

# *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* 2009

110<sup>th</sup> CONGRESS, SECOND SESSION

S. 3230

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DEPARTMENT OF LABOR  
NONDEPARTMENTAL WITNESSES

Departments of Labor, Health and Human Services, and Education, and Related Agencies  
Appropriations, 2009 (S. 3230)

**DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES,  
AND EDUCATION, AND RELATED AGENCIES APPROPRIA-  
TIONS FOR FISCAL YEAR 2009**

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**HEARINGS**  
BEFORE A  
SUBCOMMITTEE OF THE  
COMMITTEE ON APPROPRIATIONS  
UNITED STATES SENATE  
ONE HUNDRED TENTH CONGRESS

SECOND SESSION

ON

**S. 3230**

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, 2009, AND  
FOR OTHER PURPOSES

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**Department of Health and Human Services  
Department of Labor  
Nondepartmental witnesses**

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**DEPARTMENTS OF LABOR, HEALTH AND  
HUMAN SERVICES, AND EDUCATION, AND  
RELATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 2009**

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**WEDNESDAY, MAY 7, 2008**

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

The subcommittee met at 9:48 a.m., in room SD-124, Dirksen  
Senate Office Building, Hon. Tom Harkin (chairman) presiding.  
Present: Senators Harkin, Murray, Cochran, and Specter.

**DEPARTMENT OF LABOR**

**OFFICE OF THE SECRETARY**

**STATEMENT OF HON. ELAINE L. CHAO, SECRETARY**

**OPENING STATEMENT OF SENATOR TOM HARKIN**

Senator HARKIN. Good morning. The Appropriations Subcommittee on Labor, Health and Human Services, and Education will now come to order for the hearing on funding for the Department of Labor (DOL).

Madam Secretary, earlier this year you gave a speech in which you said: "The Department's fiscal year 2009 budget is nearly 15 percent less than 10 years ago. That is proof-positive that the Government can do more with less."

Last year, President Bush vetoed the 2008 Labor appropriations bill stating that the bill "spends too much," and that "health care education, job training, and other goals can be achieved without this excessive spending if the Congress sets priorities." He also said, there were "too many earmarks" in our bill.

I hope you do not mind if I respectfully disagree. Your Department, I think, is doing much less since President Bush took office. Much less. Under this administration, the Labor Department's ability to protect America's workers and support a prepared and competitive workforce has declined significantly. Two examples I want to point out.

Last November, the Department of Labor Inspector General (IG) found that the Mine Safety and Health Administration (MSHA) had missed 15 percent of its mandated inspections nationally and in some areas as many as 30 to 50 percent. The IG also said that inspection quality was low, which jeopardized the safety of miners. You know what MSHA said in response? It said MSHA lacked the

resources to hire new personnel to replace retiring inspectors and keep up with increases in mining activity.

Again, with all due respect, Madam Secretary, that is not what I call doing more with less. It is called doing less with less.

Let us look at another worker protection agency, the Occupational Safety and Health Administration (OSHA), where the enforcement staff is down 9 percent since 2001. Last year, the Chemical Safety and Hazard Investigation Board released a report on the BP Texas City refinery explosion in 2005 that resulted in the deaths of 15 workers and more than 100 injuries. The board found that the Occupational Safety and Health Administration had not conducted one planned comprehensive inspection in the oil refining industry. Not one during the entire Bush presidency.

As a result, OSHA committed to completing inspections at all refineries under its jurisdiction by the end of fiscal year 2008. Now OSHA says it cannot finish them until the end of 2009. So, again, is that doing more with less? I do not think so.

It is not just worker protection programs where I believe the President's budget is underfunded. For the 7th year in a row, the President calls for disinvesting in our workforce and drastically cutting programs aimed at improving our global competitiveness. His budget would cut \$474 million, or 16 percent, for State grants for employment and training programs. These are the programs that will help workers develop the skills they need to find employment. Yet, the President sent this budget to us in February when the economy was shedding jobs and millions were out of work. So, Madam Secretary, ask the manufacturing worker in Ohio who has just lost his job, has two kids to support, is this doing more with less?

Now, there is one area where the Bush administration wants to do more and is putting more funding into it, and that is going after labor unions. His budget proposes a 30 percent increase for the Office of Labor-Management Standards (OLMS) to support onerous new financial disclosure requirements for rank and file members, as well as other reporting requirements. Now, this is one office that has not been asked to do more with less.

Meanwhile, much of the money that the Department has spent on President Bush's initiative to "give workers the skills they need to realize their dreams"—that is quoting the President—was awarded without any competition. From 2001 to 2006, the Department provided more than \$250 million in grants on a noncompetitive basis under the High Growth Job Training Initiative. This amounted to 90 percent of the funds available under this initiative going out without any competition, otherwise known as an earmark.

Now, regrettably, we have learned that there were significant problems with how these grants were awarded. We also know that the grantees were not monitored or evaluated effectively to determine whether the funds were well spent. We know this because of the Inspector General audit that I requested last year. Just this morning, the GAO, the Government Accountability Office, released a report that found many of the same problems identified by the IG.



So, Madam Secretary, budgets are about priorities, and I believe this budget does not reflect the right priorities for American workers. Again, it proposes the greatest increase of all for new reporting requirements for rank and file union members, while slashing funding for job training and the fight against child labor. So as we move forward through the budget process, I am going to do everything I can to fight for investments that keep our work sites safe and workers' skills sharp.

With that, I will recognize my ranking member, Senator Specter, for an opening statement.

#### OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you, Mr. Chairman. At the outset, I thank you for our long cooperative relationship. When the power in the Senate has changed, as you and I say, the gavel shifts seamlessly.

I join you in welcoming the Secretary of Labor, who has the distinction of having served the entire tenure of President Bush's two terms, the longest serving cabinet officer and the only cabinet officer to be through two terms. So we note that, Madam Secretary, and the very hard and devoted work you have undertaken in a very, very difficult circumstance.

The reduction in the overall budget for your Department I think is unfortunate, but I understand what is happening here with the limited discretionary funding. It would be my hope that one day in the not too far distant future, there would be a re-evaluation of priorities.

I talk in the far distant future of becoming chairman of the committee, and I am second only to Senator Cochran who is term-limited. Every 6 years or so, the parties change. I may get to be chairman ahead of Senator Harkin.

Senator HARKIN. You know that would be okay with me.

Senator SPECTER. Do I have your vote?

Senator HARKIN. If you were chairman—well, anyway, I will not get into that.

Senator SPECTER. I mention that not at all in jest because of what I consider to be the need for the re-evaluation of priorities to give you more funding.

I was disappointed, for example, that your budget proposes major decreases in community service employment for older Americans in Job Corps and eliminates adult employment in youth training programs. Well, that is unfortunate, but I understand you have a limited budget which has been decreased in absolute dollars, and when you take the cost-of-living adjustments, even more.

I do want to note a couple of issues specifically, and one is the tremendous incidence of juvenile crime hitting my hometown of Philadelphia especially hard—400 homicides a year. Earlier this week, a police officer brutally killed in a robbery. I note the \$50 million which has been put in mentoring, and commend you for the prompt disbursement of those funds. I would urge you to do more.

The initiative that I put in for \$25 million for mentoring, \$5 million to each of five major cities in America, one of which is Philadelphia, should be helpful.

In the balance of your administration, I would urge you to take a very, very close look at what is happening in the Utah mine tragedy. Worker safety is vital. Senator Harkin has highlighted it on what OSHA needs to be doing far in advance of the end of fiscal year 2009. I associate myself with those remarks.

I would also commend to you special activities to try to have confirmations of the National Labor Relations Board (NLRB). It has two members and cannot function. There are enormous delays which prejudice both labor and management where cases take 5 years or more before they come up.

I regret the necessity to excuse myself at this point, but the Judiciary Committee is having a very key hearing on the confirmation for the Sixth Circuit, and I am the ranking member there. So, I will be following the hearing closely. We will have some questions for the record. My absence will not be really missed because I note the presence of our distinguished ranking member, Senator Thad Cochran.

Thank you.

Senator HARKIN. Thank you.

Senator Cochran.

#### STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, thank you. I am glad to be here to join you in welcoming the distinguished Secretary of Labor to our committee to review the budget request for the next fiscal year.

It is increasingly important, I think, that our Nation's workers and employers have the necessary resources to meet the demands of the global economy. We have always tried to work with the administration to ensure that American workers receive both the education and the skill preparations they need to enter and maintain in a quality performance level in our workforce.

But increasingly higher levels of education and advance skills are required to be competitive in the new environment. That is why I am pleased to see the President include in the budget a request for approximately \$7.3 billion for the Department's Employment and Training Administration (ETA), which is designed to increase the competitiveness of the American workforce. I look forward, Madam Secretary, to hearing your ideas on how these programs will evolve and how the funds will be used to accomplish this important goal.

Getting our youth more interested and involved in the opportunities of the workplace will help fill the demands of our labor force in the years ahead. The Job Corps and YouthBuild programs are good examples of how we can reach young people and provide the training they need to be productive members of the workforce. The President includes a request for \$1.5 billion and \$50 million, respectively, for these two programs. Your perspective on the future of the programs and how these funds will be put to use would be appreciated.

Madam Secretary, I know the challenges the Department faces are very interesting and unique, particularly in the development and maintenance of our labor market. I am impressed with your efforts and hard work over the years and certainly those efforts

that are designed to maintain qualified and sustainable workforce participants. That is critical to our Nation's future.

Thank you.

Senator HARKIN. Thank you very much, Senator Cochran.

Madam Secretary, again, welcome to the committee and the floor is yours. Please proceed as you so desire.

#### SUMMARY STATEMENT OF HON. ELAINE L. CHAO

Secretary CHAO. Thank you, Mr. Chairman, Senator Cochran, for the opportunity to present the administration's fiscal year 2009 budget for the Department of Labor.

The total Department budget is \$53.1 billion, of which \$10.5 billion is for discretionary spending.

The Department's fiscal year 2009 budget focuses on five overall priorities: protecting worker safety and health; protecting workers' pay, benefits, pensions, and union member rights; securing the employment rights of America's veterans; increasing the competitiveness of America's workforce; and modernizing the temporary foreign labor certification programs.

In fiscal year 2009, \$1.4 billion is requested for the Department's worker protection activities. The Department has consistently increased our budget for worker protection, and the Department has consistently requested increases in our budget for worker protection activities. Over the last 7 years, we have seen consistent record results on worker safety and protection.

In terms of MSHA, \$332.1 million and 2,361 FTEs are requested. Please note again that we are increasing funding for enforcement. While there was a slight reduction over the fiscal year 2008 enacted level, this is due to the fact that some funds appropriated for fiscal year 2008 were one-time expenses, including the overtime, travel expenses, and new roof needed in the training facility in Beckley, West Virginia. This request enables MSHA to continue implementing the historic MINER Act and maintains our strong commitment to mine safety and health. It includes \$7.4 million specifically targeted to support and train an additional 55 mine safety enforcement personnel. This is also in addition to the 304 coal enforcement personnel hires since June 2006. This budget will support MSHA's efforts to finalize rules on belt air and mine refuge chambers and vigorously enforce increased monetary penalties.

Our fiscal year 2009 request also includes \$501.7 million and 2,173 FTEs for OSHA. This is, again, a 3 percent increase over last year's enacted level.

The request for ESA is for \$468.7 million and 3,190 FTEs.

This includes \$193 million and 1,283 FTEs for Wage and Hour including \$5.1 million to hire an additional 75 inspectors. The ESA request also includes \$89 million and 585 FTEs for OFCCP, and another \$110 million and 872 FTEs are requested for the Worker Compensation programs.

Let me note that the Department of Labor recently passed a \$3.5 billion mark in compensation to EEOICPA beneficiaries, and initial decisions have been made in all of the 22,000 part E cases that were transferred to DOL from the Department of Energy in 2004.

The ESA request also includes \$58.3 million and 369 FTEs for the Office of Labor-Management Standards. This is the same request as requested last year.

There seems to be some angst among some special interest groups about the increases in this budget. This is less than one-tenth of 1 percent in the total budget of the Department of Labor. 1,500 audits were conducted in 1985. By the end of 2000, the number of audits had dropped below 220. We are merely trying to restore the budget and enforce the law.

For EBSA, the request is \$147.9 million. This is an increase of 6 percent over the fiscal year 2008 levels, and a total of 867 FTEs.

For VETS, our budget request is \$238.4 million and 234 FTEs. This is a 5 percent increase over the previous year's enacted level.

#### PREPARED STATEMENT

As you know, our country is transitioning to a knowledge-based economy. New jobs are being created, but many require more education and higher skills. It is noteworthy to note that States have carried forward over \$1 billion in unspent Workforce Investment Act funds on average every year. There is an urgent need for worker training now, and I will be more than glad to talk about ETA and the budget and what we should do about reforming the system to better suit the needs of workers in the 21st century economy.

Thank you.

[The statement follows:]

#### PREPARED STATEMENT OF ELAINE L. CHAO

Good morning Mr. Chairman, Senator Specter, distinguished members of the subcommittee, ladies and gentlemen. Thank you for the opportunity to appear before you today to present the fiscal year 2009 budget for the Department of Labor.

The total request for the Department in fiscal year 2009 is \$53.1 billion and 16,848 FTE, of which \$13 billion is before the committee. Of that amount, \$10.5 billion is requested for discretionary budget authority. Our budget request will allow us to build on the accomplishments achieved in recent years and enable the Department to meet its critical priorities for fiscal year 2009, while helping to achieve the President's deficit reduction goals by reforming programs and reducing or eliminating ineffective or duplicative activities.

#### NOTABLE ACCOMPLISHMENTS

Over the past 7 years, the Department's agencies that protect workers' health, safety, benefits, pay, and union member rights have achieved record-setting results for America's workers and their families. For example:

- Since 2001, the Wage and Hour Division has increased by 67 percent the back wages recovered for workers. In 2007 alone, a record \$220.6 million was recovered for workers, including many vulnerable workers in low-wage industries, who did not receive the wages they were due.
- Between 2001 and 2007, the Employee Benefits Security Administration, which has oversight over nearly every private pension plan in America, closed over 28,000 civil cases and over 1,200 criminal cases; recovered or protected nearly \$11 billion for plans and participants; and, working with the Department of Justice and State and local prosecutors, obtained indictments against more than 800 individuals for crimes against plans and participants.
- Since 2001, the workplace fatality and serious injury and illness rates have fallen to record lows. Since 2002, the overall injury and illness rate has declined by 17 percent and the worker fatality rate has remained at historically low levels. Perhaps most notable is the reduction in the fatality rate among Hispanic workers, which has declined by 17 percent since 2001.
- Since 2001, the Department's Office of Federal Contract Compliance Programs has posted record results in enforcing equal opportunity rights for employees of Federal contractors, with an increase in financial recoveries of 78 percent be-

tween 2001 and 2007. Our efforts to ensure that Federal contractors achieve equal opportunity workplaces resulted in a 245 percent increase from fiscal year 2001 to fiscal year 2007 in the number of Americans recovering back pay and benefits.

- Since 2001, we have rebuilt the Department's Office of Labor-Management Standards' capability to enforce the laws that require union transparency and protect union democracy. As a result, from fiscal year 2001 to fiscal year 2007, the number of financial compliance audits has risen by 226 percent, and the number of convictions has increased by 16 percent.
- We have implemented a number of new programs to assist America's veterans. The Department launched the national HireVets First campaign designed to help employers tap this pool of talent as our service men and women transition to civilian life. In 2004, the Department created REALifelines, a comprehensive new program to provide individualized job training, counseling, and re-employment services to each and every service member seriously injured or wounded in the War on Terrorism.

#### FISCAL YEAR 2009 PRIORITIES

The Department's fiscal year 2009 budget seeks to build on the success of previous years. The budget features five critical priorities: protecting workers' safety and health; protecting workers' pay, benefits, pensions, and union member rights; modernizing the temporary foreign labor certification programs; providing additional resources and services for our Nation's veterans and transitioning service members; and increasing the competitiveness of America's workforce. In fiscal year 2009, the Department will continue to pursue regulatory reforms and strengthening policies that encourage growth, job creation, and opportunity.

#### PROTECTING WORKERS' SAFETY AND HEALTH

The 2009 budget includes \$1.5 billion in discretionary funds for DOL's worker protection activities. Within this funding level, \$833.7 million is requested to enable the Department to continue to pursue its record-setting protection of workers' safety and health.

##### *Mine Safety and Health Administration (MSHA)*

The fiscal year 2009 budget request for MSHA is \$332.1 million and 2,361 FTE. The request will allow MSHA to continue implementing the historic Mine Improvement and New Emergency Response (MINER) Act, the most sweeping mine safety legislation in 30 years.

The request includes \$7.4 million specifically targeted to support and train an additional 55 mine safety enforcement personnel. These additional personnel, in addition to the more than 300 enforcement personnel hired since July 2006, will enable MSHA to complete 100 percent of mandated annual mine inspections in both coal and metal and nonmetal mines. The 2009 budget will also support MSHA's work to finalize rules on belt air and mine refuge alternatives and implement stronger civil penalties, in accordance with the final rules published in fiscal year 2007 and fiscal year 2008.

##### *Occupational Safety and Health Administration (OSHA)*

The fiscal year 2009 budget request for OSHA is \$501.7 million and 2,173 FTE. The request provides resources to support 87,200 Federal and State safety and health inspections.

The request reflects an increase of \$15.7 million and 47 FTE above fiscal year 2008, which includes an increase of \$11.4 million to support enforcement programs and \$5.2 million to provide compliance assistance to employers and employees, especially small businesses. The budget supports OSHA's balanced approach to worker safety and health which includes aggressive enforcement, cooperative programs, outreach, and education.

#### PROTECTING WORKERS' PAY, BENEFITS, AND UNION DUES

In fiscal year 2009, the Department will also continue its high priority programs to protect workers' pay, benefits and union dues.

##### *Employment Standards Administration*

The Department's Employment Standards Administration (ESA) is DOL's largest agency, which administers and enforces a variety of laws designed to enhance the welfare and protect the rights of American workers. The fiscal year 2009 budget re-

quest includes discretionary resources for ESA administrative expenses of \$468.7 million and 3,190 FTE, and a proposal to cancel \$30 million in H-1B fund balances.

#### *Wage and Hour Division*

The Wage and Hour Division is responsible for the administration and enforcement of a wide range of worker protection laws, including the Fair Labor Standards Act, Family and Medical Leave Act, Migrant and Seasonal Agricultural Worker Protection Act, worker protections provided in several temporary non-immigrant visa programs, and prevailing wage requirements of the Davis-Bacon Act and the Service Contract Act. These laws collectively cover virtually all private sector workers, as well as State and local government employees.

The fiscal year 2009 budget request for the Wage and Hour Division totals \$193.1 million and 1,283 FTE, which excludes \$31 million in estimated fee revenue from DOL's portion of the H-1B visa fraud prevention fee authorized by the 2004 H-1B Visa Reform Act. Given the strict statutory limits on the use of these funds, DOL has only been able to spend around \$6 million in any single year. Therefore, the fiscal year 2009 budget cancels \$30 million of the H-1B fund balances and proposes amendments to the Immigration and Nationality Act to permit a more effective use of the fraud prevention fees collected under this provision.

The fiscal year 2009 budget also includes \$5.1 million to hire an additional 75 Wage and Hour enforcement staff to target resources on industries and workplaces that employ low-wage immigrant workers. Finally, the fiscal year 2009 Budget includes \$962,500 for seven legal enforcement support FTE for the Office of the Solicitor.

#### *Office of Federal Contract Compliance Programs*

The fiscal year 2009 budget request for the Office of Federal Contract Compliance Programs (OFCCP) totals \$89 million and 585 FTE. OFCCP is responsible for ensuring equal employment opportunity and non-discrimination in employment for businesses contracting with the Federal Government. OFCCP carries out this mandate by conducting compliance evaluations to identify instances of systemic discrimination in the workplace, taking appropriate enforcement action, and providing relevant and effective compliance assistance programs. The fiscal year 2009 budget request for OFCCP includes \$2 million to launch the design phase of the Federal Contractor Compliance System, a new case management system to improve the effectiveness and efficiency of OFCCP's compliance and enforcement strategies. It will replace the existing OFCCP Information System, which was developed more than 20 years ago and is functionally inadequate to meet current program needs.

#### *Office of Workers' Compensation Programs*

The fiscal year 2009 discretionary Budget request for administration of the Office of Workers' Compensation Programs (OWCP) totals \$110.2 million and 872 FTE to support the Federal Employees' Compensation Act (FECA) (\$96.2 million) and the Longshore and Harbor Workers' Compensation program (\$14.1 million). The fiscal year 2009 budget for the Longshore program includes \$500,000 for addressing workers' compensation claims submitted under the Defense Base Act for civilian workers in Iraq and Afghanistan.

The OWCP budget includes mandatory funding totaling \$108.2 million and 598 FTE for the Department's role in administering the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). EEOICPA provides compensation and medical benefits to employees or survivors of employees of the Department of Energy and certain of its contractors and subcontractors, who suffer from a radiation-related cancer, beryllium-related disease, chronic silicosis or other covered illness as a result of work at covered Department of Energy or DOE contractor facilities. The 2009 budget requests that resources for the EEOICPA program activities carried out by the National Institute for Occupational Safety and Health be requested directly in the Department of Health and Human Services budget. This funding request will enhance congressional oversight, while improving the financial management and transparency of EEOICPA's dose reconstruction and Special Exposure Cohort program.

Lastly, OWCP's fiscal year 2009 budget includes \$37 million in mandatory funding and 195 FTE for its administration of Parts B and C of the Black Lung Benefits Act, and \$52.7 million and 127 FTE in FECA Fair Share administrative funding.

The 2009 budget includes two legislative proposals affecting OWCP programs that play a critical role in protecting workers' economic security, by providing monetary and medical benefits to Federal employees and coal miners whose ability to work has been diminished by an occupational injury or illness. The first re-proposes reforms to FECA to update its benefit structure, adopt best practices of State workers' compensation systems, and strengthen return-to-work incentives. This proposal is

expected to generate Government-wide savings of \$377 million over 10 years. The second is a proposal to restructure, and eventually retire, the mounting debt of the Black Lung Disability Trust Fund—a debt that now stands at \$10 billion.

#### *Office of Labor-Management Standards*

The fiscal year 2009 Budget request for the Office of Labor-Management Standards (OLMS) totals \$58.3 million and 369 FTE. OLMS enforces provisions of Federal law that establish standards for union democracy and financial integrity. OLMS conducts investigative audits and criminal investigations, primarily for embezzlement; conducts civil investigations of union officer elections and supervises remedial elections where required; administers statutory union financial reporting requirements; and provides for public disclosure of filed reports. OLMS also administers employee protective provisions created under Federal transit legislation. The resources requested will allow OLMS to continue all core mission work and to further the goals of union financial integrity, democracy, and transparency.

