division of Transplantation has a proven track record of successfully increasing the rate of organ donation with limited resources.

Recognizing the importance of this issue, Congress passed, and the President signed, the Organ Donation and Recovery Improvement Act of 2004 (Public Law 108–216) authorizing an increase of $25 million for organ donation activities in the first year, and such sums as necessary in following years, and yet, it was only last year that additional funding of $1 million has been provided to implement this legislation. To address these needs, UNOS recommends that the Division of Transplan-

tation receive a $2 million increase in fiscal year 2012, to allow the Division to more aggressively pursue program efforts to increase the supply of organs available for transplantation.

In addition, the shortage of organs for donation can be positively impacted by healthcare professionals, particularly physicians, nurse, and physician assistants that are frequently the first to identify and refer a potential donor. These professionals also have an established relationship with the family members that weigh the option to donate their loved one's organs. In order to improve the knowledge and skills of the several key health professions, UNOS requests funding to develop curriculum and continuing medical education programs for targeted health professions. To launch a new 5 year effort to improve the competency of health professionals to help meet the goal of increasing the number or organs available for transplantation $450,000 is requested for the United Network for Organ Sharing (UNOS) to be made available from within the base funding of the Division of Health Professions based on the authority provided in Section 765 of Title VII to improve the workforce.

*Office of the Secretary*

On March 3, 2008 the Department published a request for information in the Federal Register to gather information to assist the Department to determine whether it should engage in a rulemaking with respect to vascularized composite allografts (VCAs). Three years later, the Department still has not finalized this decision. As it currently stands, the Food and Drug Administration has jurisdiction over VCA transplants, as they are currently defined as human tissue. However, as the numbers of these transplants are growing, finalizing the decisions associated with this issue and allowing HRSA's Division of Transplantation to have jurisdiction over VCA's will permit this category of transplants to benefit from the policy oversight and expertise of the Organ Procurement Transplant Network (OPTN).

Worldwide there have been more than two dozen limb transplants, a growing number of transplants of portions of the face, and a small number of transplants of other anatomical parts. Although the body parts vary significantly, they share important common characteristics with organ transplantation. As with organs, the VCA graft is subject to damage or death from the lack of blood flow and the need for revascularization is done through a surgical reconnection of blood vessels. Additionally, all the expertise and skills of healthcare professional trained to work with families, individuals and hospitals in the organ donation and procurement process are also needed in the donation and procurement of VCAs. All of these vital activities are already performed and overseen by the organ transplant community. Further, for 25 years the OPTN has overseen the processes and crafted policies to regulate them under Federal contract. It therefore seems logical, efficient and will serve the best interests of patients and the Nation's transplant system to bring VCAs under the umbrella of the OPTN.

UNOS urges the Office of the Secretary to take action on this decision, and issue the rule and begin the necessary process of amending the definition of human organs. This is especially critical given the recent activities of private entities that, lacking Federal leadership, have begun taking the necessary steps to form registries for VCAs. As we learned over 20 years ago when the OPTN was established, it is crucial to have Government oversight over registries such as this in order to establish fair and ethical distribution of body parts.

*National Institutes of Health*

Mr. Chairman, as you know, the National Institute of Allergy and Infectious Diseases has jurisdiction over transplantation research at the NIH. Recent research funded by NIAID has resulted in the development of desensitization protocols related to kidney transplantation that have shown remarkable progress in helping allow the most vulnerable of patients live with a transplant. Up to 30 percent of the people on the renal transplant waiting list—without special intervention—will likely never have the chance to receive a transplant due to an inability to find a compatible donor. These patients have become "sensitized" to human antigens (HLA) through pregnancy, transfusions, or prior transplants and therefore must wait significantly longer for a compatible donor. This added time on the wait list directly increases both their disease-related complications and mortality.