#### *Employee Benefits Security Administration*

The Department's Employee Benefits Security Administration (EBSA) protects the integrity of pensions, health plans, and other employee benefit plans holding some \$5.6 trillion in assets for more than 150 million Americans. The fiscal year 2009 budget request for EBSA is \$147.9 million and 867 FTE. The request will maintain the strong enforcement record of recent years, and support oversight of pension and health care plans and other employee benefits. Also in fiscal year 2009, EBSA will transition to a streamlined, entirely electronic filing system for the Form 5500 Annual Report which is filed by approximately 1 million employee benefit plans. These reports provide essential information on pension and other benefit plans' financial condition, investments, and operations. The move to electronic filing will substantially reduce processing times for the Form 5500 and improve the reliability of the data reported on the form. By making data on the funding of pension and other benefit plans more transparent and accessible, this new system will support the President's efforts to strengthen retirement security for the Nation's workers and retirees.

#### *Pension Benefit Guaranty Corporation*

The fiscal year 2009 request for the Pension Benefit Guaranty Corporation's (PBGC) administrative expenses is \$444.7 million. The PBGC is now responsible for paying the benefits of 1.3 million workers and retirees. While the Pension Protection Act of 2006 made significant structural changes to the retirement system, the PBGC is still not solvent on a long-term basis. Although PBGC will be able to pay benefits for some years to come, it is projected to be unable to meet its long-term obligations under current law. Further reforms are needed to address the \$14 billion gap between PBGC's liabilities and its assets. If there is not enough money in the system to cover worker benefits, taxpayers are at risk for having to cover the shortfall. The fiscal year 2009 budget proposes to give PBGC's Board the authority to adjust premiums to produce the revenue necessary to meet expected future claims and retire PBGC's deficit over 10 years. Proposed premium reforms will improve PBGC's financial condition and safeguard the future benefits of American workers and retirees.

### INCREASING THE COMPETITIVENESS OF AMERICA'S WORKFORCE

#### *Reforming the Workforce Investment System*

The fiscal year 2009 budget request for the Department's Employment and Training Administration (ETA) is \$6.3 billion in discretionary funds and 1,148 FTE, which includes the 152 FTE associated with the legislative proposals for application fees in the permanent and temporary labor certification programs. Through innovative reforms, the budget request for ETA will allow the Department to increase the competitiveness of the American workforce in a knowledge-based economy.

The United States competes in a global economy that is far different from the international markets of the past. In the future, as in the past, our long-term economic growth will also be enhanced by supporting international trade, by opening world markets to U.S. goods and services and by keeping our markets open. Congress can help create jobs and economic opportunity by passing the pending Free Trade Agreements with Colombia, Panama and South Korea. As our Nation's economy and businesses transform to meet the challenges of the 21st century, so too must the Government systems and structures that support our economic growth and job creation.

It is in this context that the President has sought to transform worker training programs into a demand-driven system that prepares workers for jobs in growth sectors of the economy. The workforce investment system should recognize and

strengthen workers' ownership of their careers, and provide more flexible resources and services designed to meet their changing needs.

American workers will need higher levels of education and skills than at any time in our history, as evidenced by the fact that almost 90 percent of new jobs in high-growth, high-wage occupations are expected to be filled by workers with at least some post-secondary education. However, the current workforce investment system does not provide the necessary education and training opportunities for workers. Too much money is spent on competing bureaucracies, overhead costs, and unnecessary infrastructure, and not enough on meaningful skills training that leads to employment opportunities and advancement for workers.

To increase the quality of training offered, as well as the number of workers trained, the Department proposes legislative reforms to consolidate funds for the following programs into a single funding stream:

- Workforce Investment Act (WIA) Adult Program;
- WIA Dislocated Worker Program;
- WIA Youth Program; and
- Employment Service programs (including Employment Service formula grants, labor market information grants, and grants for administration of the Work Opportunity Tax Credit).

States would use these funds primarily to provide Career Advancement Accounts (CAAs) to individuals who need employment assistance. CAAs are self-directed accounts of up to \$3,000, an amount sufficient to finance approximately 1 year's study at a community college. The accounts could be renewed for one additional year, for a total 2-year account amount of up to \$6,000 per worker. CAAs would be used to pay for expenses directly related to education and training. The accounts would be available to both adults and out-of-school youth entering the workforce or transitioning between jobs, and incumbent workers in need of new skills to remain employed. The funds would also be used by States to provide basic employment services such as career assessment, workforce information, and job search assistance to job seekers. By removing bureaucratic restrictions that can prevent workers from being trained, increasing the flexibility of State and local officials to shift funding to where it is most needed, and requiring the majority of dollars in the system to be spent on training, these reforms will significantly increase the number of individuals who receive job training and attain new and higher-level job skills.

#### *Community-Based Job Training Initiative*

The fiscal year 2009 budget provides \$125 million for the fifth year of grants under the President's Community-Based Job Training Initiative. This competitive grant program leverages the expertise of America's community colleges and takes advantage of the strong natural links between community colleges, local labor markets and employers to train workers for jobs in high-demand industries. In October 2005, the Department awarded the first grants totaling \$125 million to 70 community colleges in 40 States. A second competition for Community-Based Job Training Grants was held in the summer of 2006, and in December 2006, the Department awarded \$125 million in grants to 72 entities in 34 States. In March 2008, the Department awarded \$125 million to 69 community colleges and community-based institutions that competed successfully for the third round of Community-Based Job Training Grants. The administration strongly supports providing standalone funding for this program, rather than redirecting funds from the National Reserve, which should be preserved to allow the Department to respond to emergency and unanticipated situations.

#### *Foreign Labor Certification*

The fiscal year 2009 budget builds on our successes in reforming the Foreign Labor Certification programs. The Department has eliminated the backlog in the Permanent (PERM) program, which peaked at 363,000 applications in 2005. In the fiscal year 2009 budget, the Department is requesting \$78 million for the foreign labor programs, an increase of \$24 million from fiscal year 2008. The request includes \$7.5 million for a new case management system for the foreign labor programs, \$5.7 million to assist States in processing anticipated H-2A and H-2B workload increases, \$4 million for Federal staff to process anticipated workload increases, and \$6.2 million to restore funds for inflationary costs not provided under the fiscal year 2008 Omnibus appropriation. This system will allow on-line application filings, replace four separate systems with a single integrated system, and combat fraud by allowing ETA to track employers' use of the various programs.

In fiscal year 2009, the Department will complete its reforms to the H-2A and H-2B Temporary Labor programs. The budget also proposes legislation to authorize cost-based, employer-paid application fees in the foreign labor programs to cover the



costs of running the programs. This will enable the programs to efficiently manage the workload with a predictable funding source. It is essential to prevent the re-emergence of backlogs in the PERM program, and to streamline processing under the temporary programs.

#### *A Second Chance for Ex-Offenders*

As you know, last month the President signed into law the Second Chance Act of 2007. This act builds on the work begun under the President's Prisoner Re-Entry Initiative, and authorizes the Department of Labor to award grants to nonprofit organizations to provide mentoring, job training and job placement services to assist eligible offenders in obtaining and retaining employment. The Second Chance Act authorizes \$20 million to be appropriated in each of fiscal years 2009 and 2010 for these grants. The administration will work with the Congress to determine the appropriate level of funding for the new program within the fiscal year 2009 Budget request of \$39.6 million for Reintegration of Ex-Offenders, the predecessor pilot program.

#### *Strengthening Unemployment Insurance Integrity and Promoting Re-Employment*

The fiscal year 2009 budget continues the administration's efforts to ensure the financial integrity of the Unemployment Insurance (UI) system, and help unemployed workers return to work promptly. Our three-pronged approach includes:

- A package of legislative changes that would prevent, identify, and collect UI overpayments and delinquent employer taxes. These changes include: allowing States to use a small amount of recovered overpayments and collected delinquent taxes to support additional integrity efforts; authorizing the U.S. Treasury to recover UI benefit overpayments and certain delinquent employer taxes from Federal income tax refunds; requiring States to impose a penalty on UI benefits that individuals obtain through fraud and using those funds for integrity activities; and requiring employers to include a "start work" date on New Hire reports to help identify persons who have returned to work but continue to receive UI benefits. We estimate that these legislative proposals would reduce overpayments of UI benefits by \$5 billion and employer tax evasion by \$400 million over 10 years.
- A \$40 million discretionary funding increase over the fiscal year 2008 enacted level to expand Reemployment and Eligibility Assessments, which review UI beneficiaries' need for re-employment services and their continuing eligibility for benefits through in-person interviews in One-Stop Career Centers. This initiative has already yielded quicker returns to work for UI beneficiaries. We estimate that a total of \$155 million in benefit savings could result from this investment.
- A legislative proposal to permit waivers of certain Federal requirements to allow States to experiment with innovative projects aimed at improving administration of the UI program, and speeding the re-employment of UI beneficiaries.

We urge the Congress to act on these important proposals to strengthen the financial integrity of the UI system and help unemployed workers return to work.

#### *Senior Community Service Employment Program*

The fiscal year 2009 budget requests \$350 million for the Senior Community Service Employment Program (SCSEP). At this level, SCSEP will support 72,000 participants. This program was rated "ineffective" by the Performance Assessment Rating Tool (PART), largely due to inadequate competition in the grants process, lack of data on program performance and impact, and duplication with other Federal programs. Recent legislative reforms, though limited in terms of their promotion of competition, will promote improvement in program efficiency (allowing more participants to be served per dollar), collection of performance data, and the share of participants placed in unsubsidized jobs.

#### *Job Corps*

The budget includes \$1.6 billion to operate a nationwide network of 123 Job Corps centers in fiscal year 2009. Job Corps provides training to address the individual needs of at-risk youth and ultimately equip them to become qualified candidates for the world of work. The request includes \$59 million for the construction of new Job Corps centers. In the fiscal year 2006 appropriation act, the Congress directed the Department to transfer the Job Corps program out of the Employment and Training Administration (ETA) into the Office of the Secretary. The 2009 budget again proposes to return the program to ETA, where it had been administered for more than 30 years, to ensure close coordination with the other job training and employment programs administered by ETA, including the YouthBuild program.

## SECURING EMPLOYMENT RIGHTS AND OPPORTUNITIES FOR VETERANS

*Veterans' Employment and Training Service*

This Nation's commitment to our veterans must be honored. No veteran should return home without the support that is needed to make the transition back to private life a smooth and successful one. For the Department's Veterans' Employment and Training Service (VETS), the fiscal year 2009 budget request is \$238.4 million and 234 FTE. This will enable VETS to maximize employment opportunities for veterans and protect their employment and re-employment rights.

The \$168.9 million requested for VETS to provide State grants under the Jobs for Veterans Act includes an increase of \$7 million above the fiscal year 2008 level and will help approximately 700,000 veterans seeking employment in the civilian workforce. The additional funds will help serve 185,000 Transition Assistance Program (TAP) participants in domestic and overseas workshops, an increase of 25,000 participants above the fiscal year 2008 level. TAP employment workshops play a key role in reducing jobless spells and helping service members transition successfully to civilian employment. The fiscal year 2009 budget includes \$25.6 million for the Homeless Veterans Reintegration Program (HVRP), allowing the program to provide employment and training assistance to an estimated 15,100 homeless veterans. The fiscal year 2009 request will also enable VETS' staff to more effectively administer the Uniformed Services Employment and Reemployment Rights Act (USERRA) to protect the civilian employment opportunities and re-employment job rights and benefits of veterans and members of the armed forces, including members of the Guard and Reserve.

## OTHER PROGRAMS

*Bureau of Labor Statistics*

In order to maintain the development of timely and accurate statistics on major labor market indicators, the fiscal year 2009 budget provides the Bureau of Labor Statistics (BLS) with \$592.8 million and 2,418 FTE. This funding level allows BLS to focus resources on its core surveys that produce sensitive and critical economic data, including the Consumer Price Index (CPI) and the monthly Employment Situation report. The CPI is a key measure of the Nation's economic well-being that directly affects the income of millions of Americans. To ensure that the CPI is accurate and up-to-date, the Budget includes funding of \$10.4 million to continually update the housing and geographic samples that underlie the index to ensure that these samples fully incorporate the most recent demographic and geographic trends and changes. The current sample was derived from the 1990 Census and has not been updated since the late 1990s. In addition, the budget requests \$8.7 million to cover the rising cost of the Current Population Survey, including enhanced efforts to safeguard respondent confidentiality, secure data, and maintain response rates.

*Office of Disability Employment Policy*

The fiscal year 2009 budget request provides the Office of Disability Employment Policy (ODEP) with a total of \$12.4 million and 40 FTE. The fiscal year 2009 budget reflects the elimination of ODEP's grant-making function, which duplicates those of other Federal agencies. The fiscal year 2009 budget returns ODEP to its core mission of providing national leadership in developing disability employment policy and influencing its implementation to increase employment opportunities and the recruitment, retention and promotion of people with disabilities. The request also includes a transfer of \$550,000 to the BLS to finalize ODEP's partnership with BLS in the development and testing, and for BLS to begin and sustain monthly publication, of the unemployment rate for people with disabilities.

*Bureau of International Labor Affairs*

The request for the Bureau of International Labor Affairs (ILAB) in fiscal year 2009 is \$14.8 million and 58 FTE. In recent years, ILAB has had a very large grant-making function. Several Federal agencies have grant initiatives that support the objectives of improving international labor conditions and providing educational opportunities to children. DOL believes funding for such international grant activities should be provided to the Department of State, so it can better coordinate these projects. The Budget returns ILAB to its mission of developing international labor policy and performing research, analysis, and advocacy. The President's Budget also includes \$1.5 million to allow ILAB to monitor the use of forced labor and child labor in violation of international standards, as required in the Trafficking Victims Protection Reauthorization Act of 2005.

The requested funding levels would allow ILAB to implement the labor supplementary agreement to NAFTA and the labor provisions of trade agreements nego-

tiated under the Trade Act of 2002, participate in the formulation of U.S. trade policy and negotiation of trade agreements, conduct research and report on global working conditions, assess the impact on U.S. employment of trade agreements, and represent the U.S. Government before international labor organizations, including the International Labor Organization.

ILAB will continue to implement ongoing efforts in more than 75 countries funded in previous years to eliminate the worst forms of child labor and promote the application of core labor standards.

#### *Office of the Solicitor*

The fiscal year 2009 budget includes \$108.2 million and 643 FTE for the Office of the Solicitor (SOL). This amount includes \$100.8 million in discretionary resources and \$7.4 million in mandatory funding. The Solicitor's Office provides the legal services that support all of the five critical priorities of the Department, including litigation and legal advice necessary to the success of the Department's enforcement programs. This appropriation level will allow SOL to provide legal services and legal enforcement support for the nearly 200 laws the Department must enforce, including recently enacted legislation to strengthen mine safety and retirement security. The requested appropriation level is essential to allow SOL to fulfill its primary mission of ensuring that the Nation's labor laws are forcefully and fairly applied, and providing the legal assistance necessary to ensure that the Department's mission goals identified for fiscal year 2009 are achieved.

#### *Women's Bureau*

The fiscal year 2009 budget includes \$10.2 million and 60 FTE for the Women's Bureau. This budget will allow the Women's Bureau to continue its mission of designing innovative projects addressing issues of importance to working women and providing information about programs and policies that help women succeed in the 21st century workplace.

#### *President's Management Agenda and Department-wide Management Initiatives*

Before I close today, Mr. Chairman, I also want to highlight the Department's sustained efforts to implement the President's Management Agenda (PMA). In August 2001, President Bush sent to Congress his Management Agenda, a strategy for improving the management and performance of the Federal Government. The PMA called for focused efforts in the following five Government-wide initiatives aimed at improving results for citizens: Strategic Management of Human Capital; Competitive Sourcing; Improved Financial Performance; Expanded Electronic Government; and the Performance Improvement Initiative (formerly Budget and Performance Integration). DOL is also responsible for three of the PMA initiatives that are found only in selected departments: Faith-Based and Community Initiative, Real Property Asset Management, and Eliminating Improper Payments.

I am proud to say that, in June 2005, the Department became the first Cabinet agency to earn "green" ratings in all five Government-wide PMA initiatives. Through the PMA, the Department placed a strong emphasis on human capital and E-Government—both of which strengthen the integration of all the PMA initiatives. DOL's MBA Fellows program—which I established in 2002—has been successful in bringing on bright new talent as we build a foundation of future leaders at the Department. And our E-Government efforts have provided numerous solutions that have supported our management efforts. I remain particularly proud of the Department's role as the managing partner of GovBenefits.gov—a partnership of Federal agencies that provides improved, personalized access to Government programs.

DOL is making progress and achieving results in eliminating improper payments. To better support these efforts, DOL was instrumental in ensuring the enactment of the State Unemployment Tax Act (SUTA) Dumping Prevention Act of 2004—which President Bush signed into law in August 2004. This law provided State UI programs access to the National Directory of New Hires (NDNH). In 2005, the Department's Office of the Chief Financial Officer and the Employment and Training Administration launched an Unemployment Insurance (UI) pilot program in three States to determine how a cross-match between the NDNH and State UI claimant data could help identify individuals no longer eligible to receive UI benefits. The pilot program showed significant potential to detect and reduce improper payments and now 41 States are actively matching against the NDNH. These steps have resulted in the saving of millions of taxpayer dollars, but we have more work to do—and we are committed to seeing this effort through to the end.

In recognition of our efforts since 2001, DOL has been honored with four President's Quality Awards from the Office of Personnel Management for our achievements and management excellence in implementing the PMA.

The Program Assessment Rating Tool, or PART, remains central to our efforts at the Department of Labor to improve the performance of our programs. To date, 35 DOL programs have been assessed through the PART. The PART assessments have not only been useful to informing the public and policy makers of our programs' strengths and weaknesses, but they have provided our programs and their managers a systematic method of self-assessment. A PART review helps inform both funding and management decisions aimed at making programs more effective. The Department is actively implementing program improvements identified through PART assessments—and looks forward to building upon our progress to date.

#### CONCLUSION

With the resources we have requested for fiscal year 2009, the Department will continue its strong enforcement of worker protection laws, provide innovative programs to increase the competitiveness of our Nation's workers, secure the employment rights of veterans, and maintain fiscal discipline.

Mr. Chairman, this is an overview of the programs we have planned at the Department of Labor for fiscal year 2009.

I am happy to respond to any questions that you may have.

Thank you.

Senator HARKIN. Madam Secretary, if you have more—I do not know why that light was on like that. If you have more, take the time you needed to finish. I did not mean to have that stop at 5 minutes.

Secretary CHAO. No. I think that is fine. Thank you.

Senator HARKIN. There was not anything else you wanted to—

Secretary CHAO. I saw the light coming, so I kind of skipped through this really quickly.

Senator HARKIN. Well, I am sorry about that. I did not mean to have that come on at 5 minutes. I just noticed it myself. Well, that is all right for our questions, but not for her statement. So I apologize.

Secretary CHAO. No, not at all. We try to be very responsive to you.

Senator HARKIN. Well, thank you, Madam Secretary. I appreciate that.

#### NONCOMPETITIVE GRANTS

Madam Secretary, let me get right into it here. Something that has been of interest to me for the last couple of years is the awarding of noncompetitive grants by the Department of Labor.

In his veto message last year, the President stated that “this bill has too many earmarks. Congressional earmarks divert Federal taxpayer funds to localities without the benefit of a merit-based process. Americans sent us to Washington to achieve results and be good stewards of their hard-earned tax dollars.”

Now, for the record I want to point out that less than—much less than—1 percent of the funds in the bill were subject to congressionally directed spending.

However, from 2001 to 2006, the Department of Labor earmarked more than \$250 million under the High Growth Job Training Initiative without any competition or transparency. Now, Federal regulations allow for the awarding of noncompetitive grants in certain situations.

However, 90 percent of these funds raised serious questions for me. So last year I asked the DOL Inspector General to examine how these decisions were made and what we have achieved with these funds. The IG's report includes some troubling findings, in-

cluding inadequate justification for the grant decisions, unfulfilled commitments by grantees to provide matching funds, and insufficient monitoring and evaluation of grant activities.

So, Madam Secretary, your Department responded to the recent IG report by maintaining that it was not necessary or valuable to formally evaluate all grant activities. Well, how does that square with the President's veto message when he said that he was opposed to earmarks? How does that square with that? I mean, \$250 million.

Secretary CHAO. The High Growth Job Training Initiative was originally designed to help the workforce investment system become more demand-driven. What we want to make sure is that when dislocated workers, unemployed workers invest their time and trust in us to come into our training system, that we give them relevant training. So the High Growth Job Training Initiative was to be a demand-driven program.

Due to the broad-based demand for this kind of program, we had 450 unsolicited bids. In an effort to quickly and strategically respond to the workforce challenges identified by the high growth industries who were lacking skilled workers, this program was initiated.

It was ETA's intent always from the beginning to go into a competitive mode, and after this initial phase, all High Growth Job Training grants are awarded through a competitive process.

Just because it did not go through a competitive process, did not mean that it did not go through a solicitation process within the Department. There is something called the Procurement Review Board which reviews all sole-source contracts, and all of these contracts went through that.

Second of all, these were all pilot programs. So after the pilot programs were initiated, they were all competitively bid.

The IG report itself acknowledges that they only examined 10 of the 133 noncompetitive grants and that many others, in fact, were fine. If you look at the number of the 10 grantees reviewed in the audit, they included the Service Employees International Union, the Down River Community Conference, the Shoreline Community College, the Maryland Department of Labor. This is a very wide base and it was a demand-driven initiative to fulfill the needs of our economy for high-skilled workers. Again, the purpose is to ensure that workers are getting relevant training, so when they graduate from our programs, they can actually get a real job.

Senator HARKIN. Well, Madam Secretary, I have here the years from 2001 to 2007. Competitive grants, 2001, 0; 2002, 0; 2003, 0; 2004, 0; 2005, 12; 2006, 0; and 2007, 17. I do not know what kind of planning that is to have—let me read you the noncompetitive.

Secretary CHAO. But the program did not start until 2003, number one.

Number two, when we are talking about our Department, we have a budget of \$10.5 billion. The majority, 99.9 percent, of the grants are, number one, formulaic or they are competitive grants. This is a very, very small part of the total number of grants that are given out.

Senator HARKIN. Madam Secretary, okay, let us take 2003. As I said, competitive, 0, 0, 12, 0. Last year 17. I will tell you why.

In noncompetitive grants, 2003, 15; 2004, 37; 2005, 55; 2006, 21; last year, 1. Now why was it one last year? Because in our bill last year, we said you cannot do that anymore.

Secretary CHAO. We responded.

Senator HARKIN. Yes, that is true. You did respond. I will hand you that. That is true.

But my point is that was \$263.8 million for 137 grants.

Secretary CHAO. Out of an annual budget of more \$10.5 billion.

Senator HARKIN. Well, now, would you like to come up here and argue for Congress's directed spending? Would you like to talk to your boss down at the White House?

Secretary CHAO. Not at all.

Senator HARKIN. You see why I am making this point. First of all, I am making the point that when we do congressionally directed funding—and the former chairman knows this—it is transparent, it is open, everybody knows about it, and we follow up on these.

Quite frankly, what the IG did—now, you mentioned 10. The first phase of the investigation by the IG took 39 grants, and in 90 percent of the samples, the DOL did not follow proper procedures for making earmarks, including a lack of documentation for how DOL made earmark award decisions. DOL has not required grantees to contribute their own funds or leverage funds from third parties, even though that was the basis for making noncompetitive awards in many cases. Now, that was the first phase.

The second phase, the IG reviewed 10 grantees that completed their activities to find out what they did and were the objectives met. Thirty percent of the grant objectives were not met or were not clear enough to determine whether they were met. For example, the National Retail Federation could only demonstrate that it placed in employment just more than half of the minimum 2,500 job seeker goals that it set. Then in four of the nine grants where DOL justified it on the basis that funding organizations would match the funds, the IG could not identify any matching funds at all.

So, again, we have said no. That is what our committee said, and obviously you have not done that anymore. You put one grant out but that was last fiscal year under the continuing resolution. So now we are going to go more to competitive grants.

Now, I will say this. There is one other item I have got relating to this, and that is that we included bill language in the last appropriations bill that required all the Departments under our jurisdiction to provide a report to this committee on all funding in excess of \$100,000 made available on a noncompetitive basis. The Education Department has submitted its report for the two quarters, the first quarter being last October, November, December; the second quarter, January, February, and March. We have gotten them. As of today, we have not received one of the required reports from the Department of Labor.

Secretary CHAO. That is correct.

Senator HARKIN. When are we going to get those?

Secretary CHAO. I think you might be pleased to hear that we have been overwhelmed with data requests from the Hill, number one. Number two, they have to go through clearance. So that cur-

rently is under clearance. I was made aware of it preparing for this hearing, and we are trying to get it out as quickly as possible.  
[The information follows:]

LIST OF REPORTS DELIVERED TO CONGRESS AFTER THE SECRETARY'S MAY 7TH HEARING  
[Reports—Completed and Submitted to Congress]

Agency	Material	Date submitted
OSHA .....	Issuance of OSH Standards .....	First quarterly report was sent to Congress on 5/15/08.
OSHA .....	Regulatory Agendas .....	First quarterly report was sent to Congress on 5/15/08.
All DOL .....	List of Non-Competitive Contracts, Grants & Awards.	First and second quarter reports delivered to Congress on 5/13/08.
ETA/TES .....	Status of H-1B and NEG Grants .....	First quarterly report was sent to Congress on 5/8/08.
ETA/TES .....	Farmworker Housing Funds .....	The report was submitted to Congress on 5/16/08.
ESA/Wage Hour .....	Contractors that employ pineros .....	The report was submitted to Congress on 5/28/08.
DM/ASP, OSHA & ESA/Wage Hour.	National Plan on Pandemic Influenza Preparedness.	The report was submitted to Congress on 5/16/08.
Job Corps .....	Enrollment Levels .....	The report was submitted to Congress on 5/16/08.
EBSA .....	Schedule of EFAST2 .....	Fourth monthly report was sent to Congress on 5/30/08.
ILAB .....	Operating Plan .....	The plan was submitted to Congress on 6/6/08.

Senator HARKIN. Well, the Department of Education did not seem to have much of a problem complying.

Secretary CHAO. I usually beat Margaret Spellings on a whole bunch of things, so I am not very pleased that she has beat me to this one. But we are going to do better on that one.

Senator HARKIN. Okay. Well, we would like to have those. Again, one of the reasons we are asking that request again is to just find out what is happening on this and where these are going. As I said, we in Congress in our congressional funding now, we have to put it in the record. It has to be out there. It is all transparent. Everybody knows who is doing what. We just want to make sure this applies to the administration. I do not mean just yours. I mean every administration, that they have to do the same thing in every one of their Departments. So what is good for the goose is good for the gander I guess you might say.

Did my time run out? I will pick up some more questions. I think my 5 minutes are up here, but I will yield to Senator Cochran. Then I will pick up some more later.

Senator COCHRAN. We could use some skilled labor training to figure out how to work those.

Madam Secretary, thank you for the conscientious and effective work you have done as Secretary of Labor. I have been very impressed and we appreciate your service in that capacity.

YOUTHBUILD

In our State, we are troubled and concerned about the availability of labor to help us rebuild and recover from Hurricane Katrina, and that is true not only of Mississippi, but Louisiana certainly and other areas there. I know there is a program—and it is

funded in the budget request at \$50 million—called YouthBuild. I was wondering whether this is a program that could be helpful or has been used in training or trying to identify people who are at risk maybe because of the effects of the hurricane situation so we could put them to work maybe or training to fill some of the voids in the labor market so we can improve the performance of reconstruction. Low income housing comes to mind as an area where there might be a particular opportunity for at-risk youth to be employed there if they had the training and supervision necessary.

What is the Department of Labor able to do to help in that situation?

Secretary CHAO. You make a very good point about the short supply of skilled labor, trade labor, skilled trades people, workers. That has been a real problem down in the gulf area and in rehabilitating and rebuilding the gulf area.

At the risk of appearing as if I am going back to a topic that the chairman does not like, the High Growth Job Training Initiative actually includes skills training in the skilled trades because those are good paying jobs. They have good future prospects, and yet we have a dearth of skilled trades people in this country. So we do need to emphasize that.

On YouthBuild, that was recently transferred over from HUD to the Department of Labor. I am pleased to say that the transition appears to have gone well. Both Departments thought it was a much better fit for YouthBuild, which is more involved in skills training, to be shifted over to the Department of Labor.

Your suggestion that YouthBuild workers be more involved in the Gulf area recovery and rebuilding effort is a good one. I think there have been some efforts in incorporating these young people in this area, but certainly I think we can take another look at that and see how these young people can gain real life experience that would be very satisfying for them as they gain new skills and see the actual results of how their skills can help people.

#### JOB CORPS

Senator COCHRAN. One other program that I paid a lot of attention to when it was first created was Job Corps. Is that still an active program? Is it growing, or do you have the funds necessary to continue to support the efforts of Job Corps? What is your evaluation of its effectiveness?

Secretary CHAO. I have just come back from the reopening of the Cleveland Job Corps Center. This was a dilapidated, old facility that over the last 18 months saw a \$25 million renovation of its facilities. We want these young people—the national director Esther Johnson calls them at-promise young people—to feel pride in their surroundings and to have the right equipment and facilities with which to learn and gain new skills and put their lives back on track. So I went there yesterday, and I went also to the reopening of the Job Corps center in New Orleans just less than 3 months ago. So we have a very aggressive building program.

It is under some challenge because of funding pressures, but overall we are very focused on ensuring that Job Corps remains a strong program. The new director has been focusing on academics. We are very concerned about ensuring, again, that young people



get the skills that they need. So we have cut the budget for Job Corps in terms of the slots, which I think is a source of discussion, and we can talk more about that later. But we have about 4,000 slots that need to be reallocated, and part of that process is ongoing as well.

Senator COCHRAN. Well, thank you very much.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Cochran.

Let us just pick up on that because obviously Job Corps centers have broad support up here, and you actually cut it. What is the justification for cutting Job Corps centers?

Secretary CHAO. Well, the budget request maintains a level of service currently offered by the Job Corps program. I think there is a great deal of discussion about the empty slots. There are about 4,000 of them. We want to ensure that there is funding for all current students and any students who want to enter the program in the future. We want to continue making improvements and upgrades to the facilities, but there is this concern about unused slots which we can discuss as well.

#### OFFICE OF DISABILITY EMPLOYMENT POLICY

Senator HARKIN. Madam Secretary, this is not a trick question I am going to ask you. If you were to look at different groups of people, categories of workers, in our country, what group would spring to mind that would have the highest rate of unemployment?

Secretary CHAO. Probably young people and disabled.

Senator HARKIN. Disabled. Thank you. Much higher. The rate of unemployment among disabled people who actually look for work, who want work is—

Secretary CHAO. 70.

Senator HARKIN [continuing]. About 70 percent.

Secretary CHAO. Yes.

Senator HARKIN. It is one of the highest. Well, your budget proposes a cut of \$14.8 million, or a 54 percent cut, for the Office of Disability Employment Policy. I mean, now this screams out that something is wrong here. This budget proposal, I am told, would eliminate all grant activity at ODEP. What is the justification for a 54 percent cut in ODEP when we have the highest rate of unemployment in America among our people with disabilities? What is the justification for a 54 percent cut?

Secretary CHAO. Mr. Chairman, I know that you have a personal—I know that you are very committed to the disabled community.

Senator HARKIN. Actually you are too.

Secretary CHAO. I am too. I know that you started ODEP, and it would not have happened without you.

Senator HARKIN. Well, I appreciate that. I am not asking about your commitment. I know you are personally committed. I am just asking why this big a cut. This does not make sense to me.

Secretary CHAO. I think we are just going to have to differ on what the purpose—what the core mission of ODEP is. There seems to be a disagreement about whether ODEP should be a research or policy agency rather than a grantmaking agency. When we talk about grants, this is, in fact, one area in which we have been found

that we have been unable—that it has been very hard to gauge what has been the real achievements or results of these grants. What we should be doing is working more with the employer community and urging them, exhorting them to hire more Americans with disabilities. That is not done through primarily grants.

Senator HARKIN. Now, Madam Secretary, as you know, this is a personal interest of mine and professional interest of mine, not just personal. So I follow this up every year, and I have my staff follow it.

Last year, when you sat there, I asked you about the accomplishment of ODEP grant funding and your Department's response was, "46 States have adopted evidence-based policies and practices that ODEP has developed based on the findings of the grants that the agency has funded." Well, I would think based on that, that ODEP should fund more grants. So I am getting another story from you this year than what I got last year. I would think based on this, we ought to be doing more of that grant-making.

Secretary CHAO. Well, we are continuing with grants. It is just not as much as you would like.

Senator HARKIN. Well, yes, a 54 percent cut, I guess not.

Secretary CHAO. We gave approximately \$12 million.

Senator HARKIN. I mean, the overall cut in your budget—your overall cut was what? 7 percent?

Secretary CHAO. No, it was not a cut. It has always been—

Senator HARKIN. I mean overall.

Secretary CHAO. The President's budget has always been that way. It has always been at this level. Then the committee has put more in.

Senator HARKIN. I do not mean ODEP. I mean your entire budget request. Is it not down from last year?

Secretary CHAO. Primarily because—

Senator HARKIN. I thought you told me in your opening statement it was down.

Secretary CHAO. No, not in the worker protection areas. Basically it is in—ODEP—the President's request has always been the same. It is less than what the enacted was.

Senator HARKIN. I am just saying that your overall request is down a few percentage points from last year.

Secretary CHAO. That is primarily probably due to the overhang in ETA.

Senator HARKIN. Well, but anyway, 54 percent is illogical to be cutting from ODEP. It is just not so. Now, again, that would eliminate all grant activity.

Again, Madam Secretary, I've got to read you the law, Public Law 106-1033. "Beginning in fiscal year 2001, there is established in the Department of Labor an Office of Disability Employment Policy which shall, under the overall direction of the Secretary, provide leadership, develop policy and initiatives, and award grants furthering the objective of eliminating barriers to the training and employment of people with disabilities. Such office shall be headed by an Assistant Secretary."

It did not say you may award grants. It says you shall. Now you have submitted a budget to me that says we will not award any grants, and from what I just heard you say, that is not a big deal

with ODEP. Grant-making is just not that important. Well, we put it in the law specifically for that.

That is why I asked you about it last year. I thought your answer last year was pretty good, you know, that 46 States have developed these things. I thought, well, that cries out for more grant activity to pursue these and to find out just what are the barriers. Why is it 70 percent? What are those barriers out there?

Anyway, I just want to tell you this is over the top on that 54 percent cut. I mean, we will have to put it back in, but I just do not think it represents the priorities that we ought to be doing when we are trying to help people get employment.

#### BUREAU OF INTERNATIONAL LABOR AFFAIRS

Now, there is one other area, as you know, that is an intense interest of mine. It is called international child labor.

Secretary CHAO. Right.

Senator HARKIN. You knew I was going to ask that question.

Well, here we go. As it has done each year under this administration, the Department's budget drastically reduces funding for the elimination of child labor worldwide. Your 2009 budget requests \$14.8 million for ILAB, a decrease of \$66.3 million, or—hang on to your hats—82 percent decrease in funding. 82 percent. Why did you not just zero it out?

The 2009 budget proposal will set back efforts to continue the positive progress. According to your own Department, this program has resulted in almost 230,000 children prevented or withdrawn from child labor and provided education opportunities just in 2007. That is pretty good. So, again, cut it by 82 percent.

You and I have disagreed on this before. You cut the budget and we have to fight to get it in. You have often said that one of the reasons the funding is eliminated is the Bush administration believes grant-making should not be a part of ILAB's mission. Is that still your position?

Secretary CHAO. I think we are going to have a disagreement about this. Every year we go through this, and I am sorry to be here to say the same thing again. But we really do disagree on the mission of ODEP and on the mission of ILAB. We believe that ILAB should go back to its core functions, and our budget request every year has been the same. So it has not been a cut from the budget request point of view.

Senator HARKIN. Madam Secretary, here is a book I just got handed to me the other day. It is the Honor Awards, the 95th Anniversary Celebration, Wednesday, April 30, the United States Department of Labor Honor Awards. Secretary's Exceptional Achievement Award, in recognition of individual employees and groups of employees who have achieved an unusually significant work product that fosters one or more of the Department's strategic goals. The first one was Employment Standards Administration.

Here we are, next page. Bureau of International Labor Affairs, ILAB. Here it is right here. Office of Child Labor, Forced Labor, and Human Trafficking Team. In recognition of outstanding commitment and dedication to the implementation of a high quality program that has enabled more than 1 million children in over 75

countries to be removed or prevented from exploitive labor and provided with educational and training opportunities.

That is what the grants do. This is not reporting. This is not a report. This is what ILAB has done, and you said it yourself and you gave them an exceptional award. So I am having a hard time getting my head around this one. You honor this team, ILAB, for what they have done, and now you tell me that you do not agree with this mission.

Secretary CHAO. We do not, but since the money has been given to us, we do have a responsibility to be good stewards of the taxpayers' dollars, which is why when this money was given, we are going to do the best we can with it, and this team did a good job.

Senator HARKIN. Well, I just wonder. I was in Ghana earlier this year too, and I noticed you here at the primary school outside Accra. We went out and looked at some child labor things in the cocoa fields and stuff in both Ghana and the Ivory Coast. Here is a nice picture of you with all these kids who have been taken away from forced labor and exploitative labor. I bet you were proud to stand there with them, were you not?

Secretary CHAO. Well, I have an interest in child labor and I went to visit a lot of child labor sites.

Senator HARKIN. I bet you were proud to stand there with them.

Secretary CHAO. I was very proud of that.

Senator HARKIN. To see those happy faces, no more exploitation, they are in schools, and ILAB had a big part to do with it.

Now you come up here and say we should not have that mission? Now, Madam Secretary, have you told these people that you are going to request that we are going to cut them by 82 percent?

Secretary CHAO. We are not the only ones doing this work, and as I mentioned, we are going to have a disagreement about this.

Senator HARKIN. I know you are not the only one, but you do a big part of it. I am just saying, have you told all these people you are going to request, when you see them over there—I am going to cut your budget by 82 percent? Because what I keep hearing from them is are we going to be able to do our job. Are we going to be able to continue to do the good work that we do in a lot of places around the world?

So I have a hard time understanding why you say this should not be a mission, and yet you seem to be quite proud of the work they do. You ought to be proud of it. They do a great job. They are doing a great job.

As long as I am here, we are going to make sure we fund them. But this idea of cutting them 82 percent—budgets represent priorities. So when I see you cutting this 82 percent, I've got to believe this is on the bottom rung.

Secretary CHAO. We have always had a disagreement about this.

Senator HARKIN. So you do not think we should be doing this.

Secretary CHAO. No. It is our position that we should not be doing it through ILAB. It should be done through some other agency. We have not cut this budget.

Senator HARKIN. What agency should it be done through?

Secretary CHAO. There are many other Departments within the Federal Government. We have not cut this budget. We have consistently been very steady in asking for \$12 million for ILAB every

single year, and we get more than that. If we do get more, of course, we are going to be responsible and try to do a good job with it.

Senator HARKIN. Well, I do not know. Again, it just represents to me a low priority, very low, and I think it ought to be a very high priority. You say, well, it could be done in other areas. Well, there are a lot of things that could be done in some other Department. With all due respect, Madam Secretary, I just do not think that is really a legitimate response on that, to say somebody else can do it. The fact is it is in your Department. It does good work. You recommend it with an outstanding service award.

I would think you would tell your boss down there at the White House that this is something that gives us pride as Americans. It is one of the best things we do in some of these countries to help get these kids out. Maybe the President does not even know about it. He probably does not even know about it. I do not know. He has got a lot on his plate, but it would seem to me this would be a source of pride, which I think represents that picture you took. It looks like you are pretty proud of that.

All right, moving right along. I wanted to also cover just a couple of other things.

#### OSHA SAFETY AND HEALTH REGULATIONS

Labor-management reporting. I mentioned in my statement this is one area that got an increase. I have been looking at this OSHA thing seeing what has happened over the last few years. Do you realize, Madam Secretary, that during the entire tenure that you have been there, OSHA has issued only three significant safety and health regulations, two of which were issued as a result of court orders or lawsuits? In all these years, only one that you have issued that was not demanded by a court order or a lawsuit.

Let me read for you what happened in the—well, I have got the three here. 2006, one in 2007, and another one in 2007. One was court ordered. One was in response to a lawsuit. Here is what the Clinton administration did, 18. You have got one.

Now, lest you think this is just some kind of Democrat-Republican thing, how about if I read you the Bush I administration, which was only 4 years? Bush I, 17. That is for 4 years.

Let us look at what President Reagan did in his two terms, 20. You have issued one.

Well, that indicates to me that you are just not doing much with OSHA in safety and health regulations. I do not know what your response might be to that. Why is it just one, when I go back over the last administrations and find it is pretty consistent? It is 20, 18, 15.

Secretary CHAO. I am a little bit surprised at that number. I do not know where it came from. OSHA has completed 23 final regulatory actions since 2001. We have had the lowest injury and illness rate ever in the history of this country. We have had the lowest fatality rate ever in this country. Let us look at results. We have also issued the most violations since 1994. So I am a bit puzzled also as to what that number comes from.

Senator HARKIN. I am told that those 23 do not represent significant safety and health. These are very minor little things. I did not

include those in the Clinton and Bush. I will go back and get those too. We will probably be up around 50 in each one of them. So that is what I am talking about.

Secretary CHAO. We issued 23 regulations. That seems a lot already.

Senator HARKIN. What?

Secretary CHAO. 23 regulations since 2001.

Senator HARKIN. 23?

Secretary CHAO. Yes.

Senator HARKIN. Would you give those to us so we can see how significant they are?

Secretary CHAO. Sure.

[The information follows:]

#### OSHA'S 23 FINAL REGULATORY ACTIONS SINCE 2001

(TITLE, PUBLICATION DATE, FEDERAL REGISTER CITATION)

1. Recordkeeping (Interim Guidance Hearing Loss & MSDs) (Regulation) (10/12/2001; 66:52031)

OSHA delayed implementation of provisions for recording occupational hearing loss and musculoskeletal disorders published in its January 19, 2001, revised recordkeeping regulation. This delay provided OSHA the opportunity to gather further public comment and to re-evaluate the recording criteria for these specific conditions.

2. Recordkeeping Final Provisions Hearing Loss (Regulation) (07/01/2002; 67:44037)

OSHA published specific criteria for recording occupational hearing loss on the OSHA Form 300. These criteria are set forth in 29 CFR 1904.10. The recording criteria are a modification of the criteria published in OSHA's January 19, 2001, recordkeeping revision and are based on public comment solicited after the 2001 rule-making.

3. Occupational S&H Standards for Shipyard Employment (Technical Amendments) (07/03/2002; 67:445336)

OSHA published technical amendments to its Shipyard Employment standards. This document corrected general errors, as well as several inaccurate cross-references in these standards.

4. Signs Signals & Barricades (Direct Final) (04/15/2002; 67:18091)

The direct final rule amended construction standards to require that traffic control signs, signals, barricades, or devices protecting construction workers conform to Part VI of either the 1988 Edition of the Federal Highway Administration (FHWA) Manual on Uniform Traffic Control Devices (MUTCD), with 1993 revisions (Revision 3) or the Millennium Edition of the FHWA MUTCD (Millennium Edition), instead of the American National Standards Institute (ANSI) D6.1-1971, Manual on Uniform Traffic Control Devices for Streets and Highways (1971 MUTCD). By ensuring conformity on signs and signals, this rule will alleviate confusion among workers as well as the traveling public regarding hazards during road and highway construction.

5. Update & Revisions on Exit Routes (11/07/2002; 67:67949)

The Agency revised the means of egress standards clarifying existing requirements so they will be easier to understand by employers, employees, and others who use them.

6. Recordkeeping (Regulation) (Removal of MSD Provisions) (06/30/2003; 68:38601)

The final rule deleted two provisions of the Occupational Injury and Illness Recording and Reporting Requirements rule published January 19, 2001. These provisions required employers to check the MSD column on the OSHA 300 Log if an employee experienced a work-related musculoskeletal disorder (MSD), and stated that MSDs are not considered privacy concern cases.

7. Commercial Diving Operations: Revision (02/17/2004; 69:7351)

OSHA issued this final rule to amend its Commercial Diving Operations (CDO) standards. This final rule allows employers of recreational diving instructors and

diving guides to comply with an alternative set of requirements instead of the decompression-chamber requirements in the current CDO standards. This rule recognizes advances in technology of diving equipment and provides greater flexibility.

8. Controlled Negative Pressure Fit Testing Protocol: Amendment to the Final Rule on Respiratory Protection (08/04/2004; 69:46986)

OSHA approved an additional quantitative fit testing protocol, the controlled negative pressure (CNP) fit testing protocol, for inclusion in Appendix A of its Respiratory Protection Standard. Proper fit is essential to the effectiveness of respirators in protecting against respiratory disease hazards.

9. Fire Protection in Shipyard Employment (Part 1915, Subpart P) (09/15/2004; 69:55667)

OSHA promulgated a fire protection standard for shipyard employment that provides increased protection for shipyard workers from the hazards of fire on vessels and vessel sections and at land-side facilities. The Standard affects 669 employers and 98,000 employees. It is estimated that 1 death and 292 injuries (102 lost workdays/190 non-lost workdays) will be averted annually.

10. Standards Improvement Project—Phase II (01/05/2005; 70:1111)

The final rule removed and revised provisions of its standards that were outdated, duplicative, unnecessary, or inconsistent. The Agency estimated that the final standard would result in total annual cost savings of \$6.8 million annually with no adverse effect on employee safety or health.

11. Procedure for Handling Discrimination Complaints under Section 6 of Pipeline Safety Improvement Act of 2002 (04/08/2005; 70:17889)

This document provided the final text of regulations governing the employee protection (“whistleblower”) provisions of Section 6 of the Pipeline Safety Improvement Act of 2002 (“Pipeline Safety Act”), enacted into law December 17, 2002.