To improve access to transplantation for most these broadly sensitized patients, desensitization protocols have evolved to decrease the breadth and strength of their antibodies. Survival rates are excellent, equaling or exceeding the rates for kidney transplantation generally. It is reasonable to estimate that if these protocols were confirmed to be as safe and effective as early peer reviewed data has suggested, a large number of these long-suffering people could be successfully transplanted and removed from the waiting list each year. UNOS recommends that NIAID support

a multi-center initiative with a companion data collection and analysis center to facilitate the use of this protocol at an increasing number of transplant centers across the country.

*Summary and Conclusion*

Mr. Chairman, again we wish to thank the Subcommittee for the opportunity to submit testimony and for your leadership in these difficult times. While UNOS recognizes the demands on our Nation's resources, we believe the ever-growing waiting list for organs for transplantation, and the number of people that die every day just waiting for an organ, continue to justify higher funding levels for HRSA's Division of Transplantation.

In conclusion, we specifically request the following for fiscal year 2012:

—A $2 million increase for HRSA's Division of Transplantation;

—$450,000 from within the base funding of the Division of Health Professions to develop curriculum and continuing medical education programs for targeted health professions;

—Report language urging the Office of the Secretary to finalize a decision to amend the definition of human organs to include vascularized composite allografts, and allow this category to come under the umbrella of the OPTN; and

—Report language within the National Institute of Allergy and Infectious Disease to support a multi-center initiative focused on "desensitizing "patients previously found incompatible with most human organs.

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## PREPARED STATEMENT OF THE UNITED TRIBES TECHNICAL COLLEGE

For 42 years, United Tribes Technical College (UTTC) has provided postsecondary career and technical education, job training and family services to some of the most impoverished, high risk Indian students from throughout the Nation. We are governed by the five tribes located wholly or in part in North Dakota. We are not part of the North Dakota State college system and do not have a tax base or State-appropriated funds on which to rely. We have consistently had excellent retention and placement rates and are a fully accredited institution. Section 117 Carl Perkins Act funds represent about half of our operating budget and provide for our core instructional programs. The requests of the United Tribes Technical College Board for fiscal year 2012 is for the following authorized Department of Education programs:

—$10 million for base funding authorized under Section 117 of the Carl Perkins Act for the Tribally Controlled Postsecondary Career and Technical Institutions program (20 U.S.C. Section 2327). This is $1.8 million above the fiscal year 2010 level and the President's requests for fiscal years 2011 and 2012. These funds are awarded competitively and are distributed via formula.

—$30 million as requested by the American Indian Higher Education Consortium for Title III–A (Section 316) of the Higher Education Act (Strengthening Institutions program).

—Maintain Pell Grants at the $5,550 maximum award level.

### AUTHORIZATION

United Tribes Technical College began operations in 1969. We realized that in order to more effectively address the unique needs of Indian people to acquire the academic knowledge and skills necessary to enter the workforce we needed to expand our curricula and services. We were scraping by with small amounts of money from the Bureau of Indian Affairs, and so decided to work for an authorization in the Department of Education. That came about in 1990 when the Carl Perkins Act was reauthorized and it included specific authorization for what is now called the Tribally Controlled Postsecondary Career and Technical Institutions program (Section 117). The Perkins Act has been reauthorized twice since then—in 1998 and in 2006, with Congress each time continuing the Section 117 Perkins program.

*Some Important Facts About United Tribes Technical College*.—We have:

—A dedication to providing an educational setting that takes a holistic approach toward the full spectrum of student needs—educational, cultural, necessary life skills—thus enhancing chances for success.

—Services including campus security, a Child Development Center, a family literacy program, a wellness center, area transportation, a K–8 elementary school, tutoring, counseling, and family and single student housing.

—A semester completion rate of 80–90 percent.

—A graduate placement rate of 94 percent (placement into jobs and higher education).