12. Oregon State Plans: Notice of Final Approval Determination (05/12/2005; 70:24947)

OSHA granted final approval under Section 18(e) of the Act to the Oregon State Plan, reflecting a determination that the State plan was at least as effective as Federal OSHA in structure and in actual operation. Concurrent Federal enforcement jurisdiction was relinquished in the State, and Federal OSHA standards no longer apply except with regard to those specific issues not covered by the State plan, e.g., Federal agencies, U.S. Postal Service, private contractors on military bases, maritime employment, etc.

13. Updating OSHA Standard Based on National Consensus Standards (12/14/2007; 72:71061)

The direct final rule removed several references to consensus standards that have requirements that duplicate, or are comparable to, other OSHA rules, and corrected a paragraph citation in one of these OSHA rules. The Agency also removed a reference to American Welding Society standard A3.0–1969 (“Terms and Definitions”) in its general-industry welding standards.

14. Rollover Protective Structures (12/29/2005; 70:76979)

In 1996, OSHA replaced the existing roll-over protective structures (ROPS) standards that regulate the testing of ROPS used on tractors with references to the source consensus standards from which they were developed. Subsequently, OSHA identified several substantive differences between the national consensus standards and the original ROPS standards. The Agency reinstated the original ROPS standards by issuing a direct final rule that also contained a number of minor revisions that improve comprehension of, and compliance with the ROPS standard. Clarity will assist employers in complying with the standards.

15. Steel Erection: Slippery Surfaces (Revocation of Requirement for Slippery Surfaces) (01/18/2006; 71:2879)

This document revoked a provision within the Steel Erection Standard which addresses slip resistance of skeletal structural steel. The provision was revoked because it was determined that insufficient progress had been made in developing coatings and surface testing methods for meeting the requirement. As a result of the revocation of this provision, the projected \$29.5 million annualized costs for affected establishments that were anticipated in the economic analysis for the final rule of Subpart R will not be incurred.

16. Occupational Exposure to Hexavalent Chromium (02/28/2006; 71:10099)

OSHA amended the existing standard which limits occupational exposure to hexavalent chromium (Cr(VI)). This Standard reduced OSHA's existing permissible exposure limit and added requirements for exposure monitoring, medical surveillance and other protective measures. An estimated 1,782 to 6,546 lung cancer cases would be prevented over the lifetime of the current worker population.

17. Occupational Safety & Health of Contractor Employees at Certain DOE Sites (06/29/2006; 71:36988)

This notice clarifies jurisdiction and enforcement responsibilities of OSHA and 14 of its approved State Plans at various Department of Energy sites which are not subject to the Atomic Energy Act. OSHA's regulations in 29 CFR 1952 are amended to reflect this jurisdiction, as appropriate.

18. New York State Plan for Public Employees Only (08/16/2006; 71:47081)

In this final rule, OSHA approved revisions to the New York State Plan for Public Employees Only and certified that the plan was structurally complete and had met all of its developmental commitments.

19. Assigned Protection Factors (08/24/2006; 71:50121)

OSHA revised the Respiratory Protection Standard to add definitions and requirements for Assigned Protection Factors (APFs) and Maximum Use Concentrations (MUCs). The revisions supersede the respirator selection provisions of existing substance-specific standards with these new APFs (except for the respirator selection provisions of the 1,3-Butadiene Standard). The APF rule helps ensure that the benefits from the 1998 revision of the Respiratory Protection Standard are fully achieved. OSHA estimated that the 1998 revised Respiratory Protection Standard would avert between 843 and 9,282 work-related injuries and illnesses annually, with a best estimate (expected value) of 4,046 averted illnesses and injuries annually, and would prevent between 351 and 1,626 deaths annually from cancer and many other chronic diseases, including cardiovascular disease, with a best estimate (expected value) of 932 averted deaths from these causes.

20. Updating National Consensus Standards in OSHA's Standard For Fire Protection in Shipyards (Direct Final) (10/17/2006; 71:60843)

In this direct final rule, OSHA replaced the references to 11 National Fire Protection Association standards by adding the most recent versions. No adverse comments were received and the Direct Final Rule became effective on January 16, 2007.

21. Occupational Exposure to Hexavalent Chromium [Amendment to General Industry Standard for SFIC Settlement] (10/30/2006; 71:63238)

OSHA amended its final rule governing occupational exposure to hexavalent chromium in general industry. This amendment implements a settlement agreement (Agreement) entered into among OSHA, the Surface Finishing Industry Council (SFIC), Public Citizen Health Research Group (HRG), and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, and the Allied Industrial and Service Workers International Union (Steelworkers).

22. Subpart S Electrical Standard (02/14/2007; 72:7135)

The Final rule revises the general industry electrical installation standard found in Subpart S of 29 CFR Part 1910. This rule focuses on safety in the design and installation of electric equipment, which poses a significant risk of injury or death in the workplace. This revision updates the standard and is based primarily on the 2000 edition of National Fire Protection Association's national consensus standard for Electrical Safety Requirements for Employee Workplaces (NFPA 70E). The final rule is expected to prevent one to two fatalities per year.

23. Employer Payment for Personal Protective Equipment (11/15/2007; 72:64341)

This final rule requires employers to pay for the PPE provided, with exceptions for specific items. The rule does not require employers to provide PPE where none has been required before. Instead, the rule merely stipulates that the employer must pay for required PPE, except in the limited cases specified in the standard. OSHA estimates that the rule will prevent about 21,800 injuries and approximately two deaths annually.

Senator HARKIN. Because I am told they are not. I am told that these do not rise to the level of a significant OSHA safety or health regulation.



Secretary CHAO. But let us take a look at the results. We have had the best injury and illness rate, the lowest fatality rate. We have issued the most regulations. That is what really matters, the overall health and safety record. Have we really helped the workforce become safer, healthier?

Senator HARKIN. I am going to go back to your statement here. Just a second here. I want to challenge you a little bit on this. I am going to find out why we have a little difference here.

You said, "Since 2001, the workplace fatality and serious injury and illness rates have fallen to record lows." They have declined by 17 percent.

#### HISPANIC WORKER FATALITIES

Here is another thing. "Perhaps most notable," your testimony says, "is the reduction in the fatality rate among Hispanic workers, which has declined by 17 percent since 2001." That is in your statement.

Here is the Department of Labor, Bureau of Labor Statistics, which you just get off your Web site. "Question: How many Hispanic workers have been fatally injured on the job?" This is from your Web site. "In 2006, 990 Hispanic workers were fatally injured while at work, a new series high."

Secretary CHAO. It is the absolute number. We are talking about the percentages. Our workforce increases by about 1 million workers every year. So our workforce continues to increase, which is why the absolute numbers will increase. But the percentage has decreased.

Senator HARKIN. This figure represents a 7 percent increase from the 923 fatalities reported in 2005. The fatality rate also increased from 4.9 to 5.0. Hispanic worker fatalities accounted for 17 percent of the total fatal work injuries that occurred in the United States in 2006. The rate of 5 fatalities per 100,000 workers recorded for Hispanic workers was a 25 percent higher rate than the rate of 4 fatalities per 100,000 recorded for all workers. Let me just finish this. While fatal work injuries to Hispanic workers increased in 2004, 2005, 2006, they decreased in 2002 and 2003, but then they shot up.

So you say the reduction in fatality rate among Hispanic workers has declined by 17 percent. Yet, your own thing says, no, it has increased.

Secretary CHAO. That was a 1-year result, and even though the up-tick occurred last year, the rate is still the lowest ever.

Senator HARKIN. The rate.

Secretary CHAO. Yes.

Senator HARKIN. The rate——

Secretary CHAO. Of the total workforce.

Senator HARKIN. The rate of fatalities among Hispanic workers as compared to the entire workforce in America is at the lowest point ever. Is that what you are saying?

Secretary CHAO. Yes. You are talking about the changes——

Senator HARKIN. Well, here the fatality rate is——

Secretary CHAO [continuing]. Which is what the increases or the decreases per year is. But if you look at the whole workforce, the rate is still the lowest.

Senator HARKIN. Well, let me read this again. The rate of 5 fatalities per 100,000 workers—that is all workers—recorded for Hispanic workers was a 25 percent higher rate than the rate of 4 fatalities per 100,000 workers recorded for all workers.

Secretary CHAO. You are talking about the changes. You need to take a look at the whole workforce.

Senator HARKIN. Well, I am looking. When I see that 990 Hispanics workers are fatally injured and it is a new series high and it represents a 7 percent increase, I do not care about the total workforce. You were talking about Hispanic workers.

Secretary CHAO. No.

Senator HARKIN. If I were to read that sentence, Madam Secretary, I would say, “oh, it just declined by 17 percent. Boy, that is pretty good news.” But I read this.

Secretary CHAO. Over a 7-year period, yes.

Senator HARKIN. That is not true. It is not true.

Secretary CHAO. It is true.

Senator HARKIN. Has declined by 17 percent of what?

Secretary CHAO. The OSHA injury and illness rate is down by 17 percent between 2002 and 2006. The fatality rate is down 7 percent between 2001 and 2006.

Senator HARKIN. For Hispanic workers.

Secretary CHAO. The Hispanic fatality rate is down by 16.7 percent. If you took the 2001 number, take a look at 2006, it is a 16.7 percent decrease. OSHA inspections in fiscal year 2007 are up by 7.6 percent.

Senator HARKIN. Well, Madam Secretary, please send that up to me because I would like to take a look at that because that is not what this says. Now, I do not know what you are talking about. All I can do is read what the plain English is on your Web site, and I will say one more time, 2006, 990 Hispanic workers fatally injured while at work, a new series high. It is a 7 percent increase reported in 2005. Per 100,000 workers, the rate of 5—

Secretary CHAO. It is the change.

Senator HARKIN [continuing]. Is 25 percent higher than before.

Secretary CHAO. You are talking about the change per year. You are talking about the change per year. We are talking about the rate overall.

Senator HARKIN. Oh, from 2001 to 2007.

Secretary CHAO. No. The rate of the whole workforce. You are talking about the changes from one year to the next.

Senator HARKIN. No. I am just talking about Hispanic workers.

Secretary CHAO. Yes, I understand that.

Senator HARKIN. You say that the fatality rate has gone down by 17 percent. 17 percent of Hispanic workers?

Secretary CHAO. Between 2001 and 2006.

Senator HARKIN. Of all Hispanic workers—

Secretary CHAO. Hispanic fatality rate, right.

Senator HARKIN. Has gone down by 17 percent.

Secretary CHAO. 16.7, yes.

Senator HARKIN. Well, I am sorry, Madam Secretary. You better change your Web site because that is not what that says. That is not what that says. I just read it. Unless I forgot my English, I mean, it just does not say that. They said here, while it decreased

in 2002 and 2003, it has gone back up in 2004 and 2005 and 2006. I guess we do not have it for 2007. The rate for Hispanics is 25 percent higher. That is for one year, but it is higher than it was in 2002 also. I am just reading from this. So maybe you need to correct your sheet here. I do not know.

Secretary CHAO. We will take a look.

[The information follows:]

Secretary Chao's testimony cited the decline in the rate of Hispanic fatalities, the number of Hispanic fatalities divided by Hispanic employment, which has fallen by 16.7 percent from 6 per 100,000 Hispanic workers in 2001 to 5.0 in 2006.

Senator Harkin cited the count of Hispanic fatalities, which, at 990 in 2006, was a series high. Because Hispanic employment has grown substantially since 2001, this count does not lead to an increase in the rate of fatal work injuries to Hispanic workers.

Also, Senator Harkin correctly noted that the Hispanic fatality rate in 2006 (5 per 100,000 workers) is 25 percent higher than that of all workers (4 fatalities per 100,000).

Below are the numbers and rates of Hispanic worker fatalities and the fatality rate for all workers from 2001–2006:

Year	Hispanic worker fatalities		All worker fatalities rate <sup>1</sup>
	Number	Rate <sup>1</sup>	
2001 .....	895	6.0	4.3
2002 .....	841	5.0	4.0
2003 .....	794	4.5	4.0
2004 .....	902	5.0	4.1
2005 .....	923	4.9	4.0
2006 .....	990	5.0	4.0

<sup>1</sup> Rate reflects the number of fatalities per 100,000 workers.

Senator HARKIN. I see our distinguished Senator from Washington is here, and I will yield to her for any statement or questions. Senator MURRAY?

Senator MURRAY. Well, thank you very much, Mr. Chairman, and welcome, Secretary Chao. I am sorry I am late. I have several committee hearings going on today.

#### HIGH GROWTH JOB TRAINING INITIATIVE

But I wanted to come and chat with you because in your testimony today and previously before this subcommittee, I have heard you speak about the Department's five critical priorities in budget and policy planning. One of those is—and I quote—"increasing the competitiveness of America's workforce."

I have also heard you and many other administration officials talk about your agency's efforts to support the President's "results-driven agenda."

Now, to me, "results" implies being able to measure the impact and effectiveness of programs that are supported by your Department. So today I was pretty disappointed that the GAO report released today finds that for almost \$900 million spent under the President's demand-driven workforce agenda, your agency has failed to establish any kind of benchmarks that would allow you to adequately monitor whether any of these grants met the statutory requirements that they were awarded under or allow you to measure the performance of the programs that received this funding.

Now, I initiated this report, along with Senator Harkin and Senator Kennedy, after we learned that the Employment and Training

Administration awarded 90 percent of its high growth dollars non-competitively over the last 6 years.

I find the GAO's findings particularly troubling given that the agency intended to use these grants to shift the focus of our Nation's workforce development system, but because there has been very little planning by your agency on the front end, it is impossible now to compare these initiatives to the other programs under the Workforce Investment Act.

It means that providing that your initiatives are more successful in "increasing the competitiveness of America's workforce" is really out of the question. In fact, GAO found that the Department failed to even integrate these initiatives fully under its strategic plan. Now, in my opinion, that fails to live up to a results-driven agenda.

So given the findings of this GAO investigation and the Inspector General's audit that I believe Senator Harkin talked about in the High Growth grants, I think everyone on this subcommittee is eager to hear how you plan to demonstrate the effectiveness of the President's demand-driven job training program today.

Reference reports: Dept. of Labor IG—Office of Audit, Rep. Number: 02-08-204-03-390, released April 29, 2008. GAO Report Number GAO-08-486.

Can you tell us why we should continue to fund what seems like an effort to derail the Nation's workforce investment development system under WIA?

Secretary CHAO. I will be more than glad to. First of all, the GAO report was conveniently released this morning. We have not had a chance to review it.

Number two—

Senator MURRAY. Conveniently released?

Secretary CHAO. I do not have it.

The High Growth Job Training Initiative was designed to respond to, as you well know, a demand-driven system. Every year there are in excess of \$1 billion in unspent funds. There are duplicative structures within the system. That is an issue that the authorization committee has to take care of. But there is something called Employment Services and there is something called Workforce Investment Act. Much of the funding that goes on goes to Employment Services, which is a duplicative, side-by-side structure next to workforce investment. If we are really concerned about increasing the competitiveness of our workforce, there is a crying need to reform the system, and that is what we are trying to do.

Of the High Growth Job Training program, that is an effort to respond to the skills that are needed in our economy. As I mentioned before, if we are to have the trust and confidence of workers to come into our system seeking training, we need to give them relevant training, number one. Number two, we need to ensure that when they get the training, they actually can get a job when they leave. They demand no less. We can do no less.

Senator MURRAY. Will you give us your commitment that you will look at this GAO report as soon as possible?

Secretary CHAO. Sure.

Senator MURRAY. Will you implement its recommendations?

Secretary CHAO. I need to see what it is, but sure.

Senator MURRAY. Well, we expect you to do that, and I am certain the committee would like to hear back about that.

#### WIA CONSOLIDATION

I am concerned about the consolidation of the WIA funding streams for adult dislocated workers and youth. Obviously, that is something you continue to push. Even though your proposals have been rebutted by Congress on a bipartisan basis here, we have seen a continual decline in dollars in training and employment. This is a time when the economy is really hurting. Our constituents are asking how can we get the employment and training we need. We have seen proposals to eliminate employment services by zeroing out the \$703 million that we have available for State grants. So line item after line item, we are seeing a continued decline in dollars here, yet people are very worried about holding on to their jobs. Does that not concern you?

Secretary CHAO. Of course, it concerns me. It concerns me that there are such duplication and excess funds in this system that is not helping people get the training that they need.

Senator MURRAY. Give me a specific.

Secretary CHAO. We have \$863 million, something like that, in unspent funds in the system.

Senator MURRAY. Why is that? Is it being held back?

Secretary CHAO. We have duplicative systems. If we visit the workforce investment system, on the one side of the building is employment services. On the other side is workforce investment. They should be combined so that workers can get the training that they need. Currently that is not happening, and we are training people for jobs that do not exist. That is terrible.

Senator MURRAY. That is exactly why under WIA we think the Workforce Development Councils at the local level who know their own local communities better than any of us here in Washington, DC—

Secretary CHAO. But they are separate from—

Senator MURRAY. Well, we have a difference of philosophy that is not going to be solved in the next several months.

I came in when the chairman was asking you about the workplace injuries and illnesses, and this is something that we have had a number of OSHA oversight hearings in my Employment Workforce Safety Subcommittee, when Dr. David Michaels testified recently. He told us that the true incidence—and I am quoting him—“is far higher than reported by the Bureau of Labor Statistics since these data do not include approximately two-thirds of occupational injuries and illnesses.”

In all of our oversight hearings, it became very clear that the under-reporting of workplace injuries and illnesses is a serious issue today. Is this something you are hearing about or you are concerned about—under-reporting?

Secretary CHAO. I do not believe there is under-reporting, but if you are concerned about it, I will take a look at it.

Senator MURRAY. This is something that our committee looked extensively at. It is very clear that there is under-reporting throughout the process. We will give you some of our hearing back-

grounds because I think it may change your view on whether or not there is a decreased number of injuries.

Mr. Chairman, I have several other questions I will submit for the record, but I appreciate the opportunity this morning. Thank you, Madam Secretary.

Secretary CHAO. Thank you.

Senator HARKIN. Thank you, Senator.

#### WIA RESCISSIONS

I would just follow up a little bit on that, Madam Secretary. Of the 20 States that responded, 19 reported they needed waivers so they could cover the rescissions with fiscal years 2007 and 2008 funds. In other words, they did not have enough 2005 and 2006 funds left that could be used to cover the rescission. We went through this last year.

Secretary CHAO. We did not ask for the rescission. It was the Congress.

Senator HARKIN. No.

Secretary CHAO. I take it back. I am sorry.

Senator HARKIN. Yes. You asked for \$335 million and we did—well, let me get the right figure here. Yes, we did \$250 million. You asked for \$335 million.

Secretary CHAO. So the question was—

Senator HARKIN. Well, I am just pointing out that the States did not have enough funds. I just thought I heard you say that there is all this leftover money out there. Did I hear that?

Secretary CHAO. Yes.

Senator HARKIN. Yes. Well, the data we have does not show that there is all that leftover money. Of 20 States that responded, 19 said they needed waivers.

Secretary CHAO. Okay. I will take a look at that.

[The information follows:]

As indicated in the attached table, a total of 47 States (including the District of Columbia and the Navaho Nation) have requested approval to use Program Year (PY) 2007 funds to satisfy the rescissions. The appropriations language specifically allows the Secretary to grant such approval. However, the appropriations language does not contain any authority for the Secretary to grant a waiver enabling a State to pay back money due to the rescission from a subsequent program year (i.e., PY 2008). Therefore, a waiver allowing the use of Program Year 2008 or other future funds cannot be granted and no States have made such a request. Additionally, the State of Tennessee has requested a separate waiver in response to the rescissions that will provide greater flexibility in the recapture and reallocation of local funds. This waiver does not contradict any of the requirements contained within the rescissions and is regularly granted under the Workforce Investment Act.

#### DEPARTMENT OF LABOR EMPLOYMENT AND TRAINING ADMINISTRATION \$250 MILLION RESCISSION OF UNEXPENDED BALANCES DISTRIBUTION OF RESCISSION BY FUNDING YEAR AS REQUESTED BY THE STATES

State	Funding year			Requested waiver to use PY 2007 funds
	PY 2005	PY 2006	PY 2007	
ALASKA .....	645,570	752,251	.....	N
ALABAMA .....	864,407	876,360	1,118,950	Y
ARKANSAS .....	.....	1,308,786	2,915,426	Y
ARIZONA .....	74,501	3,512,795	5,891,464	Y
CALIFORNIA .....	262,937	1,501,341	11,790,901	Y
COLORADO .....	51,160	3,569,938	5,144,692	Y

State	Funding year			Requested waiver to use PY 2007 funds
	PY 2005	PY 2006	PY 2007	
CONNECTICUT .....			669,896	Y
DC .....			2,292,101	Y
DELAWARE .....		378,486	58,289	Y
FLORIDA .....	1,659,910	2,099,438	6,833,750	Y
GEORGIA .....		7,183,495	2,250,192	Y
HAWAII .....			239,536	Y
IOWA .....		286,198	993,132	Y
IDAHO .....			210,683	Y
ILLINOIS .....	1,220,530	5,203,752	1,751,880	Y
INDIANA .....	6,876,594	4,093,268		N
KANSAS .....		751,532	4,896,619	Y
KENTUCKY .....	82,357	135,469	2,290,279	Y
LOUISIANA .....			4,426,629	Y
MASSACHUSETTS .....	393,273	789,873	431,815	Y
MARYLAND .....			2,087,739	Y
MAINE .....		220,066	40,068	Y
MICHIGAN .....	216,223	123,913	5,213,936	Y
MINNESOTA .....		573,853	294,427	Y
MISSOURI .....			1,503,748	Y
MISSISSIPPI .....	30,677	1,912,858	1,407,583	Y
MONTANA .....		189,376		N
NORTH CAROLINA .....	1,561,572		1,308,565	Y
NORTH DAKOTA .....	238,238		147,895	Y
NEBRASKA .....	437,191	1,154,684	759,836	Y
NEW HAMPSHIRE .....		216,222	145,238	Y
NEW JERSEY .....			2,393,715	Y
NEW MEXICO .....	132,350	1,489,196	1,185,327	Y
NEVADA .....			390,190	Y
NEW YORK .....	20,657,557	9,954,817	7,053,353	Y
OHIO .....	2,500,000	10,557,343	6,725,717	Y
OKLAHOMA .....	822,272	5,221,830	4,213,712	Y
OREGON .....	674,514	1,925,147	2,231,011	Y
PENNSYLVANIA .....			4,434,297	Y
PUERTO RICO .....	3,170,099	6,581,296		N
RHODE ISLAND .....			314,971	Y
SOUTH CAROLINA .....			5,637,141	Y
SOUTH DAKOTA .....		555,825	362,605	Y
TENNESSEE .....	661,037	5,153,561	4,508,974	Y
TEXAS .....	5,782,445	3,635,845		N
UTAH .....		1,884,533		N
VIRGINIA .....	1,279,747	2,510,039	868,365	Y
VERMONT .....			141,574	Y
WASHINGTON .....			2,651,487	Y
WISCONSIN .....			583,404	Y
WEST VIRGINIA .....			476,806	Y
WYOMING .....		78,180	184,289	Y
NAVAHO NATION .....	73,492		1,777,574	Y
Total .....	50,368,654	86,381,565	113,249,781	

Senator HARKIN. Okay.

#### WORKERS COMPENSATION DATA

Madam Secretary, I want to cover a couple of other issues with you. One is this. Your whole statement about the fact that injuries are down and fatalities are down. Serious injury and illness rates have fallen to record lows, et cetera. I went over the Hispanic thing with you. I will not go back over that. Just the totality of it, and we are finding some really disturbing information here.

I will just read this again. This is from your own Web site. "While BLS occupational injury and illness data have been the sub-

ject of scrutiny from time to time, a study released in early 2006 is the first specific research documenting missing cases in individual firms as determined by comparisons between BLS and State workers compensation data.”

Well, I have asked my staff to take a closer look at this. It looks like what we have here is under-reporting. So how do we know that what you are telling us is so when your own BLS says that the first specific research documented missing cases out there? So how do we know that these figures are even remotely correct when BLS says that there are missing cases out there documented that they picked up?

In other words, what they did is they went to State workman's comp offices, looked at people who had got workman's comp for an injury, looked at the injury data from that place back to your Department and said they were not reported. They were injured or had serious illness—I do not know which—were receiving workman's comp but were not reported. This is very disturbing that we do not know. That way we do not have the accurate data.

Secretary CHAO. OSHA conducts audit programs for these. They do audits of all these programs, and OSHA has conducted these audit programs for about the last 10 years. They believe that the accuracy rate is about 90 percent.

Senator HARKIN. Well, the Bureau of Labor Statistics is saying that they have got missing cases that they documented. So if OSHA is out there doing it, they are missing something. Something is being missed here. What I do not know is the extent of it. We do not know the extent of it. I intend to get to the bottom of it sometime either this year or next or something like that and find out. We may include language in this bill to find out. I may have to get the GAO to do another investigation. I do not know.

Secretary CHAO. We will be more than glad to work with you because OSHA basically checks the record keeping on every inspection that it does.

Senator HARKIN. If the BLS says they are not doing it right or they are missing something, then you have got to wonder about the validity of their data.

#### LM-30 REPORTING REQUIREMENTS

Now, as I said earlier, only three significant safety and health regulations were issued, and you are going to send me these other ones that you did so I can see what they look like.

In contrast, however, DOL has issued revised regulations for the LM-2 and the LM-30 reporting programs. Now, I have heard a lot about this. The new LM-30 reporting requirements force rank and file union members to report on personal loans even at market rates, such as a mortgage, student loan, or car loan. Because of these reporting requirements, unions are telling me that this has a dampening effect, discouraging members from serving even as a shop steward because then they have got to give all this data out, or they do not serve as board members.

Now anticipating that you might say, “Well, this has to do with ensuring there are no conflicts of interest,” these are loans that are offered to the general public. These are market rate loans, and yet you are requiring that data to be submitted.



So I am just wondering what is the purpose of having rank and file union members report on personal loans that they get at market rates, such as mortgages, student loans, car loans, et cetera, since these loans in question are on terms offered to the general public. What is the purpose of collecting that kind of data?

Secretary CHAO. You know, there is so little that we do in OLMS. We have only issued two regulations—not even issued. We have updated these regulations, LM-2, LM-30s. They have not been updated since 1959. The LM-30s are required by law, and there was very bad compliance. Until we focused on this, there was no compliance at all. I have no other laws within the Department of Labor in which there is no compliance. With LM-2s, it was 50 percent compliance within a 3-year period.

This is a very small office. The budget is only \$50 million in a budget of \$10.5 billion.

On the issue that you raise, if there is no conflict of interest, then there is no need to file.

Senator HARKIN. Well, I am told they have to file it if they have got a loan, if they have got a mortgage or they have got a student loan or a car loan. They still have to file that. Is that wrong?

Secretary CHAO. I will check into that for you. If there is no conflict of interest, then there is no need to file. The only purpose for this is to ensure that rank and file members know about non-arm's-length transactions occurring with the leadership of their unions.

Senator HARKIN. I have no problem with that. Well, maybe my information is wrong. I do not know. We will find out.

Secretary CHAO. If there is a misunderstanding, we need to clarify that.

Senator HARKIN. Will you have somebody find out for me if this is wrong or not?

Secretary CHAO. Sure.

[The information follows:]

Under the revised Form LM-30 rules, no report is due unless there is a potential conflict of interest. For this reason, there are different rules depending on whether the financial institution is affiliated, or does business, with the union.

Generally, a union official or employee filing a Form LM-30 need not report bona fide loans, interest or dividends from national or State banks, credit unions, savings or loan associations, insurance companies, or other bona fide credit institutions, so long as these transactions are made on terms unrelated to the official's status in the labor organization.

However, union officials and employees must report such payments when the labor organization established, or selects the directors of, the financial institution. In this circumstance, there is a potential conflict of interest because of the potential for self dealing when a financial institution affiliated with a union is lending money, or making other payments, to an official of that union.

In addition, loans to union officials must be reported when made by financial institutions that do business with the union or union-affiliated organizations, or do substantial business with the employer of the union members. The potential conflict of interest is plain. Union members have a right to know if their union is doing business with a financial institution because it is offering the best terms available or because a union official is getting special deals from the institution.

Finally, there is never any requirement to report everyday financial matters such as credit card transactions (including unpaid balances) or interest and dividends paid on savings accounts, checking accounts or certificates of deposit.

Senator HARKIN. But I would just point out that on page 157 of your performance and accountability report, you say that OLMS—I quote—"met its target of 7.5 percent for the percentage of unions

with indicators of fraud. Private sector research indicates that this rate of fraud is significantly lower than fraud in corporations, which is estimated at 10 percent.” So, again, why do we keep increasing the money for that office when your own thing says it has met its target of 7.5 percent? Why keep asking for more money and for more people?

Secretary CHAO. In the 1980s, the compliance audits was about 1,500. By the year 2000, there were less than 204 international audits. There were international audits in fiscal year 2000 of two labor unions. Of the 33,000 labor organizations, only 3,000 have been audited since 2001. This is required by the law. The FTE in that little office was slashed more than 7—I do not want to say 7—my impression was 70 percent. We are just trying to build it up. In the late 1980s, the FTE was 435. We are currently at 321. It is still much below what it was then. In the decade of the 1990s, the FTEs were slashed. There are international unions that have never been audited.

Senator HARKIN. Again, your documentation here—this is from your performance and accountability report. I was intrigued by this because here on page 156 it talks about the union financial integrity and transparency. That is where we got the 7.5 percent.

Down here it says, “Percent of union reports meeting standards of acceptability.” Your target for fiscal year 2004 was 75 percent. The result, 92 percent. Your target for 2005 was 95 percent. The result was 94 percent. Fiscal year 2007 goal was 95 percent. I am sorry. The target was 97 percent. The result is 95 percent. So 95 percent of union reporting meeting standards of acceptability are 95 percent.

Secretary CHAO. That is great. That is how it should be. But you have to have audits.

Senator HARKIN. But now you are telling me—I thought I just heard you say that these were not acceptable reports and stuff that were coming in, and so you have to have more audits. I am saying no.

Secretary CHAO. We have to have audits.

Senator HARKIN. By your own thing—

Secretary CHAO. But that is our statutory responsibility. We have to conduct audits. We have not been conducting audits.

Senator HARKIN. When did you start?

Secretary CHAO. No, no. They have been going on, but it has been much reduced. In fiscal year 2001, for example, we did 220 audits.

Senator HARKIN. When?

Secretary CHAO. Fiscal year 2001, I believe. We did 220 audits. There were 110 indictments. That is an incredible number. What we are trying to do is to enforce the law.

Senator HARKIN. That was 2001?

Secretary CHAO. Yes. It was 2001. I do not have the exact, but it is around that time frame. Yes. I can get that for you.

[The information follows:]

OLMS audits, indictments and convictions for each year 2001–2007 are as follows:

	Fiscal year							Total
	2001	2002	2003	2004	2005	2006	2007	
Indictments .....	99	166	131	110	115	121	100	842
Convictions .....	102	89	152	111	97	133	118	802
Compliance Audits (CAP) .....	238	277	255	532	612	737	775	3,426
International Compliance Audits (I-CAP) .....	1	2	.....	1	7	5	7	23

Senator HARKIN. The figures you just gave me—there were 220—

Secretary CHAO. Audits done in fiscal year 2001.

Senator HARKIN. 110 indictments.

Secretary CHAO. Yes.

Senator HARKIN. Do you know what they were for subsequent years?

Secretary CHAO. I do not have that. That was just the first year. The Inspector General's Semi-Annual Report shows all of the activities in OLMS as does the OLMS Annual Report as well.

Senator HARKIN. Would you get me the same type of data, how many audits and how many indictments for every year?

Secretary CHAO. Yes. I thought I had that, but I do not.

Senator HARKIN. I just do not have it. All I have got is this right here.

Secretary CHAO. But again, we are just trying to enforce the law here and to ensure compliance. That is all.

#### LABOR-MANAGEMENT REPORTING

Senator HARKIN. Well, I guess my point is that—I remember one time a long time ago when we were having a debate on food stamp fraud and people were going on about all the fraud in food stamps and stuff. I made the point. I said there is a clear way to stop all fraud in food stamps or any other Government program like that. You just make sure that every recipient has an account assigned to them and a priest, rabbi, or minister. You will stop all the fraud. Of course, it will cost 10 quadrillion dollars to do it, but you will not have any fraud.

So, again, in all of these things, it has to do with what is the acceptable level, and if we are down to 7.5 percent in indicators, then it seems to me that to be adding more money and more money and requiring more reports does not seem to be cost effective.

Secretary CHAO. This is one of the least regulated areas in the whole Department. As I mentioned, there have only been two regulations, LM-2, LM-30s, and there has been very little compliance. With LM-2s, we can get you the numbers on that, and there has been a tremendous decrease in audits, tremendous increase in enforcement, tremendous decrease in compliance. It is not that we are singling out any one community. We are just trying to enforce the law, and the record for compliance in this area has been very disappointing.

Senator HARKIN. I come back to that point and you have only issued three in 8 years, three OSHA. But you are going to send me the other 23 too I guess and let me take a look at it.

Secretary CHAO. OSHA has a huge program. This is a little agency of \$50 million. It has a disproportionate level of attention. I do

not understand it. It is not that we are singling it out. It is a \$50 million little agency. All we are trying to do is enforce two regulations.

Senator HARKIN. Yes, but the LM-30s that you have issued, in terms of all this reporting—but you are going to tell me whether or not it is right that they have to report all these things.

Secretary CHAO. Yes, we will.

Senator HARKIN. I will find out about that.

Secretary CHAO. We have actually had workshops to try to clarify, not that it is so complicated, but what is requested. We have actually held workshops. But we will certainly provide that information.

Senator HARKIN. I would like to know whether I am right on that or not. I do not know.

#### MINE SAFETY AND HEALTH

In November 2007, the DOL Inspector General issued a report regarding missed safety and health inspections in underground coal mines. MSHA is required by law to inspect underground mines not fewer than four times a year. Here is what the IG found. During fiscal year 2006, 15 percent of the Nation's underground coal mines were inspected at least one time fewer than the four times required by law. Second, the number of inspectors relative to mining activity increased from fiscal year 1997 to 2001, but decreased significantly, 25 percent inspectors—decreased 25 percent from fiscal year 2002 to 2006. MSHA said inspector resource limitations affected their ability to complete all of the required inspections in fiscal year 2006, noting that lack of funding prevented MSHA from hiring or filling vacancies.

Again, it is priorities. You are asking more money for labor-management reporting, which I pointed out you said you have already met your goal of 7.5 percent, and yet you cut the funding from MSHA. Your request is \$332 million. It is a reduction of almost \$2 million from the amount provided in 2008. Congress had to provide MSHA with \$20 million more than your budget request last year to help MSHA meet its obligations. So, again, on the one hand, you are putting more money here, but you are taking money out of MSHA. I have to wonder about priorities here.

Secretary CHAO. The budget request for OLMS is the same this year as it was last year. Last year the Congress added \$936 million more to the President's request for worker protection, and yet it cut \$2 million from OLMS. We are just asking for the same amount of money in an effort to try to restore the funding and the functions of this office to pre-1991 levels.

On the issue of worker protection, we have consistently asked for increased budgets for worker protection programs throughout our whole tenure here. In 2008, MSHA's budget was not cut. There was a one-time expense to MSHA such as roof replacement for the MSHA academy, high methane detectors for inspectors. We have had earmarks of \$3.4 million, Wheeling Jesuit, \$1.2 million; UMW, \$2.2 million. We have had regulations for technical support equipment. These are one-time expenses. So if you take out the one-time expenses, our request this year is actually higher than the previous year.

Senator HARKIN. Okay. Is your budget request less than what we provided last year for MSHA?

Secretary CHAO. Yes, it is.

#### ERGONOMIC INJURIES

Senator HARKIN. Ergonomics. Again, this has been an issue that quite frankly, Madam Secretary, we just keep kicking the can down the road on ergonomics. As you know, that was the first thing I think that President Bush argued for after he took office.

One-third of all injuries—we were told, approximately one-third—and illnesses and days away from work are musculoskeletal disorders from exposure to ergonomic hazards on the job. In 2006, 375,540 serious ergonomic injuries resulting in time off the job reported by employers.

Getting back to issuing regulations, 375,540. Yet, no regulations.

In 2002 you, Madam Secretary, announced a comprehensive plan to address ergonomic injuries, including “industry-targeted guidelines and tough enforcement measures.” Those were your words. To quote you further, “Our goal is to help workers by reducing ergonomic injuries in the shortest possible timeframe.”

Well, let us see what has happened. OSHA has only issued 19 ergonomic citations since 2001, and there was one in 2005, none in 2006 or 2007. In 2006, there were 375,540 serious ergonomic injuries resulting in time off the job.

According to information you provided to the committee last year, the number of hazard alert letters also appears to be declining. In 2003, there were 224 ergonomic hazard alert letters issued. In 2004, 109. The number fell to 52 in 2005 and 31 letters issued in 2006.

So if we see there were 375,540 serious ergonomic injuries in 2006, why have the number of hazard alert letters declined so significantly? Is OSHA inspecting workplaces for ergonomic hazards?

Secretary CHAO. Yes.

Senator HARKIN. They are.

Secretary CHAO. Yes.

Senator HARKIN. But then why are the hazard alert letters going down when we see all these injuries?

Secretary CHAO. We send out approximately 625 hazard alert letters.

Senator HARKIN. How many?

Secretary CHAO. 625.

Senator HARKIN. 625? When?

Secretary CHAO. I do not have those dates. I can get that for you, but we have sent approximately 625 hazard alert letters to notify employers of ergonomic problems.

We have also issued final ergonomic guidelines for nursing homes, retail grocery stores, poultry processing, and shipyards. We have also conducted over 700 ergonomic inspections per year, and overall ergonomic injuries have been declining.

Senator HARKIN. Well, just a second about that. I will tell you that I do not have 2001 or 2002, but I do have 2003, 2004, 2005, and 2006, and that adds up to maybe 330-some. I do not know where the 625 comes from. Maybe that comes from 2001 and 2002 that I just do not have here.

My point is that it went from 224 to 109 to 52 to 31, and I am just wondering why are the number of hazard alert letters going down so precipitously.

Secretary CHAO. I will take a look at the numbers, but I think, as I mentioned, we have issued approximately 625 hazard alert letters. I will go and try to clarify that for you.

[The information follows:]

The Occupational Safety and Health Administration did not start tracking the ergonomics hazard alert letters until mid-2002 when the Secretary's four-pronged ergonomics program was launched. For 2002–2008, the following information is provided on the number of ergonomics hazard alert letters that were issued by OSHA:

Year	Alert letters
2002 .....	31
2003 .....	259
2004 .....	128
2005 .....	81
2006 .....	38
2007 .....	49
2008 .....	<sup>1</sup> 18

<sup>1</sup> Through April 2008.

Secretary CHAO. Let us take a look at the injury rate involving days away from work declined because of ergonomic injuries—our injury rate for all injuries, and they have basically have been declining. So in terms of injuries and days lost in terms of work, the trend again has been positive and it has been better than in previous years.

Senator HARKIN. I would ask you to submit that for the record what data you have on showing that decline in ergonomic injuries. Again, I will just say once again if BLS says that they have evidence that they are documenting missing cases because they have workman's comp cases out there but they are not being reported, then I wonder about the validity of how much ergonomic injuries are going down. Even if they are going down, in 2006, it was 375,540. So even if it is coming down, that is way, way—

[The information follows:]

NUMBER AND INCIDENCE RATE OF OCCUPATIONAL INJURIES AND ILLNESSES INVOLVING DAYS AWAY FROM WORK WITH MUSCULOSKELETAL DISORDERS IN PRIVATE INDUSTRY FOR ALL UNITED STATES

Year	Number of cases <sup>1</sup>	Rate per 10,000 workers
2006 .....	357,160	38.6
2005 .....	375,540	41.3
2004 .....	402,700	45.2
2003 .....	435,180	49.6
2002 <sup>2</sup> .....	487,915	55.3
2001 .....	522,528	57.5

<sup>1</sup> Includes cases where the nature of injury is: sprains, strains, tears; back pain, hurt back; soreness, pain, hurt, except back; carpal tunnel syndrome; hernia; or musculoskeletal system and connective tissue diseases and disorders and when the event or exposure leading to the injury or illness is: bodily reaction/bending, climbing, crawling, reaching, twisting; overexertion; or repetition. Cases of Raynaud's phenomenon, tarsal tunnel syndrome, and herniated spinal discs are not included. Although these cases may be considered MSDs, the survey classifies these cases in categories that also include non-MSD cases.

<sup>2</sup> Effective January 1, 2002, the Occupational Safety and Health Administration (OSHA) revised its requirements for recording occupational injuries and illnesses. Due to the revised recordkeeping rule, estimates from the 2002 survey are not comparable with those from previous years prior to 2002.

Source.—BLS Annual Survey of Occupational Injuries and Illnesses.

## Number and Incident Rate of Musculoskeletal Disorders (MSDs) (1992-2006)



Includes cases where the nature of injury is: sprains, strains, tears; back pain, hurt back; soreness, pain, hurt, except back; carpal tunnel syndrome; hernia, or musculoskeletal system and connective tissue diseases and disorders and when the event or exposure leading to the injury or illness is: bodily reaction/bending, climbing, crawling, reaching, twisting, overexertion, or repetition. Cases of Raynaud's phenomenon, tarsal tunnel syndrome, and herniated spinal discs are not included. Although these cases may be considered MSD's, the survey classifies these cases in categories that also include non-MSD cases.

Secretary CHAO. We are concerned about it, of course.

Senator HARKIN [continuing]. Way too many.

Secretary CHAO. Yes, but that is the overall measurement, is it not? Overall injuries and illnesses?

Senator HARKIN. Yes, but you have only issued 19 ergonomic citations since 2001. You had one in 2005 and none in—

Secretary CHAO. We have a four-prong approach. It is enforcement. It is education and outreach. It is research. It is compliance assistance. Obviously that four-prong approach is working.

Senator HARKIN. Well, when there are 375,540 in 2006, it does not seem like it is working too well.

Secretary CHAO. Obviously, it is working. The current approach has provided positive results, but we can always do better.

Senator HARKIN. Your National Advisory Committee on Ergonomics recommended 16 industries for the development of guidelines, but only 4 were issued. Do you have a timeline when the rest of them will be issued?

Secretary CHAO. The appropriations bill last year asked us to further evaluate these 16 and that is what we are doing now.

Senator HARKIN. I am sorry.

Secretary CHAO. The fiscal year 2008 appropriations bill asked for the Department to further evaluate these 16, and we are doing so.

Senator HARKIN. You are evaluating the 16? Four were issued.

Secretary CHAO. Right. There were 16 additional ones. You are asking for 16 additional ones.

Senator HARKIN. You are evaluating those now?

Secretary CHAO. So we are looking at those, yes.

Senator HARKIN. Okay. Well, just let us know when those are going to be issued.

I do not have the 2007 figures for ergonomic injuries. Do you have them for 2001, 2002, 2003, 2004, and 2005?

Secretary CHAO. I do not have them with me.

Senator HARKIN. I only have 2006.

Secretary CHAO. I will provide them.

[The information follows:]

The Department of Labor has taken a comprehensive approach to ergonomics since 2002, including development of industry- and task-specific guidelines, enforcement, outreach and assistance, and research. As part of this effort, OSHA has committed considerable resources to preventing MSDs in the workplace.

OSHA published guidelines for three industries recommended for guideline development by the National Advisory Committee on Ergonomics (NACE): nursing homes, retail grocery, and poultry processing. OSHA has also just recently published its fourth set of guidelines in the series, which is Ergonomics for the Prevention of Musculoskeletal Disorders: Guidelines for Shipyards.

Further OSHA analysis has identified industries for which the incidence rates for MSDs resulting in days away from work were more than twice the national average for at least 2 of the 3 years for which data were examined. The analysis identified the following 24 industries:

- (NAICS 238140) Masonry contractors
- (NAICS 311423) Dried and dehydrated food manufacturing
- (NAICS 311500) Dairy product manufacturing
- (NAICS 312000) Beverage and tobacco product manufacturing
- (NAICS 321992) Prefabricated wood building manufacturing
- (NAICS 327100) Clay product and refractory manufacturing
- (NAICS 331420) Copper rolling, drawing, extruding and alloying
- (NAICS 331500) Foundries
- (NAICS 334416) Electric coil, transformer, and other inductor manufacturing
- (NAICS 336100) Motor vehicle manufacturing
- (NAICS 336214) Truck trailer and camper manufacturing
- (NAICS 336391) Motor vehicle air-conditioning manufacturing
- (NAICS 336600) Ship and Boat Building
- (NAICS 337215) Showcase, partition, shelving, and locker manufacturing
- (NAICS 424400) Grocery and related product merchant wholesalers
- (NAICS 424800) Beer, wine and distilled alcoholic beverage merchant wholesalers
- (NAICS 444100) Building material and supplies dealers
- (NAICS 481000) Air transportation
- (NAICS 485100) Urban transit systems
- (NAICS 492000) Couriers and messengers
- (NAICS 493100) Warehousing and storage
- (NAICS 562100) Waste collection
- (NAICS 621900) Other ambulatory health care services
- (NAICS 623000) Nursing and residential care facilities

OSHA is currently reviewing this list to determine the next industries to target with ergonomics guidance beyond guidance that has already been issued.

Senator HARKIN. I would like to see how much they are declining by.

Secretary CHAO. Okay, will do.

Senator HARKIN. Still one of the highest reasons for people not being able to work and losing time off the job is ergonomic injuries. Quite frankly, this is going to have to be addressed. I do not suppose it will be, obviously, this year in this administration, but whichever the next administration is, if I am here, I am telling you we are going to get onto ergonomics. Something has to be done because I have been to places.