—A projected return on Federal investment of 20–1 (2005 study).
—Highest level of accreditation from the North Central Association of Colleges and Schools.
—Over 30 percent of our graduates move on to 4-year or advanced degree institutions.
—A student body representing 87 tribes who come mostly from high-poverty, high unemployment tribal nations in the Great Plains; many students have children or dependents.
—81 percent of undergraduate students receive Pell Grants, the highest percentage of Pell Grant recipients of any North Dakota college.
—21 2-year degree programs, eight 1-year certificates, and 3 bachelor degree programs pending final accreditation this spring.
—An expanding curricula to meet job-training needs for growing fields including law enforcement, energy auditing and health information management. We have also broadened our online program offerings.
—A critical role in the regional economy. Our presence brings $31.8 million annually to the economy of the Bismarck region.
—A workforce of over 300 people.
—An award-winning annual powwow which last year had participants from 70+ tribes, featuring over 1,500 dancers and drummers, and drawing over 20,000 spectators. We annually feature indigenous dance groups from other countries.

FUNDING REQUESTS

*Section 117 Perkins Base Funding*.—Funds requested under Section 117 of the Perkins Act above the fiscal year 2010 level are needed to: (1) maintain 100 year-old education buildings and 50 year-old housing stock for students; (2) upgrade technology capabilities; (3) provide adequate salaries for faculty and staff (who have not received a cost of living increase for the past 2 years and who are in the bottom quartile of salary for comparable positions elsewhere); and (4) fund program and curriculum improvements, including at least three 4-year degree programs.

Acquisition of additional base funding is critical as UTTC has more than tripled its number of students within the past 8 years while actual base funding, including Interior Department funding, have not increased commensurately (increased from $6 million to $8 million for the two programs combined). Our Perkins funding provides a base level of support while allowing the college to compete for desperately needed discretionary contracts and grants leading to additional resources annually for the college's programs and support services.

*Title III–A (Section 316) Strengthening Institutions*.—We support Title III–A funding for tribal colleges. Among its statutorily allowable uses is facility construction and maintenance. We are constantly in need of additional student housing, including family housing. We work hard to cobble together various sources for housing construction. We would like to educate more students but lack of housing has at times limited the admission of new students. With the completion this past year of a new Science and Math building on our South Campus on land acquired with a private grant, we urgently need housing for up to 150 students, many of whom have families. New housing on the South Campus could also accommodate those persons we expect to enroll in a new police training program.

While UTTC has constructed three housing facilities using a variety of sources in the past 20 years, approximately 50 percent of students are housed in the 100-year-old buildings of the old Fort Abraham Lincoln, as well as in duplexes and single family dwellings that were donated to UTTC by the Federal Government along with the land and Fort buildings in 1973. These buildings require major rehabilitation. New buildings for housing are actually cheaper than trying to rehabilitate the old buildings that now house students.

*Pell Grants*.—We support maintaining the Pell Grant maximum amount to at least a level of $5,550. As mentioned above, 81 percent of our students are Pell Grant-eligible. This program makes all the difference in the world of whether these students can attend college. We also support the continuation of appropriations to fund two scheduled award years per year, as this has helped many of our students shorten the time to obtain their degrees.

GOVERNMENT ACCOUNTABILITY OFFICE REPORT

As you know, the Government Accountability Office (GAO) in March of this year issued two reports regarding Federal programs which may have similar or overlapping services or objectives (GAO–11–318SP of March 1 and GAO–11–474R of March 18). Funding from the Bureau of Indian Education (BIE) and the Department of Education's Perkins Act for Tribally Controlled Postsecondary Career and Technical

Institutions were among the programs listed in the supplemental report of March 18. The GAO did not recommend defunding these or other programs; in some cases consolidation or better coordination of programs was recommended to save administrative costs. We are not in disagreement about possible consolidation or coordination of the administration of these funding sources so long as funds are not reduced.

Perkins funds represent about 46 percent of UTTC's core operating budget. The Perkins funds supplement, but do not duplicate, the BIE funds. It takes both sources of funding to frugally maintain the institution. In fact, even these combined sources do not provide the resources necessary to operate and maintain the college. Therefore, UTTC actively seeks alternative funding to assist with academic programming, deferred maintenance of its physical plant and scholarship assistance, among other things.