I have been in places where they have had ergonomic injuries and time off, and sometimes the companies took it upon themselves. Their board of directors said something needs to be done and they did it. By changing simple, little things and providing for different heights of tables and different things like that, you can really cut down on these. I think your Department—



Secretary CHAO. I agree with you on that. It is not a one-size-fits-all, but it is giving general guidelines, education, and research and how employers can adapt the technology and their knowledge to their specific workplace because there is no one-size-fits-all solution to this.

Senator HARKIN. Right, I agree.

Well, it seems to me you had a plan. Well, to me, just again looking at it, it does not seem like you are really implementing your own plan.

Secretary CHAO. It is a four-prong strategy and a great deal of it rests with education, outreach, helping employers and worker groups find their own solution on reducing ergonomic injuries.

Senator HARKIN. I do not disagree with you. That is. But sometimes a good citation——

Secretary CHAO. We certainly do that too.

Senator HARKIN [continuing]. Wakes people up.

Secretary CHAO. Yes, and we have inspections.

Senator HARKIN. Wait a minute. No, you do not——

Secretary CHAO. We use alert letters.

Senator HARKIN. You do not do citations. You did none in 2006 and none last year, not one. There are 375,540 serious injuries in 2006, and you issued no citations. I mean, if it had been three or four, okay. You only issued 19 since 2001. Like I said, sometimes a good citation wakes people up and they start doing things.

Secretary CHAO. We do have inspections too. We have 700 ergonomic inspections every year.

Senator HARKIN. You have 700 ergonomic inspections every year for the entire country. I do not find that too impressive a figure, I got to tell you.

Secretary CHAO. I understand. But the overall injury rate is down, and we can talk about that. We will give the numbers to you.

Senator HARKIN. Well, that is okay. I am glad it is down. It is just awfully high.

Your table says here for fiscal year 2007, there were only 449 ergonomic inspections.

Secretary CHAO. Well, we seem to have a difference of opinion. So let me find out what the difference is. My notes said——

Senator HARKIN. It is in your budget request.

Secretary CHAO. That is not good. Let us find out what happened because I have 700 ergonomic inspections per year.

Senator HARKIN. The actual fiscal year 2007 was 449 in your own book.

Secretary CHAO. Over what period, may I ask?

Senator HARKIN. Fiscal year 2007.

Secretary CHAO. Okay. Let me take a look at that because my notes here said it is 700. So there must be some disconnect.

[The information follows:]

In fiscal year 2006, OSHA conducted 795 ergonomic inspections. In fiscal year 2007, the Agency conducted 705 ergonomic inspections. The discrepancy between this number and the erroneous reporting for fiscal year 2007 in the Agency's fiscal year 2009 Congressional Budget Justification reflects the correction of an error in the coding of inspections that was made subsequent to the publishing of the Congressional Budget Justification.

Secretary CHAO. But from 2003 to 2006, the ergonomic injury rate again declined about 22 percent overall. So this broad-based, multi-prong approach does have value.

Senator HARKIN. From 2002 to 2006?

Secretary CHAO. Right.

Senator HARKIN. Well, I would again appreciate those every year. But again, I will always look at that askance until I find out whether or not we are getting accurate reporting, and we are going to include language in our bill for the Department to go after this and find out what the BLS is saying. Why are they saying that there is missing cases out there? Is it big? Is it small? I do not know. I have not the foggiest idea, but I think we need to find out whether that is real or not because it brings into question whether it has really been a 22 percent decline or not. I do not know until we get a better handle on missing cases and what that means in terms of reporting.

#### OSHA STATE PLANS

Iowa is an OSHA State plan State. How many States are State plans?

Secretary CHAO. About half.

Senator HARKIN. How many?

Secretary CHAO. About half.

Senator HARKIN. Half?

Secretary CHAO. Yes.

Senator HARKIN. About half the States have State plans. It means that the Division of Labor Services rather than OSHA administers the State's workplace safety and health program. Under the Occupational Safety and Health Act, States are authorized to develop their own occupational safety and health plans. The Federal Government will provide 50 percent of the costs. Half of the States operate such a plan. I have got that there.

Dave Neil, the Commissioner of the Department of Labor Services, wrote me earlier this year and noted that the Federal amount provided to Iowa in fiscal year 2008, which we are in, is \$1.6 million, or 37.8 percent, rather than the 50 percent required by OSHA. Why? Why is it less than the 50 percent? And are other States like this? I only know my own State. But why are they getting 37.8 percent rather than the 50 percent?

Secretary CHAO. I actually boned up on the answer for this, and I do not have it handy with me right now.

Senator HARKIN. Well, if you do not have it, just submit it for the record.

Secretary CHAO. Let me get that for you.

[The information follows:]

There are 26 States that operate OSHA-approved State Plans, which deliver the OSHA program to 40 percent of the Nation's employers and employees. Twenty-one States (including Iowa) and Puerto Rico operate complete plans, which cover both the private and public (State and local government) sectors. Three States and the Virgin Islands operate plans that are limited in scope to the public sector.

Section 23(g) of the Occupational Safety and Health Act provides for funding of these State programs at a level which "may not exceed" 50 percent of the total cost to the State of such a program. Annual appropriations language ensures that no State plan is required to contribute more than a 50 percent match of the available Federal funds. However, many States have chosen to contribute significant amounts

of additional funding. Iowa, for the first time in fiscal year 2008, is one of those States.

The Federal funds available for State Plan grants in fiscal year 2008 total \$89,502,000, less than the President requested as a result of final congressional action. Based on the State programs' funding, all States matched the available funds and 20 States contributed additional funds above their match. Iowa contributed \$1,096,040 over and above their \$1,580,800 match.

Senator HARKIN. That is fine. All I would like to know is what would that impact be. Why are they getting less than 50 percent, and how many other States that have State plans are getting less than 50 percent?

We have talked about disability policy.

This will be my last issue I want to go over, and that is the job training portion. Again, the BLS statistics say there are 1.6 million more individuals unemployed today than there were when this President took office, when you took office. The unemployment rate is higher, 5 percent versus 4.2 percent. Nevertheless, this budget cuts training and employment services account programs by almost 14 percent, or \$484 million.

Again, this is training and employment services. Well, with unemployment going up, the number of unemployed going up, why is your budget cutting the training and employment services account by 14 percent?

Secretary CHAO. Well, let me say, again, the workforce expands by about 1 million—800,000 workers a year—8.6 million net new jobs have been created since August 2003. The unemployment rate is 5 percent. This is lower than the average unemployment rate of the decade of the 1990's, which is 5.7 percent.

We still have an estimated \$875 million carryover of unspent WIA funds available to the States, even after completing the \$250 million rescission required by the fiscal year 2008 appropriations bill.

There is a major debate about the Workforce Investment Act and how we should proceed.

Senator HARKIN. Yes, I heard that.

Secretary CHAO. Yes. It is an issue with the authorizing committees. We obviously have very different points of view about it. With every successive round of reforms to the system, there are overlays of new systems upon the old. It is to the point now that there are duplicative structures.

So we have an employment services. They are staffed by wonderful people. I do not mean to disrespect the professionals who do this work. But I think they also must face some frustration in dealing with the bureaucracy that is duplicative, that is not responsive to the needs of a new century in which higher skill jobs are being created and more training of more specialized types is required. That is not currently being provided fully by the system.

So, again, with unspent funds of \$1.7 billion sometimes to currently this year of \$875 million, there is a lot of carryover.

Senator HARKIN. I just told my staff—I said I got to get a handle on this. I know there is a 3-year roll on that thing.

States have been reporting to you how much they have to return because of this rescission that we had. Iowa's share is \$1.3 million. They returned almost \$1 million of funds available for current operations, and they did not have any excess money out there. So as

a result, they are going to provide less training and job search and placement.

So this excess funds is not right. I keep hearing you say that, but I look at my own State and they do not have any.

Secretary CHAO. I do not have the State-by-State breakdown. I usually carry it with me. We can provide that for you. Even after the rescission—I do not know about Iowa, but most of them do have excess funds left over.

Senator HARKIN. My staff said what they are doing is they are taking it out of current money, of course. That is exactly what they are doing.

But all I know is Iowa does not have it, and I just do not know how many States—well, that might be interesting. Do we know what States?

Secretary CHAO. It is pretty much across the board.

Senator HARKIN. My staff says they are reporting today on that. The Department of Labor is reporting on this today. So I will take a look at that also.

Secretary CHAO. But there are duplicative structures. Beyond the excess unspent funds, there is a larger issue about workforce investment. WIA was supposed to be a one-stop shopping center for workers, dislocated workers, unemployed workers. It has still not fulfilled this one-stop function through a variety of reasons. There are other agencies who have not joined in. There are duplicative structures that are still outstanding.

I totally agree with you. We need to invest in our workforce, but we need to make sure that the reforms are there so that workers are, indeed, getting trained. Currently not as many are getting the training as they need, and that is the real tragedy.

Senator HARKIN. Well, I agree with you on that, but I do not think there is all that excess money out there that you keep talking about.

Secretary CHAO. Well, if you go a workforce investment system—and I love the system dearly. These are wonderful people who staff this system, but you have duplicative services. You go into a building. On the left is employment services. On the right is workforce investment, and they do not work with one another. Something needs to be done about that, which is what the reform package is all about.

I am optimistic. I think that this discussion is ongoing on a national level. It will take some more time for the system to come to some consensus on how to reform this, but there are some real reforms that are necessary.

Senator HARKIN. Well, Madam Secretary, thank you very much. You have been very kind with your time, and these are tough areas. Some of them you and I have just had disagreements on for a long time, on that ILAB and a few other things like that. But on that ILAB, I still think it is an important thing that they are doing on that grant program.

I want to get a handle on this BLS issue on under-reporting.

But I will close with this. Madam Secretary, last year's appropriations bill and report called for reports on a number of issues, including noncompetitive awards, the issuing of safety and health

regulations, among other topics. I would request that you personally look into moving those reports along.

Secretary CHAO. I will.

Senator HARKIN. Like I said, sometimes I do not know if what we have here is right or not. We have to look at these things. So I would ask that you move those reports along so we can take a look at them.

Also, I would leave the record open for any members of the subcommittee who could not be here to submit questions for you in writing for the record.

Secretary CHAO. Thank you. I also realized I did not answer your question about the refinery inspections, and I certainly do not want to drag this anymore. But if I can provide a fuller answer on what happened there, in terms of inspections, I would appreciate that.

Senator HARKIN. That would be good. That was one issue that sort of stuck out like a sore thumb there.

Well, Madam Secretary, unless you have anything else—

Secretary CHAO. Thank you very much.

[The information follows:]

The Occupational Safety and Health Administration's refinery National Emphasis Program (NEP) was initiated in June 2007. At that time, OSHA stated that the agency will conduct all of the refinery inspections covered by the NEP within 2 years—June of 2009. The agency is on track to meet that timeline.

#### ADDITIONAL COMMITTEE QUESTIONS

Senator HARKIN. There will be some additional questions which will be submitted for your response in the record.

[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

##### PROGRAM INTEGRATION

*Question.* In the Department's response to congressional concerns about adult, dislocated, and youth programs at local one-stop career centers overlapping statewide labor exchange services provided through the State unemployment insurance and employment services operations account, the Department indicated that it has worked with States to develop and submit plans for program integration.

How many States have developed and submitted such plans?

*Answer.* The Department has worked with States to develop and submit plans for Workforce Investment Act (WIA) and Wagner-Peyser Act Employment Service program integration; these plans are part of the WIA/Wagner-Peyser Act Strategic State Plans that are regularly submitted by the States. WIA section 112 requires all States to submit a State Plan as a condition of receiving funds. The Plans address multiple requirements of WIA, including program integration, governance structures, performance accountability systems, effective use of funds, and planned service delivery strategies.

*Question.* Please describe specifically the policies implemented to break down barriers to program integration; how States plan to increase the efficient use of administrative resources; and how States plan to coordinate the use of Wagner-Peyser Act and WIA funds to avoid duplication?

*Answer.* The State Plan Guidance issued by the Department for Program Years (PY) 2007–2008 was supplemented by a revised National Strategic Direction issued in Training and Employment Guidance Letter 13–06. The National Strategic Direction outlined a vision for transforming the public workforce investment system to develop and implement talent development strategies that support growth in economic regions, contributing to the Nation's economic competitiveness. Program integration is a key pillar in this approach, and the National Strategic Vision articulates a need for the workforce system to operate as a seamless system functionally

organized around service delivery rather than as an array of separate programs with separate processes, where customers are seen as customers of the entire workforce system rather than of a particular program.

In keeping with that vision of integration, the State Plan instructions required States to: (1) describe policies in place to change or modify barriers to integration; (2) describe more efficient uses of administrative resources, such as eliminating duplicative facility and operational costs; (3) promote models or strategies for local use that support integration; (4) describe how services provided through One-Stop partners will be coordinated; and (5) describe how States will coordinate Wagner-Peyser Act funds to avoid duplication. State Plans for Program Years 2007–2008 were last submitted in May 2007, and will expire June 30, 2009. States will next submit plans in April 2009 for Program Year 2009.

The Department has made an effort to use State Plans as a strategic tool to advance a transformed workforce system. To this end, the Department regularly monitors States' implementation of the strategies outlined in their State Plans, including their level of integration, and offers technical assistance to States that require it. The Department has also developed a comprehensive technical assistance plan, based in part on the needs of States the Department identified by reviewing their State Plans and monitoring their implementation.

All States have developed and submitted State Plans, and all plans address program integration. One specific example of a State effort to break down barriers to program integration is setting program integration as a State policy objective. For instance, Massachusetts has established the "Regional Directors of Workforce Integration" to ensure program integration at One-Stop Career Centers, and Oregon's workforce development leadership personally visits areas in the State that need technical assistance to achieve State integration of service goals. Another State policy to break down barriers to integration is combining and integrating State government agencies that oversee different workforce programs. For example, New Mexico's legislature recently created the New Mexico Department of Workforce Solutions, California consolidated its WIA and Employment Service programs into a single integrated unit called the Workforce Services Division, and Utah administers a number of federally-funded workforce programs under the Department of Workforce Services. Other States have looked to improve One-Stop Career Center operations to improve program integration. For instance, Maine has organized its staffing and services around a functional team concept, rather than teams driven by funding source, to deliver seamless and integrated services to participants. Lastly, several States, such as New Jersey, require satisfactory levels of integration in order to certify sites as One-Stop Career Centers.

State Plans also define strategies to increase the efficient use of administrative resources as well as strategies to use funds to avoid duplication. For instance, Texas administers a number of Federally-funded workforce programs through the Texas Workforce Commission and gives local workforce investment boards wide discretion in the use of funds to best serve their local population and regional economy. Arizona has moved to centralize service delivery in structures where overhead and administrative services are shared, particularly in rural areas.

*Question.* Is there any evidence that these plans are leading to better program integration, more efficient use of Federal resources and better program outcomes?

*Answer.* The Department believes that strategic planning does lead to better program integration, more efficient use of Federal resources, and better program outcomes. Because all States have been required to submit State Plans since the inception of WIA, the Department cannot compare States with plans to States without plans, or compare performance before and after a plan in order to produce "evidence" that plans result in positive changes. However, experience shows that States that have written strong, strategic State Plans are more likely to have integrated service structures, resulting in more efficient use of funds and improved program outcomes. For instance, Oregon, which ranks among the top 10 States on the entered employment rates for both the Adult and Dislocated Worker programs, submitted a plan that showed close coordination between workforce programs, and has recently closed a number of "stand-alone" Employment Service offices. Michigan, which also ranks among the top 10 States on both Adult and Dislocated Worker entered employment rates, submitted an exemplary State Plan that includes creative solutions for programs integration, regional planning, and innovative talent development strategies.

Although the strategic use of State Plans encourages program integration, the statutory requirements of WIA and the Wagner-Peyser Act still result in duplication in the public workforce investment system. By streamlining these systems, States can train more workers and provide more services. The Department has consistently supported legislative proposals to consolidate WIA title I and Wagner-Peyser Act

Employment Service programs, most recently in the WIA reauthorization and reform proposal, "Workforce Investment Act Amendments 2007," submitted to Congress in April 2007. Further, the Department has pursued rule making that would require local Employment Service offices to be located in the comprehensive One-Stop Career Centers and not be considered affiliate sites (Federal Register: December 20, 2006, Vol. 71, No. 244). However, Congress barred the implementation of this revision in the fiscal year 2007 and fiscal year 2008 Appropriations Acts.

#### CAPACITY BUILDING AND EVALUATION

*Question.* Please describe the specific actions (including any discretionary grant funding) ETA has taken to build the capacity in States to share best practices and undertake rigorous evaluations on the impact of WIA State grant funding?

*Answer.* One of the Department's core missions is to build the capacity in States to effectively provide workforce services and to actively engage with a wide array of strategic partners in workforce development strategies. Examples of strategies to support sharing of best practices include the Workforce<sup>3</sup>One Web site, the Workforce Innovations Conference, Transformational Forums, and the National Business Learning Partnership.

- Workforce<sup>3</sup>One is an interactive Web site designed to build the capacity of the public workforce investment system through training, resources, and regular communication ([www.workforce3one.org](http://www.workforce3one.org)). The Workforce<sup>3</sup>One Web site offers the workforce system an innovative knowledge network designed to create and support community solutions that respond directly to business needs and to develop strategies that enable individuals to be successful in the 21st century economy.
- Workforce Innovations is a forum hosted by the Department for States to share best practices. The conference draws over 3,000 participants from industry, education, the economic development community, and the workforce system, offering an opportunity to explore their important roles in meeting the national challenge of global competition.
- The Transformational Forums series, is a broad-based capacity building initiative to transform the workforce system, and provides an opportunity for States to share best practices. The Forums offer teams, comprised of State and local workforce representatives, a unique, customer-driven learning experience designed to provide support as they envision energized, and catalyzed innovative service delivery strategies.
- The National Business Learning Partnerships (NBLP), a peer-to-peer collaborative technical assistance effort among State and local Workforce Investment Boards and the Employment and Training Administration's regional and national offices, provides States an opportunity to build their workforce system capacity and share best practices.

In addition to capacity building the Department is currently conducting, a rigorous non-experimental net impact evaluation of the receipt of Workforce Investment Act (WIA) core and intensive services and the incremental impact of WIA training on participant's earning, employment, and retention. The evaluation involves comparing the outcomes of WIA participants to the outcomes of similar individuals drawn from a matched comparison group. Results from this evaluation will be provided to the Department in the fall of this year.

In June 2008, the Department will launch the Workforce Investment Act Gold Standard Evaluation (WGSE). The WGSE is a 7-year, rigorous, random assignment evaluation of the Adult, Dislocated Worker, and Youth formula programs established under title I of WIA. The evaluation will examine these programs' impacts on participants' post-program employment and earnings and their cost effectiveness. The evaluation will compare outcomes of WIA participants to the outcomes of similar individuals who do not receive WIA services. The results of the evaluation will be used to determine what aspects of the current system work versus those that do not work. This information will help improve the workforce investment system and inform any WIA reforms, as applicable. Interim evaluation results will from the WGSE will be generated periodically beginning in the fall of 2011 and final results are anticipated to being available in 2015.

*Question.* What has been the outcomes associated with these activities?

*Answer.* The outcomes associated with the Department's activities to build the capacity in States to share best practices include:

- Workforce<sup>3</sup>One.*—There is currently over 31,000 registrants of the site. Registrants engage in Webinar events, download materials, and share best practices by submitting content. Individuals have visited the site over 72,000 times

in the past year, have downloaded over 15,000 pieces of content, and thousands of individuals have engaged in Webinars.

—*Workforce Innovations*.—States have directly shared best practices through workshop sessions, conference materials, and structured and informal opportunities for networking.

—*Transformational Forums*.—A total of 55 teams, representing over 40 States, were able to explore critical workforce system challenges and opportunities, receive customized coaching from mentors and peers, develop concrete action steps for advancing talent development strategies for economic growth, and contribute to the development of a shared national vision for workforce system transformation

—*National Business Learning Partnerships*.—A total of 44 State and local workforce investment boards attended workshops, established mentor/protégé teams, shared technical assistance, documented best practices, and published numerous case studies and other technical assistance materials.

*Question.* What is proposed in the 2009 budget for this purpose?

*Answer.* The Department's fiscal year 2009 budget requests \$16.88 million to support workforce information, electronic tools, and system building. In addition, the Department has requested \$32 million for labor market information grants; these grant funds are part of the administration's WIA reform proposal. With this request, the Department will continue to share innovative demand-driven talent development strategies in support of regional economic competitiveness through the Workforce<sup>3</sup>One Web site. The Department will also implement a comprehensive technical assistance strategy that continues the work of the Transformational Forum teams, offer Webinars on topics to address capacity-building needs identified through the WIA/Wagner-Peyser State Planning process, and support various strategies to integrate program and services. Lastly, the Department will continue to develop expanded sets of strategic partnerships with community colleges, the economic development community, faith and community-based organizations, foundations, and other Federal agencies.

#### WIA YOUTH SERVICES

*Question.* In February of this year, the Government Accountability Office (GAO) issued a report on disconnected youth. The report noted that researcher estimates of the number of disconnected youth range from 2.3 million to 5.2 million. According to GAO, funding for many of the key Federal programs we reviewed that serve disconnected youth has remained the same or declined since 2000. The report also found that 15 directors with Federal WIA Youth funding noted that the need to meet certain WIA youth performance goals within short-term time frames discouraged them from serving youth that may need more time and assistance to achieve specified outcomes. What is the Department's plan for ensuring that funds are able to be used to effectively address youth most in need of WIA services?

*Answer.* As a long-term strategy to ensure that WIA Youth Formula funds are used to effectively address youth most in need of WIA services, in 2004, the Department adopted and announced its new strategic vision to serve more effectively those youth most in need of services: out-of-school youth and at-risk youth. Recognizing the need to involve other Federal agencies, the Department pursued an outreach and recruitment strategy that led to the creation of a national cross-agency group. This group has evolved into the Shared Youth Vision Federal Partnership and includes the U.S. Departments of Agriculture, Education, Health and Human Services, Housing and Urban Development, Justice, Labor, and Transportation; the Social Security Administration; and the Corporation for National and Community Service. By leveraging other Federal resources in support of WIA enrolled youth, WIA youth service providers and local workforce areas can focus their resources on employment and training needs while also collaboratively supporting other important issues faced by a needier youth population, including health, substance abuse, transportation, and housing.

The Federal Partnership has been actively involved in sponsoring numerous activities to promote the Shared Youth Vision to State and local agencies serving youth. These activities have included: (1) a series of Shared Youth Vision technical assistance forums nationwide for State teams; (2) the selection of 16 Shared Youth Vision Pilot Project State teams to develop and implement strategic approaches that leverage their State-level coordination at the local service delivery level; (3) the development and implementation of a comprehensive technical assistance plan for infusing the collaborative vision in all States throughout the country; and (4) funding a Shared Youth Vision Implementation Study to conduct an analysis of the work of the Federal Partnership and the work of the State pilot teams to better serve the



neediest youth. The findings from this analysis will be widely distributed throughout the country.

The Department also intends to work with workforce investment boards to identify constraints and plans to issue guidance to the public workforce investment system in the fall of 2008 that will provide specific examples on how local service providers successfully serve youth at varying skill levels, but with an emphasis on youth most in need. In addition, the Department will provide technical assistance to support the implementation of this guidance.

*Question.* How have the funding reductions noted in the GAO report impacted program performance, including youth participation and outcomes?

*Answer.* Although fewer total youth have been served through the Workforce Investment Act (WIA) Youth program, more of the youth being served are out-of-school youth who require more intensive services. Despite this challenge, there has been no significant change to the performance outcomes of participants in the WIA Youth program. In its report, the Government Accountability Office State that the increased Federal coordination efforts currently underway should help to address the challenges faced by local programs.

#### NATIONAL FARMWORKER JOBS PROGRAM

*Question.* According to the Department's website, the National Farmworker Jobs Program (NFJP) entered employment rate rose from 64 percent in the quarter ending 9/30/06 to 76 percent in the quarter ending 9/30/07, an increase of almost one-fifth in the percentage of exiters who found jobs. This sounds like an effective investment. Did the Department base its decision to eliminate program funding on some other outcome information? If not, why would the Department propose eliminating funding for this successful program?

*Answer.* Individuals being served by the National Farmworker Jobs Program (NFJP) have similar types of barriers to full-time employment as other workers, and the relatively small NFJP do not provide its participants with the full array of benefits they would derive from the public workforce investment system. Historically, many program participants received only supportive services in the NFJP. Rather than placing farmworkers into a program that has not always provided year-round employment to its participants, the Department believes that these workers should have access to the full spectrum of workforce investment services and a broader employment network.

For the past 6 fiscal years (fiscal year 2003–2008), the administration has not requested budget authority for Workforce Investment Act section 167 NFJP. Instead, the Department has pursued other strategies to ensure agricultural employers and farmworkers have access to the full spectrum of workforce investment services available through the broader workforce system, including:

- Providing technical assistance and information to increase the level of collaboration and coordination among One-Stop partners to increase services to farmworkers in the One-Stop system; and
- Investing \$1 million in a cross-training demonstration in California focused on integrating services available to farmworkers.

*Question.* Previously, the Department has stated that one of the reasons funding has not been requested for this program is that migrant and seasonal farmworkers can be served through the workforce investment system. Does the Department have any data that reflect service levels to this population through the workforce system?

*Answer.* The most recent performance data pertaining to services provided through Wagner-Peyser Employment Service funding indicates approximately 150,000 migrant and seasonal farmworkers have been served in PY 2007.

*Question.* State and local workforce boards have developed plans to address this population. What evidence do you have that activities planned are actually being implemented? Is there any evidence that they are resulting in effective services to migrant and seasonal farmworker population?

*Answer.* The Department has been actively implementing a strategy within the current National Farmworker Jobs Program (NFJP) and Workforce Investment Act (WIA) programs to integrate farmworker services into the broader public workforce investment system. The States have provided the Department with preliminary indications that State and local workforce boards have been expanding the network of employers using the workforce investment system, targeting occupations in high-growth industries and operationalizing the integration of services.

The most recent WIA State Plans included specific State and local activities:

- The Missouri workforce system has established a strong partnership with the NFJP grantee. This partnership results in the sharing of knowledge and collaboration to perform planned community activities and intake for the migrant

and seasonal farmworker (MSFW) population. The combined local expertise of faith-based, community, and other organizations that specialize in serving the MSFW population have increased the capacity and effectiveness of the One-Stop system.

- The New Mexico Workforce Centers will provide on-site services in local workforce investment areas where the MSFW population is employed.
- Tennessee will conduct an outreach program designed to contact MSFWs who are not reached by usual intake activities and inform them of the full range of services available.

Additionally, since WIA requires the Department to conduct a biennial grant competition for the NFJP, the last three Solicitations for Grant Applications have required applicants to design their programs around priorities engineered to continue the drive towards the full integration of services. The next round of grant applications is due June 2, 2008. In reviewing these applications, the Department will look for additional indicators of improved service delivery for farmworkers.

*Question.* The National Agricultural Workers Survey (NAWS) is an employment-based, random survey of the demographic, employment, and health characteristics of the U.S. crop labor force. It has been more than 3 years since the 2001–2002 report was released and I understand the Department collected the 2003–2004 data some time ago. When will the 2003–2004 report be issued? What is the timeline for future data collections and reports related to the NAWS?

*Answer.* The Department's Employment and Training Administration (ETA) is currently working on two National Agriculture Workers Survey (NAWS) national level findings reports. The first report will summarize NAWS data collected in fiscal years 2003 and 2004; the second will summarize fiscal years 2005–2006 NAWS data. ETA expects both of these reports to be available via the NAWS Web site in August, <http://www.doleta.gov/agworker/naws.cfm>.

NAWS data are collected annually in three interview cycles. The third interview cycle for fiscal year 2008 began on June 3, 2008 and is expected to continue through September 2008. The first interview cycle of fiscal year 2009 will begin in October 2008. Depending on the availability of resources, NAWS reports are published biannually. The summary report of the fiscal 2007–2008 findings is expected to be available by September 2009.

ETA has focused its efforts over the last 2 years in developing and obtaining approval for release of a NAWS public access data set. This decision was prompted by the large number of requests for a wide range of data and findings from the NAWS.

We are very pleased to report that the public access data set covering fiscal years 1989 to 2006, as well as the codebook, English and Spanish versions of the questionnaire, the interviewer training manual, and documents describing the statistical methodology and tips for analyzing the data, were posted to the NAWS Web site in November 2007. The release of these materials was announced to all State Workforce Agencies and liaisons via Training and Employment Notice 18–07, <http://wdr.doleta.gov/directives/attach/TEN/ten2007/TEN18-907acc.pdf>.

#### YOUTHBUILD

*Question.* Congress passed legislation to move the YouthBuild program to the Department of Labor in response to the White House Task force on Disadvantaged Youth recommending that YouthBuild was better aligned with the DOL's mission to bring the most disadvantaged youth into productive employment. How do you see YouthBuild fitting into that mission and how is this first year going? And, how do you plan to expand to meet the growing demand for YouthBuild services?

*Answer.* The YouthBuild model balances in-school learning, geared toward a high school diploma or GED, and construction skills training, geared toward career placement. The in-school component is an alternative education program that assists youth who are often significantly behind in basic skills to obtain a high school diploma or GED credential. The primary target populations for YouthBuild are high school drop-outs, adjudicated youth, youth aging out of foster care, and other at-risk youth populations. The YouthBuild model enables these youth to access the education and training they need to secure employment in the 21st century economy.

The first year of administering the YouthBuild program is going extremely well. The YouthBuild Transfer Act was enacted on September 22, 2006. Since that time, the Department has:

- Held its first YouthBuild grant competition in the spring of 2007 and awarded 96 grants on October 15, 2007;

- Developed, implemented, and trained grantees on a Web-based Case Management and Performance system that provides quarterly performance reports and captures performance data on the effectiveness of the YouthBuild program;
- Initiated the process of developing regulations for the YouthBuild program;
- Provided on-going technical assistance to YouthBuild grantees; and
- Created an oversight structure for grant monitoring.

In fiscal year 2009, the program will continue to provide job placement and employment opportunities for disadvantaged youth, and will serve an estimated 3,200 participants.

#### COMMUNITY SERVICE EMPLOYMENT FOR OLDER AMERICANS

*Question.* The 2009 budget proposes \$350,000,000 for the Community Service Employment for Older Americans program, a reduction of \$171,625,000 from the 2008 level. This would result in a cut in the number of authorized training slots from 59,316 supported by the 2008 appropriation to 36,300 allowed by the budget request. What appropriation level is needed in 2009 to avoid the reduction proposed in the 2009 President's budget?

*Answer.* An fiscal year 2009 Appropriation of \$571,924,872 would be needed to fund the number of slots funded by the 2008 level (59,316 slots).

#### ASSISTANCE TO OLDER WORKERS

*Question.* The recently released report "Current strategies to employ and retain older workers" which was commissioned by the Department to support the Task Force on the Aging of the American Workforce highlights the challenges older workers face, particularly with low skills, in the labor market. Many SCSEP participants have additional barriers to employment that WIA programs are less suited to adequately assist.

With deep cuts proposed to the workforce system and the elimination of funding for the Employment Service, One-Stop centers will have fewer resources with which to attempt to serve effectively this population. How can the administration request cuts to this program, once again, at a time when our senior population continues to grow with low employment prospects?

*Answer.* The fiscal year 2009 budget request complements the administration's proposal for job training reform, which seeks to provide services in a more cost-effective way and will benefit older workers, as well as others. Overall, the fiscal year 2009 budget makes a substantial investment in job training to the benefit of all workers, including older individuals.

Older workers are a diverse group. Some older workers have retired and want to or need to go back to work for self-fulfillment or financial reasons, or both. Other older workers are approaching retirement and are looking for more flexible alternative employment that will allow them to balance work, leisure, and the pursuit of other interests. Still others have lost their jobs due to business closures and downsizings before they qualify for a pension or Social Security and they need a new job, often in a different career field, to support themselves and their families until they are eligible for retirement. What these workers have in common is the need to acquire new skills to qualify for jobs in today's labor market. The Career Advancement Accounts proposed by the administration offer a flexible new approach that will allow older workers in each of these situations to obtain the training and education they need to obtain new jobs.

Older workers will benefit from the administration's reform proposals in other ways, too. The requirements relating to the eligibility of training providers, which under current law have had the unintended consequence of deterring many training providers from participating in WIA, would be simplified. This change in eligibility requirements will substantially increase the number of training providers, such as community colleges, and provide participants with a greater availability of choices. Also, training will be available for incumbent workers to help them move up career ladders. Most important, the public workforce investment system will be made more productive, with three times the number of workers trained compared with the current system—this means more opportunities for older workers.

#### STATE UNEMPLOYMENT INSURANCE AND EMPLOYMENT SERVICE OPERATIONS

*Question.* What is the 5-year funding history of obligations for automation investments, including the most recent year for which information on such obligations is available? How have these investments contributed toward the goals of detecting overpayments and facilitating re-employment?

*Answer.* Between fiscal year 2004 and fiscal year 2008, \$12.8 billion was appropriated for State Unemployment Insurance (UI) Administration. Of that amount,

the Department has information on a relatively small portion, approximately \$83.7 million or 0.658 percent, that it allocated to the States for specific automation investments. Additionally, States have used appropriated funds allocated for overall UI program administration, as well as a significant amount of State funds, to make automation investments. However, information about the specific uses of those funds is not collected. Such funds were typically used for major automation acquisitions, such as the replacement of computer hardware and the modernization of State benefit and tax system software systems. These major modernization projects usually cost between \$30 million to \$70 million.

The \$83.7 million the Department provided the States for specific automation investments was used as follows:

- \$6.9 million was obligated to States specifically for integrating a software package developed by the Department into their UI and Workforce automated systems that significantly improve the accuracy and efficiency of UI claimant occupational coding. Improving the accuracy of occupational coding ensures that those charged with providing re-employment services have the best information available to match UI claimants to employment opportunities.
- \$31.6 million was obligated to correct information technology (IT) security vulnerabilities identified through IT security audits. These improvements help protect electronically stored data (personal identifiable information and wage information) that States store on virtually every worker in the country that if stolen could lead to identity theft, fraudulent UI claims, and other problems for the affected workers.
- \$15.6 million purchased systems that support the detection and collection of improper payments, such as tools to aid the investigation of potential overpayments and the collection of outstanding overpayment debts.
- \$12.9 million implemented a variety of systems that helped detect fraudulently filed claims, such as multiple claims filed from the same telephone number or multiple benefit payments going to the same address.
- \$6.8 million was used for State system changes necessary for electronic access to the National Directory of New Hires which allows States to determine if UI beneficiaries have recently returned to work anywhere in the country and are ineligible to claim and collect UI benefits.
- \$6.7 million allowed States to cross-match information provided by UI claimants with other sources of information, such as departments of motor vehicles to ensure the claimants' identity, or prison records to ensure inmates were not collecting benefits.
- \$1.8 million helped implement debit cards as a means of paying UI benefits, thus, improving efficiency and also preventing stolen benefit checks.
- \$0.7 million implemented electronic access to the Social Security Administration database to validate Social Security Numbers of UI claimants, thereby eliminating the possibility of an individual using a bogus number to collect benefits fraudulently.
- \$0.7 million for internal security software to monitor employee access to confidential records to detect unusual patterns that might signal fraudulent activity.

#### RE-EMPLOYMENT AND ELIGIBILITY ASSESSMENTS GRANTS

*Question.* The Department is requesting \$40 million for the re-employment eligibility assessments initiative, to build on the grants that have been made available over the past several years. What has the experience been with this initiative in terms of helping UI claimants find jobs faster, thereby reducing the duration of unemployment and saving UI trust fund resources? Have sufficient resources been available to provide all of the follow-up services required to make this an effective initiative?

*Answer.* The Department conducted an evaluation of Reemployment and Eligibility Assessment (REA) programs in 2006 and 2007. The evaluation's final report was published in March 2008. Nine States were part of the evaluation which included an in-depth analysis of the REA initiative in two of these States, North Dakota and Minnesota. The findings of this study indicated strong positive effects on Unemployment Insurance (UI) claimants' return to work, as well as significant cost savings for the States. The analysis suggests that REAs are an effective strategy for reducing overpayments and expediting return to work.

In addition to the results from this evaluation, there is anecdotal evidence from several other States suggesting that REAs have demonstrated impact. For example, Maine and New York have independently conveyed the following information:

—During the period from April 2005 through March 2006, New York showed a savings of \$1.9 million from reduced benefit durations of claimants participating in REAs versus a comparison group. The savings were \$3 for each \$1 invested in REAs.

—During the period from June 15, 2005, through June 15, 2006, Maine calculated savings at more than \$2 million, or \$3.33 for each \$1 invested.

As a result, the Department is now pursuing further analysis of the REA initiative, as the aforementioned savings mean fewer dollars expended from the States' UI trust funds, which translates into lower taxes on employers. The planned analysis will benefit from obtaining impact and cost data from three to five States. This in-depth study will yield reliable statistical estimates of UI trust fund savings, duration reductions, and re-employment impacts, as determined for UI recipients who participate in the REA initiative.

Because of the demonstrated success of the REA initiative, some participating States requested additional funds to expand their REA programs statewide. Additionally, 11 States not currently participating with REA submitted strong proposals to implement an REA initiative in 2008. However, funds were not appropriated to expand the REA initiative.

We are not aware of resource constraints for re-employment services resulting from REA activities. An interim evaluation report indicated that the participating States saw the REA initiative as an opportunity to expose more claimants to available re-employment services.

#### STATE UNEMPLOYMENT INSURANCE AND EMPLOYMENT SERVICE OPERATIONS

*Question.* The 2009 budget justification indicates that ETA will use the 2008 appropriation for the disability program navigator initiative to support States whose grant ended on June 30, 2008 as recommended by the committee. How many of those States and new States have expressed interest in such funds? ETA also is working with States to identify alternative sources of funding. What resources have been identified to support the DPN initiative and make it sustainable without a separate funding stream?

*Answer.* Currently, 31 Disability Program Navigator (DPN) grants will expire on June 30, 2008. All 31 States have indicated an interest in receiving funds to continue their DPN grant work.

The Department has issued the annual program planning guidance instructing the State DPN grantees on how to revise and submit key program documents necessary to receive program funding in the next year, and we are now reviewing their submissions. We will award the remaining Program Year (PY) 2007 funds by June 30, 2008, and awarding new PY 2008 funds shortly after July 1, 2008. We are also extending the period of performance for all 31 States for an additional year, until July 1, 2009. By August 2008, a new Solicitation for Grants (SGA), with \$2.5 million in PY 2008 funds, will be disseminated to fund cooperative agreements for States and territories that do not currently have a DPN grant. Those States and territories are: American Samoa, Guam, Virgin Islands, Arkansas, Kentucky, Nevada, North Dakota, and Wyoming. When the Department issued an SGA for DPN funding over a year ago, several of these States were not interested in applying, and we do not know how many of these eight States and territories will now apply for DPN funding.

We have been encouraging the States with DPN cooperative agreements to develop sustainability strategies and plans. Such plans include seeking funds from Medicaid Infrastructure Grants, Vocational Rehabilitation agencies, the Workforce Investment Act 15 percent State set-aside, the Department of Transportation's related programs, other public or private organizations, or as an Employment Network (EN) under the Social Security Administration's newly revised and issued Ticket to Work Program regulations. The new Ticket to Work regulations make it much easier for the One-Stop Career Centers and State/Local Workforce Investment Boards to become ENs, thereby simplifying their ability to get reimbursed for eligible customers they are already serving.

#### EMPLOYMENT SERVICE GRANTS TO STATES

*Question.* According to the Government Accountability Office's (GAO) 2007 Study of One Stop Centers, WIA funds and Employment Services Grants to States are the primary funding sources for the one-stop infrastructure. GAO reports that over the last 4 years, 19 States have reported a decrease in the number one stop centers, often citing a decrease in funds as one of the primary reasons.

Some States reported an increase in demand for services. Given the proposed consolidation of programs and the reduction in funding that you propose, how will the Department ensure that unemployed people receive the services they need?

Answer. The services needed by unemployed people will continue to be provided under the fiscal year 2009 budget request, which complements the administration's proposal for job training reform. This reform proposal would consolidate the Employment Service and the Workforce Investment Act Adult, Dislocated Worker, and Youth funding streams into a single funding stream to be used for Career Advancement Accounts and employment services. This consolidated funding stream will provide services in a more cost-effective way by eliminating duplication, replacing the current siloed system of separate training programs, reducing administrative and overhead costs, and, most importantly, significantly increasing the number of individuals who receive job training. Under the current system, approximately 200,000 individuals receive training through the public workforce investment system each year. However, the proposed reforms would increase the number of workers trained to over 600,000.

Additionally, an estimated 10,878,000 participants would receive employment services. The need for labor exchange services, such as resume posting and job search assistance, have largely been privatized and job seekers now have free access to Internet job boards that allow them to search for jobs and often post their resumes.

#### ASSISTANCE WITH MAKING TRAINING DECISIONS

*Question.* The Department proposes to significantly restructure the way unemployed people receive the services they need to once again become productively employed. Part of the new strategy would be to consolidate ES and WIA and to shift more funds into training vouchers for the unemployed and much less funding into up front services such as counseling and assessment. Yet GAO has found that such case management services are integral to ensure that unemployed people get the right services and the most appropriate training that will lead to a job. How will the budget proposal help the unemployed make good training decisions and effectively use the vouchers you propose?

Answer. Some individuals will undoubtedly need the assistance of career counselors in making training decisions, and States and local areas can provide this type of assistance with the portion of funds that can be used for employment services. This includes counseling, both basic and intensive, and assessment. However, many, if not most individuals, will be able to make training choices through a basic up-front assessment (as contrasted with ongoing and costly case management) and good consumer information on training providers. The Department of Labor also funds the development of workforce information, including information on high-growth occupations, which may be useful in making these decisions; under the administration's WIA reform proposal this funding will be provided to the States as part of the consolidated grant.

Under the Career Advancement Account (CAA) proposal, States would be required to ensure the credibility and accountability of training providers. States would also ensure that CAA recipients have sufficient consumer information on the quality and outcomes of the education and training provided by the institutions where the accounts can be used. Furthermore, it is in the State's interest to ensure that high quality training is provided in order to meet performance outcomes.

Findings from the Individual Training Account (ITA) Experiment have informed the development of our Workforce Investment Act reauthorization and CAA proposal. The outcomes of this demonstration suggest that (1) additional counseling and career guidance do not significantly affect the employment and training outcomes of participants; (2) more people access training with ITAs when given individual choice and flexibility; and (3) individuals are capable, on their own, of choosing an appropriate training path that leads to sustainable employment. Furthermore, approximately 5 million low income individuals receive Pell Grants each year through a rather flexible process. The use of CAAs should provide similar flexibility.

#### FEDERAL SUPPORT OF EMPLOYMENT SERVICES

*Question.* The Department acknowledges in their fiscal year 2009 budget justification a majority of States (35 States) have integrated WP Act services into their one-stop career centers, and only a minority of States are running separate and duplicative systems of employment services. Because of this alleged duplication of services in a small minority of States, the Department concluded all Employment Services funds should be eliminated. In the majority of States where services are already integrated, how will States continue to undertake employment service activities with-

out Federal support? What actions has DOL taken to support better integration in the minority States that have not achieved it?

Answer. Employment services will continue to receive Federal support, but through the Workforce Investment Act (WIA) One-Stop delivery system. The fiscal year 2009 budget request complements the administration's proposal for job training reform, which seeks to provide services in a more cost-effective way. This reform proposal would consolidate the Employment Service and WIA Adult, Dislocated Worker, and Youth funding streams into a single funding stream to be used for Career Advancement Accounts and employment services. In addition to eliminating the duplication between the Employment Service and WIA One-Stop delivery system that still exists in a number of States, it would replace the current siloed system of separate training programs, reduce administrative and overhead costs, and, most importantly, significantly increase the number of individuals who receive job training.

In addition, under our budget request, an estimated 10,878,000 participants would receive employment services. While this represents a smaller number of individuals receiving labor exchange services, it needs to be recognized that the recruitment process has changed and because much more is available to individual workers. The need for labor exchange services, such as resume posting and job search assistance, have largely been privatized and job seekers now have free access to Internet job boards that allow them to search for jobs and often post their resumes.

In order to strengthen program integration within the One-Stop Career Centers in States that have not achieved it, the Department offers technical assistance through tools such as Workforce<sup>3</sup>One, the Department's interactive communications and learning platform, which is designed to build the capacity of the workforce investment system, and Workforce Innovations, the Department's annual workforce system and partners conference.

The Department also uses the WIA/Wagner-Peyser Act State Plan process as a vehicle for States and workforce investment boards to set forth policy expectations for program integration. As part of a State plan modification required to be submitted by each State in 2007, States were specifically required to (1) describe policies in place to change or modify barriers to integration; (2) describe more efficient uses of administrative resources, such as eliminating duplicative facility and operational costs; (3) promote models or strategies for local use that support integration; (4) describe how services provided through One-Stop partners will be coordinated; and (5) describe how States will coordinate Wagner-Peyser Act funds to avoid duplication. The Department regularly monitors State WIA and Employment Service programs, including implementation of the integration strategies outlined in their State Plans, and offers technical assistance to States that require it.

#### OFFICE OF FOREIGN LABOR CERTIFICATION

*Question.* The Department's budget lacks any measures of program integrity with respect to program performance under the foreign labor certification program. This is a major management challenge identified by the DOL inspector General due to the existence of fraud and vulnerabilities in this program. What actions are being implemented in 2008 and are proposed in the 2009 to address this challenge? How will resources proposed in the 2009 budget request be used specifically to both improve the timeliness and increase the integrity of the certification process? What performance measures related to program integrity is the Department considering for this program?