Second, as mentioned, UTTC and other tribally chartered colleges are not part of State educational systems and do not receive State-appropriated general operational funds for their Indian students. The need for postsecondary career and technical education in Indian Country is so great and the funding so small, that there is little chance for duplicative funding.

There are only two institutions targeting American Indian/Alaska Native career and technical education and training at the postsecondary level—United Tribes Technical College and Navajo Technical College. Combined, these institutions received less than $15 million in fiscal year 2010 Federal funds ($8 million from Perkins; $7 million from the BIE). That is not an excessive amount of money for two campus-based institutions which offer a broad (and expanding) array of programs geared toward the educational and cultural needs of their students and toward job-producing skills.

UTTC offers services that are catered to the needs of our students, many of whom are first generation college attendees and many of whom come to us needing remedial education and services to address the sociobehavioral, socioeconomic, and academic characteristics that pose problems. Our students disproportionately possess more high risk characteristics than other student populations. We also provide services for the children and dependents of our students. Although BIE and Section 117 funds do not pay for remedial education services, UTTC must make this investment with our student population through other sources of funding to ensure they succeed at the postsecondary level.

Federal funding for American Indian/Alaska Native employment and training is barely 1 percent of the annual Federal employment and training budget but has an enormous impact on the people and communities it serves.

Perkins funds are central to the viability of our core postsecondary educational programs. Very little of the other funds we receive may be used for core career and technical educational programs; they are competitive, often one-time supplemental funds which help us provide the services our students need to be successful. We cannot continue operating without Carl Perkins funds. Thank you for your consideration of our requests.

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PREPARED STATEMENT OF THE U.S. HEREDITARY ANGIOEDEMA ASSOCIATION

Thank you for the opportunity to present the views of the U.S. Hereditary Angeioedema Association (USHAEA) regarding the importance of hereditary angioedema (HAE) research.

USHAEA was founded in 1999 with the express purpose of helping those living with HAE and their families to live healthy lives, provide support, and find a cure. The Association provides patient services to those living with HAE, including referrals to knowledgeable healthcare providers and information on the disease. USHAEA also provides research funding to scientific investigators to increase the knowledge base on HAE. Additionally, USHAEA also provides research materials and forums to educate the patients and their families, healthcare providers, and the general public on HAE. Finally, USHAEA acts as a voice for those living with HAE to the world at large.

HAE is caused by a genetic defect which controls C1-Inhibitor blood protein, causing an inability to regulate complex biochemical interactions in blood-based systems involved in disease fighting, inflammatory response, and coagulation. Episodes of HAE are characterized by swelling in the body including the hands, feet, gastrointestinal tract, face, and airway. During an episode, HAE patients experience abdominal pain, nausea, vomiting, and airway swelling, which can lead to asphyxiation. Episodes are often caused by infections, minor injuries or dental procedures, emotional or mental stress, and certain hormonal or blood medications. HAE impacts approximately 1 in 10,000 to 1 in 50,000, making proper diagnosis difficult.

Many of the initial HAE episodes occur in children and adolescents. In families were one parent has HAE, there is a 50 percent probability that their children will inherit this condition. HAE has an annual cost which can exceed $500,000 per year per patient in addition to the human and economic burdens associated with the disease.

*Research Through the National Institutes of Health*

In years past, HAE research was conducted at the National Institutes of Health (NIH) through the National Institute of Allergy and Infectious Diseases, the National Institute of Neurological Disorders and Stroke, the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, National Center for Research Resources, and the National Institute on Diabetes and Digestive and Kidney Diseases. However, NIH has not engaged in any basic or clinical research on HAE since 2009, nor is there any Federal research as it relates to HAE. As a rare disease, HAE stands to benefit from from recent NIH commitments such as the Cures Acceleration Network and the Therapeutics for Rare and Neglected Diseases program, as well coordination with the Office of Rare Diseases Research.

In order to enable research to resume on HAE, it is vital that NIH receive increased support in fiscal year 2012. USHAEA recommends an overall funding level of $35 billion for NIH in fiscal year 2012 and the inclusion of recommendations emphasizing the importance of HAE research.

Thank you for the opportunity to present the view of the HAE community.

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## PREPARED STATEMENT OF YWCA USA

Thank you Chairman Harkin, Ranking Member Shelby and members of the Subcommittee for the opportunity to submit testimony. My name is Gloria Lau, and I am the Chief Executive Officer of the YWCA USA. As Congress works on the appropriations and priorities for the fiscal year 2012 Federal budget, I am here to speak about one priority in particular under the jurisdiction of this subcommittee: the critical need for childcare for women and families.

The YWCA USA is a national not-for-profit (501(c)(3)) membership organization committed to social service, advocacy, education, leadership development, economic empowerment and racial justice. The YWCA is dedicated to eliminating racism, empowering women and promoting peace, justice, freedom and dignity for all. We represent more than 2 million women and girls, and we can be found in many communities in the United States. With nearly 300 local associations nationwide, we serve thousands of women, girls, and their families annually through a variety of programs; including violence prevention and recovery programs, housing programs, job training and employment programs, childcare and early education programs, and more. Our clients include women and girls from all walks of life, including those escaping violence, low-income women and children, women veterans, elderly women, disabled women, and homeless women and their families.

The YWCA is one of the largest providers of childcare in the United States. Many of our associations provide accessible, affordable, and high-quality childcare services to working families nationwide. In one example close to the Nation's Capital, the YWCA of Baltimore, Maryland, an association committed to providing quality childcare for all children, serves more than 600 children annually. At this and other YWCA childcare centers, the day is designed to meet the developmental needs and the interests of each child. Each day includes a variety of intellectual, physical, social, emotional, and creative activities as well as opportunities to interact with other children and adults. In another example, the childcare program at the YWCA in Lawrence, Massachusetts has been ranked in the top 10 childcare programs in Massachusetts by Root Cause, an organization that encourages social innovation and helps corporations source exceptional programs. Starting with this program, many children join YWCA as infants or toddlers and stay in programming into their teen years, which provides continuity of care for children and siblings. Finally, at the YWCA Greater Cincinnati, the State of Ohio has recognized that association's programs with a three-star rating for having met all State benchmarks for quality. If members of the Subcommittee wish, we can provide you far more examples of how YWCAs are providing quality childcare critical to the country's children and their families.

As a major provider of childcare throughout the United States, the YWCA is a strong supporter of the Childcare Development Block Grant (CCDBG). Across the country, YWCAs use CCDBG funding for a variety of programs, including childcare for infants and toddlers, and before- and after-school care for children in school.

CCDBG also provides childcare subsidies for low-income and moderate-income YWCA clients who attend our job training programs, live in our housing facilities, or are served by domestic violence and sexual assault programs. Every day, in communities across this country, we witness the important role CCDBG plays in helping parents find and keep employment and in helping children learn and grow.

Because of our strong support for the CCDBG, the YWCA asks the Subcommittee to concur—at a minimum—with the President's fiscal year 2012 funding request, which includes $2.9 billion for the CCDBG in the Department of Health and Human Services. This call for support comes directly from communities across the country, as local YWCA associations surveyed in December 2010 identified this vital block grant as one of their most critical funding sources. We also support Head Start and Early Head Start, which the President has requested for fiscal year 2012 at $8.1 billion and which rounds out the continuum of services for young children and their families.

The YWCA wholeheartedly supports the core purpose of the CCDBG, which is to help make quality childcare affordable for low-income and moderate-income women and families, through block grant funding for States and tribes. CCDBG is not a cookie-cutter/one size fits all program: it provides States flexibility in developing childcare programs and policies most appropriate to fulfill the needs of children and parents within that State, as well as empowers working parents to make their own decisions on childcare services that best suit their family's needs. CCDBG helps keep parents educated about their childcare options through consumer information so that they can make informed choices, while helping them to achieve economic stability and independence.

The need is simple—if working parents do not have access to affordable, quality childcare for their children, they cannot be full contributors to the economy. Each week, more than 11 million children under 5 years of age are in some type of childcare setting[1].

The problem is: childcare costs are high—compared to family income and household expenses—and they are growing. The average amount parents paid for full-time care for an infant in a center ranged from more than $4,560 in Mississippi to more than $18,773 a year in Massachusetts ($5,356 in Alabama and $8,273 a year in Iowa)[2]. Furthermore, the average center-based childcare fees for an infant exceeded the average annual amount that families spent on food in every region of the country. In addition, childcare fees per month for two children of any age exceeded the median monthly amount for rent, and were nearly as high, or even higher than, the average monthly mortgage payment in every State. YWCAs offer quality childcare at a low cost to the families they serve, but many of them would have to turn people away or simply end programs without State CCDBG funds. This, in turn, would result in parents losing childcare which would impact their ability to work and could possibly result in children being placed in unfit or unsafe childcare situations, further impacting their ability to learn and grow.

Investments in early education are critical to our effort to build a smarter and stronger country, even in economic times that call for budget-cutting measures. Quality, affordable early childhood care and education result in positive outcomes for children, such as preparing them for school and helping parents find and keep jobs. It also benefits taxpayers and enhances economic vitality. Research[3]—by Nobel Prize-winners and Federal Reserve economists, in economic studies in dozens of States and counties, and in longitudinal studies spanning 40 years—demonstrate that return on public investment in high quality childhood education is substantial.

Specifically, it was found that, in the short term, quality, affordable childcare provides significant return as an industry: employing nearly 3 million people nationwide; providing employees wages to spend, pay taxes and purchase goods and services; and enabling employers to attract and retain employees and increase productivity. In the long term, quality, affordable childcare has been found to result in lower costs for remedial and special education and grade repetition; higher rates of completing school and building skills; improved job preparedness and ability to meet

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[1] U.S. Census Bureau, 2006–2008 American Community Survey. U.S. Census Bureau. (2008, March). Who's minding the kids? Childcare arrangements: Spring 2005: Detailed tables. Retrieved April 19, 2010, from http://www.census.gov/population/www/socdemo/child/ppl-2005.html.

[2] *Parents and the High Cost of Childcare: 2010 Update* from the National Association of Childcare Resource and Referral Agencies (provides average costs of childcare for infants, 4-year-olds, and school-age children in centers and family childcare homes in every State), http://www.naccrra.org/publications/naccrra-publications/parents-and-the-high-cost-of-child-care.php.

[3] Early Childhood Education for All: A Wise Investment. U.S. Census Bureau (2005, April). "The Economic Impacts of Childcare and Early Education: Financing Solutions for the Future;" a conference sponsored by Legal Momentum's Family Initiative and the MIT Workplace Center. Retrieved April 7, 2011, from http://web.mit.edu/workplacecenter/docs/Full%20Report.pdf.

future labor force demands; and higher incomes and tax payments from those who complete school.

As stated in a letter to both of you and the Chair and Ranking Member of the Senate Appropriations Committee signed by 17 Senators on February 24, 2011, "noted economists agree that investing in early childhood education is fiscally responsible because it yields a tremendous return on investment, ranging from $3 to $17 for every dollar invested." The letter goes on to state, "Given these gaps and the importance of early learning to our country's economic success, the American Recovery and Reinvestment Act (ARRA) included a prudent and essential expansion of these programs. We strongly believe that Congress must build on this progress, not reverse it."[4] The YWCA strongly believes that as Congress focuses on effective and efficient uses of Federal funds, Congress should not overlook the benefits of allocating Federal dollars toward childcare and early education programs, particularly to cultivate younger generations.

Congress and several Presidential administrations have historically shown strong bipartisan support for CCDBG. Even so, for the 21 years CCDBG has been in existence, the program has always been underfunded and supply has never met demand. Even before the current economic downturn, it was estimated that only 1 in every 7 children who were eligible for CCDBG received assistance. It was also not uncommon for children and their families to be put on waiting lists, to see their assistance cut, or to see it eliminated altogether. The economic downturn has exacerbated this already alarming situation as States continue to cut back social service programs more than they had been scaled back, prior to economic collapse.

In a positive response, as referred to in the joint Senate letter to the Appropriations Committee referenced earlier, the ARRA made a major, $2 billion investment in childcare. The significant increase for CCDBG included in the President's fiscal year 2012 budget request would allow children served by ARRA funding to continue receiving services. This level of funding would allow 1.7 million children to receive childcare assistance, an increase of 220,000 children—at great relief to their working parents. The $1.3 billion increase would translate into an increase of $800 million for discretionary funding (which does not require a State match) and $500 million for mandatory funding (which requires a State match. Approving the President's proposed level of funding will ensure positive impact to the working women and families that are an essential part of our Nation's economic recovery.

The need for and importance of investments in childcare and early childhood education, including CCDBG funding, to the viability of our country is now greater than ever. In addition, the current budget crises facing States across this Nation illustrate why Federal investments in quality childcare and early educations programs are both necessary and vital. For example, the National Women's Law Center (NWLC) reported on April 7, 2011[5], States have begun to cut back on childcare assistance:

"Until recently, most States have managed to maintain their childcare assistance programs, largely thanks to an additional $2 billion in Childcare Development Block Grant (CCDBG) funding for fiscal year 2009 and fiscal year 2010 from the American Recovery and Reinvestment Act (ARRA). However, as States exhaust these funds, and as State budget gaps persist, many will be forced to scale back childcare assistance for families unless additional Federal funding is provided. Already, a number of States and communities have begun to cut back on childcare assistance". . . .

—California's governor is proposing to eliminate childcare assistance for 11- and 12-year-olds, lower the income eligibility limit for childcare assistance from 75 percent of State median income to 60 percent of State median income, and reduce reimbursement rates to childcare providers serving children receiving childcare assistance—which would likely result in families being forced to make up the difference.

—Florida's waiting list for childcare assistance increased from approximately 67,000 children in early 2010 to 89,000 children as of December 2010.

—Maryland will place all families who apply for childcare assistance after February 28, 2011 on a waiting list.

—North Carolina's waiting list for childcare assistance increased from approximately 37,900 children in early 2010 to nearly 45,700 children in December 2010.

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[4] The letter includes support for Head Start and Early Head Start.

[5] *Additional Childcare Funding Essential to Prevent State Cuts* from the National Women's Law Center. Retrieved April 8, 2011, from http://www.nwlc.org/resource/additional-child-care-funding-essential-prevent-state-cuts.

—New York City's mayor is proposing to cut childcare assistance to more than 16,600 children.

YWCA childcare programs in these States, and many more States across the country, are already being impacted by State cutbacks. These cutbacks will be amplified, and their impacts will be amplified, if CCDBG funding does not continue at the levels requested by the President's fiscal year 2012 budget request. For the YWCA, this means our associations will have to cut vital programs and services, reduce the number of families served, and possibly even close YWCA facilities leaving many women and families without affordable, quality, childcare to allow them to work and provide their children a safe, developmentally appropriate environment.

The YWCA recognizes these are unique times in our Nation's history and we agree that our Nation must address its deficit and debt. Yet, the YWCA believes strongly that investments in childcare and early education programs are wise uses of Federal funds that provide substantial returns to our Nation. Childcare and early education programs help not only our Nation's current workforce, but also help prepare the next generation our Nation's children. On behalf of YWCAs nationwide and the many women, children and families we serve, we look to you for a continued commitment to women and families through the provision of essential childcare resources. That is why we respectfully ask you to support the President's fiscal year 2012 budget request for $1.3 billion in additional funding for CCDBG. Thank you once again for the opportunity to provide testimony in support of childcare services, and CCDBG especially, to your Subcommittee. Your attention and assistance are greatly appreciated.

# LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

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OFFICE OF THE SECRETARY

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### Office of the Secretary

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