Answer. These critical activities are an integral part of our ongoing application processing, and the Department will undertake a number of measures in fiscal year 2008 and fiscal year 2009 to strengthen the integrity of its employment-based immigration programs.

The following are actions that are being implemented in fiscal year 2008 or are planned for fiscal year 2009 based on resources contained in the fiscal year 2009 budget request:

- Establishment of a new Fraud Detection and Prevention Division within OFLC.
- Implementation of the most recent regulation amending the permanent labor certification program, "Labor Certification for the Permanent Employment of Aliens in the United States: Reducing the Incentives and Opportunities for Fraud and Abuse and Enhancing Program Integrity," which includes the authority to debar employers, attorneys, and or agents in certain specific circumstances.
- Linkage of the web-based technologies currently used in the Permanent Labor Certification Program (PERM) program to the H-1B database. This technology will add greater efficiency in confirming the status of employers filing applica-

tions and support both the timeliness and integrity of the PERM program. This action will begin in January 2009 as a pilot under a re-engineered Labor Condition Application form (ETA Form 9035).

- The PERM program application (ETA Form 9089) is expiring and has been significantly re-engineered based upon program experience over the past 3 years. This re-engineering will include changes to the database “behind” the actual application and its accompanying audit flags and triggers. The new system is set to be operational in January 2009.

Many of these integrity activities have the potential to lengthen the timeliness of case processing. However, the Department plans to monitor and review appropriate performance indicators both before and after the additional integrity functions are implemented.

Additionally, the Department has begun collecting new internal measures that will be used to track fraud and integrity efforts. These measures include the number of:

- Referrals or follow-ups by the Office of the Inspector General, the Department of Homeland Security, or others;
- Grand Jury testimonies or other witness testimonies;
- Targeted audits;
- Cases assigned to supervised recruitment;
- Program debarments initiated;
- Cease and desist orders issued; and
- User accounts disabled as a result of inappropriate usage.

#### OIG AUDIT ON CONSULTATION PROGRAM

*Question.* The budget proposes to increase funding for OSHA’s voluntary protection programs by \$5 million over the 2008 amount. However, DOL’s Inspector General found in a 2007 Audit Report that consultation program officials did not ensure the existence of interim protection for serious hazards before granting employers’ requests for additional time to correct them; OSHA considered serious hazards as “corrected in a timely manner” if employers completed corrective actions within 14 days of the latest correction due date agreed to by the consultant, rather than the original date corrective action is expected; and employers were not referred for enforcement action because they feared it would discourage employers from participating in this voluntary program.

What specific actions have been taken by DOL to address the findings and recommendations of the IG, including the recommendation related to the performance measure for “timely” correction of serious hazards with which OSHA disagrees? What has the impact been of these actions in terms of timely correction of serious hazards relative to the original due date; and referral of employers for enforcement for not correcting serious hazards?

*Answer.* The proposed increase of \$5.1 million in the Compliance Assistance budget activity for fiscal year 2009 represents inflationary increases and the restoration of funding and staffing eliminated by the across-the-board budget reductions in the fiscal year 2008 Consolidated Appropriation. This same approach was taken in all OSHA budget activities and does not represent programmatic increases for any specific program area.

In response to the audit by the Office of the Inspector General (OIG) on the consultation program, OSHA accepted all four of the recommendations contained in the report to tighten and ensure compliance with existing program requirements by State consultants. OSHA’s Assistant Secretary highlighted the OIG’s recommendations and reinforced the importance of adhering to the corresponding corrective actions being taken by the agency in a memorandum sent to OSHA Regional Administrators and Consultation Project Managers in October 2007.

With respect to the recommendations made by the OIG, OSHA added a provision in the Consultation Cooperative Agreements that required documentation of good faith efforts and all available interim protection measures being taken by employers whenever an extension was made for the correction of serious hazards. OSHA also added a provision to the Agreements in response to another OIG recommendation to require notification of the proper OSHA enforcement authority if an employer fails to take the action necessary to correct a serious hazard within the established time frame. In accordance with a third OIG recommendation, OSHA established a specific performance measure related to the initial correction due date of serious hazards. Finally, in response to the remaining recommendation for OSHA to provide guidance to States on acceptable types of interim protections, the October 2007 memorandum from OSHA’s Assistant Secretary contained information on the availability of resources and guidance for States in the selection of acceptable interim



protection. The OIG accepted all of OSHA's actions as being responsive to its recommendations.

#### ATTRACTING AND RETAINING STAFF

*Question.* Many Federal agencies are facing human capital changes associated with the retirement of the baby boom generation. Please describe OSHA's plan for attracting and retaining individuals with the skills and abilities OSHA needs to carry out its mission. What level of resources is proposed in fiscal year 2009 to carry out OSHA's plan?

*Answer.* OSHA has used training dollars and Departmental and Government-wide programs to assist in succession planning and leadership development. The agency has also successfully utilized the Department of Labor's Senior Executive Service candidates' program, Management Development and the Masters in Business Administration Fellows' program to invest in its human capital.

In addition, OSHA will continue to explore three levels of leadership development. Technical/Professional (GS-11/12 employees), Supervisory/Management (GS-13/14 employees), and Executive Development (GS-14/15 employees). The agency will also use programs for the hiring of summer interns to expose students and others to the mission of the agency.

The OSHA Training Institute (OTI) provides training and education in occupational safety and health for Federal and State compliance officers, and State consultants, by offering a series of basic, intermediate and advanced courses. To meet the continuing need for highly trained CSHOs, OSHA has developed a new training program for newly hired and experienced compliance personnel. The curriculum is designed to ensure that more comprehensive training is provided to compliance personnel so they are better equipped to apply technical information and skills in their work.

#### OSHA STANDARDS AND GUIDANCE ACTIVITY

*Question.* For each of the past 15 years, please provide the number of notices of proposed rulemaking, final rules, guidance/informational materials and SBREFA reviews conducted or issued by OSHA.

*Answer.* The three charts below provide the requested information:

#### OSHA FINAL AND PROPOSED RULES BY YEAR, 1993–2007

Year	Proposed rules <sup>1</sup>	Final rules <sup>1</sup>
1993 .....	Occupational Exposure to 2-Methoxyethanol, 2-Ethoxyethanol and their Acetates (Glycol Ethers).	Air Contaminants (remand) Lead Exposure in Construction—Interim Rule Permit-Required Confined Spaces
1994 .....	Retention of Markings and Placards (DOT) Permit Required Confined Spaces (general industry). Respiratory Protection Longshoring and Marine Terminals Abatement Verification Indoor Air Quality	Electrical Power Generation, Transmission, and Distribution; Electrical Protective Equipment Reporting of Fatality or Multiple Hospitalization Incidents Personal Protective Equipment for General Industry Logging Operations Occupational Exposure to Asbestos Safety Standards for Fall Protection in the Construction Industry Confined and Enclosed Spaces and Other Dangerous Atmospheres in Shipyard Employment Retention of DOT Markings, Placards, and Labels
1995 .....	Powered Industrial Truck Operator Training (general industry).	Occupational Exposure to Lead Basic Program Elements for Federal Employee Occupational Safety and Health Programs; Record keeping Requirements Basic Program Elements for Federal Employee Occupational Safety and Health Programs

## OSHA FINAL AND PROPOSED RULES BY YEAR, 1993–2007—Continued

Year	Proposed rules <sup>1</sup>	Final rules <sup>1</sup>
1996 .....	Exit Routes (Means of Egress) ..... Miscellaneous Changes to General Industry and Construction Standards; Proposed Paperwork Collection, Comment Request for Coke Oven Emissions and Inorganic Arsenic. Occupational Injury and Illness Recording and Reporting Requirements. Powered Industrial Truck Operator Training (construction).	Personal Protective Equipment for Shipyard Employment (PPE) Safety Standards for Scaffolds Used in the Construction Industry Occupational Exposure to 1,3-Butadiene
1997 .....	Occupational Exposure to Tuberculosis .....	Occupational Exposure to Methylene Chloride Reporting Occupational Injury and Illness Data to OSHA Abatement Verification Longshoring and Marine Terminals
1998 .....	Methylene Chloride ..... Dipping And Coating Operations (Dip Tanks) Safety Standards for Steel Erection	29 CFR Parts 1910 and 1926 Standards Improvement (Miscellaneous Changes) for General Industry and Construction Standards; Paperwork Collection for Coke Oven Emission and Inorganic Arsenic Methylene Chloride Powered Industrial Truck Operator Training Permit-Required Confined Spaces Procedures for the Handling of Discrimination Complaints Under Federal Employee Protection Statutes Occupational Exposure to Asbestos Respiratory Protection Dipping and Coating Operations
1999 .....	Ergonomics Program ..... Nationally Recognized Testing Laboratories; Fees; Reduction of Public Comment Period on Recognition Notices. Employer Payment For Personal Protective Equipment.	
2000 .....	None .....	Nationally Recognized Testing Laboratories—Fees Occupational Exposure to Cotton Dust
2001 .....	None .....	Safety Standards for Steel Erection Occupational Exposure to Bloodborne Pathogens; Needlestick & Other Sharps Injuries Occupational Injury and Illness Recording and Reporting
2002 .....	Fire Protection in Shipyard Employment ..... Standards Improvement Project—Phase II	Occupational Injury and Illness Recording and Reporting Requirements (hearing loss) Exit Routes, Emergency Action Plans, and Fire Prevention Plans Safety Standards for Signs, Signals, and Barri-cades
2003 .....	Longshoring and Marine Terminals; Vertical Tandem Lifts. Assigned Protection Factors Controlled Negative Pressure REDON Fit Testing Protocol. Commercial Diving Operations	Procedures for the Handling of Discrimination Complaints Under Section 519 of the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century

## OSHA FINAL AND PROPOSED RULES BY YEAR, 1993–2007—Continued

Year	Proposed rules <sup>1</sup>	Final rules <sup>1</sup>
2004 .....	Occupational Exposure to Hexavalent Chromium Steel Erection; Slip Resistance of Skeletal Structure Steel. Electrical Standard (subpart 5)	Commercial Diving Operations Fire Protection in Shipyard Employment Controlled Negative Pressure REDON Fit Testing Protocol Fire Protection in Shipyard Employment Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters; Subpart I for Record keeping and Reporting Requirements Updating OSHA Standards Based on National Consensus Standards; General, Incorporation by Reference; Hazardous Materials, Flammable and Combustible Liquids; General and Environmental Controls, Temporary Labor Camps; Hand and Portable Powered Tools and Other Hand Held Equipment, Guarding of Portable Powered Tools; Welding, Cutting, and Brazing, Arc Welding and Cutting; Special Industry, Sawmills Procedures for the Handling of Discrimination Complaints Under Section 806 of the Corporate and Criminal Fraud Accountability Act of 2002, Title VIII of the Sarbanes-Oxley Act of 2002
2005 .....	Electric Power Generation, Transmission, and Distribution; Electrical Protective Equipment (Subpart V).	Standards Improvement Project—Phase II Procedures for the Handling of Discrimination Complaints Under Section 6 of the Pipeline Safety Improvement Act of 2002 Roll-Over Protective Structures
2006 .....	None .....	Occupational Exposure to Hexavalent Chromium Updating OSHA Standards Based on National Consensus Standards in OSHA's Standard for Fire Protection Assigned Protection Factors Occupational Exposure to Hexavalent Chromium (amendment to implement settlement agreement)
2007 .....	Abbreviated Bitrex® Qualitative Fit-Testing Protocol. General Working Conditions in Shipyard Employment. Confined Spaces in Construction Updating OSHA Standards Based on National Consensus Standards; Personal Protective Equipment. Explosives	Procedures for the Handling of Retaliation Complaints Under the Employee Protection Provisions of Six Federal Environmental Statutes and Section 211 of the Energy Reorganization Act of 1974, as Amended Electrical Standard (subpart S) Employer Payment for Personal Protective Equipment Updating OSHA Standards Based on National Consensus Standards

<sup>1</sup> Proposed and final rules include traditional health and safety standards, rules concerning Federal agency standards, anti-discrimination, and the process by which OSHA recognizes Nationally Recognized Testing Laboratories (NRTLs).

Proposed and final rules do not include rules that are purely administrative, grants, technical amendments, corrections notices, withdrawals, changes to State plan and consultation regulations, and procedural notices such as extensions of comment periods, hearing notices, and extensions of compliance dates. They also do not include alternate standards for Federal agencies, variance application notices, and the recognition of specific NRTLs.

Direct final rules are published with a concurrent proposed rule. For this table, both notices are counted as one final rule.

**SUMMARY OF THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA) SMALL BUSINESS  
ADVOCACY REVIEW PANELS MANDATED BY THE SMALL BUSINESS REGULATORY ENFORCEMENT  
FAIRNESS ACT OF 1996**

Rule title	Date convened	Date completed	Published NPRM <sup>1</sup>	Final rule published
Tuberculosis .....	09/10/96	11/12/96	10/17/97	.....
Safety & health program rule .....	10/20/98	12/19/98	.....	.....
Ergonomics program standard .....	03/02/99	04/30/99	11/23/99	11/14/00
Confined spaces in construction .....	09/26/03	11/24/03	11/28/07	.....
Electric power generation, transmission, and distribution .....	04/01/03	06/30/03	06/15/05	.....
Occupational exposure to Crystalline Silica .....	10/20/03	12/19/03	.....	.....
Occupational exposure to Hexavalent Chromium .....	01/30/04	04/20/04	10/04/04	02/28/06
Cranes and derricks in construction .....	08/18/06	10/17/06	.....	.....
Occupational exposure to Beryllium .....	09/17/07	01/15/08	.....	.....

<sup>1</sup> Notice of Proposed Rulemaking (NPRM) published in the Federal Register.

A number of guidance products were issued by OSHA in the 1990s associated with rulemaking efforts and include such items as booklets and brochures that summarize employer responsibilities as well as Hazard Information Bulletins (now called Safety and Health Information Bulletins or SHIBs). OSHA has made an effort to compile a comprehensive listing of its work products responsive to this question but it is difficult to ensure a completely accurate catalogue of these products since no itemized database was ever maintained prior to 2005. Over the past 15 years, the issuance of electronic guidance has become a much more common and effective way to disseminate information than publishing guidance in print. Virtually all current OSHA compliance assistance products are posted on OSHA's public Web site at <http://www.osha.gov/pls/publications/publication.html>. OSHA began a compliance assistance database in 2005 to track non-policy guidance from its national office (this excludes such items as enforcement compliance directives, which are often used by employers as guidance for how to interpret standards). The following table includes guidance that has been issued by OSHA's national office since 2005.

Product name	Type
29 CFR Part 1910. Subpart T, Commercial Diving Operations Directive ....	Directive (with outreach component)
Abrasive Blasting in Shipyards .....	Guidance Document
Aerial Lifts .....	Fact Sheet
Aerial Lifts Card .....	Card
All About OSHA .....	Booklet
All Terrain Vehicles .....	Safety and Health Information Bulletin (SHIB)
Application of HAZWOPER to Worksite Response and Cleanup Activities ...	Guidance Document
Asbestos .....	Fact Sheet
Asbestos-Automotive Brake and Clutch Repair Work .....	Safety and Health Information Bulletin (SHIB)
Avian Flu Quick Card: Animal Handlers .....	Card
Avian Flu Quick Card: Food Handlers .....	Card
Avian Flu Quick Card: General Precautions .....	Card
Avian Flu Quick Card: Health Care Workers .....	Card
Avian Flu Quick Card: Laboratory Workers .....	Card
Avian Flu Quick Card: Poultry Workers .....	Card
Avian Flu fact sheet .....	Fact Sheet
BLSR Hazards Associated with E & P Waste Liquids .....	Safety and Health Information Bulletin (SHIB)
Basic Steel Products .....	Safety and Health Topics Page
Best Practices for the Safe Use of Glutaraldehyde in Health Care .....	Guidance Document
Business Case for Safety .....	Safety and Health Topics Page
Carbon Monoxide Card .....	Card
Chain Saws .....	Fact Sheet
Chain Saws Card .....	Card
Chippers Card .....	Card
Cleaning Industry .....	Safety and Health Topics Page
Cleanup Hazards .....	Fact Sheet
Combustible Dust .....	Safety and Health Topics Page
Combustible Dust Explosions .....	Fact Sheet
Combustible Dust in Industry: Preventing and Mitigating the Effects of Fire and Explosions.	Safety and Health Information Bulletin (SHIB)
Concrete and Concrete Products: Manufacturing and Construction .....	Safety and Health Topics Page
Confined Spaces Card .....	Card

Product name	Type
Confined Spaces Poster .....	Poster
Confined Spaces, Atmospheric Testing Card .....	Card
Construction eTool, Spanish translation .....	eTool
Container Gantry Crane Radio Communication on Marine Terminals .....	Fact Sheet
Crane Safety Card .....	Card
Critter fact sheet: Black Widows .....	Fact Sheet
Critter fact sheet: Brown Recluse Spiders .....	Fact Sheet
Critter fact sheet: Cottonmouth (Water Moccasin) .....	Fact Sheet
Critter fact sheet: Fire Ants .....	Fact Sheet
Decontamination, General .....	Fact Sheet
Decontamination, General (Card) .....	Card
Demolition Safety Tips .....	Fact Sheet
Demolition Safety Tips Card .....	Card
Downed Electrical Wires .....	Fact Sheet
Drop-in Article: Lay press on landscaping safety for summer jobs among teens.	Other
Drop-in Article: Protect Your Working Teen from Machinery Hazards .....	Other
Drop-in Article: Protect Your Working Teen from Pesticides .....	Other
Drop-in Article: Protect Your Working Teen from Strains and Sprains .....	Other
Drop-in Article: Protect Your Working Teen from Summer Sun and Health Illnesses.	Other
Electricity, Working Safely With .....	Fact Sheet
Electricity, Working Safely With (Card) .....	Card
Entanglement Hazards of Augur Drilling .....	Safety and Health Information Bulletin (SHIB)
Ergonomic Guidelines for Shipyards .....	Guidance Document
Ergonomic Solutions for Electrical Contractors: Installation and Repair Module.	eTool
Ergonomic Solutions for Electrical Contractors: Prefabrication Module .....	eTool
Ergonomics Guidelines for Shipyards .....	Guidance Document
Ergonomics for the Printing Industry: Flexography Module .....	eTool
Ergonomics for the Printing Industry: Lithography Module .....	eTool
Ergonomics for the Printing Industry: Screen Printing Module .....	eTool
Fire Department S&H Topics Page .....	Safety and Health Topics Page
Fire Service Features of Buildings and Fire Protection Systems .....	Booklet
First Aid Best Practices .....	Guidance Document
Flavorings-Related Lung Disease .....	Safety and Health Topics Page
Flood Cleanup .....	Fact Sheet
Four Leading Construction Hazards .....	Card
Four Leading Construction Hazards Card .....	Card
Frequently Asked Questions for OSHA's Injury and Illness Recordkeeping Rule for Federal Agencies.	FAQs
Fungi Hazards and Flood Cleanup .....	Fact Sheet
Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Guidance Document.	Guidance Document
Guardrail System for Tunnel Form Stripping Platform .....	Safety and Health Information Bulletin (SHIB)
Guidance for Hazard Determination .....	Guidance Document
Guidance on Preparing Workplaces for a Potential Pandemic Influenza ....	Guidance Document
Guidance on Safe Sling Use .....	Guidance Document
Hand Hygiene and Gloves .....	Fact Sheet
Hand Hygiene and Gloves Card .....	Card
Handling Human Remains .....	Fact Sheet
Hazard Communication Guidance for Diacetyl and Certain Food Flavorings Containing Diacetyl.	Guidance Document
Hazards Associated With Transporting Granite and Marble Slabs .....	Safety and Health Information Bulletin (SHIB)
Hazards of Manually Lifting Balloon Framed Walls .....	Safety and Health Information Bulletin (SHIB)
Hazards of Manually Lifting Balloon Framed Walls (Spanish translation).	Safety and Health Information Bulletin (SHIB)
Hazards of Unintended Movement of Dump Truck Body Beds .....	Safety and Health Information Bulletin (SHIB)
Hazards of Wood Chippers .....	Safety and Health Information Bulletin (SHIB)
Hazards with Hand-Feeding Bar Straightening Machines .....	Safety and Health Information Bulletin (SHIB)
Health Effects of Hexavalent Chromium .....	Fact Sheet
Hearing Conservation Issues for the Hearing Impaired .....	Safety and Health Information Bulletin (SHIB)
Hearing Loss in Construction Toolbox Training .....	Guidance Document
Heat Stress .....	Fact Sheet
Hexavalent Chromium FAQs .....	FAQs
Hexavalent Chromium Fact Sheet(s) .....	Fact Sheet

Product name	Type
Hexavalent Chromium Small Entity Compliance Guide .....	Guidance Document
Hexavalent Chromium fact sheet .....	Fact Sheet
Hospitals and Community Emergency Response—What You Need to Know.	Booklet
Hydrogen Sulfide .....	Fact Sheet
Hydrogen Sulfide Card .....	Card
ICS Survival Sheet .....	Other
Inspection Guidelines for the Chromium (VI) Standards .....	Directive (with outreach component)
Inspection Procedures for 29 CFR 19.10.120 and 1926.65(q): Emergency Response to Hazardous Substance Releases.	Directive (with outreach component)
Latex SHIB .....	Safety and Health Information Bulletin (SHIB)
Lead Hazards .....	Fact Sheet
Lead in Construction .....	Fact Sheet
Lead in Construction Card .....	Card
Longshoring and Marine Terminal .....	Directive (with outreach component)
Machine Guarding eTool: Thermoforming Module .....	eTool
Marine Terminal Fall Protection for Personnel Platforms .....	Fact Sheet
Mass Care Shelter Workers Checklist .....	Guidance Document
Mold .....	Fact Sheet
Mold Card .....	Card
Motor Vehicle Safety Guidance for Employers to Reduce Motor Vehicle Crashes.	Brochure
OSHA Guidance Update for Protecting Workers From Avian Flu (Influenza).	Guidance Document
OSHA Poster .....	Poster
Occupational Exposure to Ethylene Oxide .....	Guidance Document
Oil and Gas Well Drilling, Servicing and Storage: Storage Tank Module ...	Safety and Health Topics Page
Overhead Launching Gantry Crane .....	Safety and Health Information Bulletin (SHIB)
Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers.	Guidance Document
Personal Protective Equipment: Construction .....	Card
Pest Control Pyrotechnics .....	Card
Portable Generators .....	Fact Sheet
Portable Generators Card .....	Card
Portable Generators: Grounding .....	Fact Sheet
Portable Ladder Safety .....	Card
Portable Ladder Safety Card .....	Card
Potential Flammability Hazard Associated With Bulk Transportation of Oilfield Exploration and Production Waste Liquid.	Safety and Health Information Bulletin (SHIB)
Preparing and Protecting Security Personnel in Emergencies .....	Guidance Document
Preventing Falls .....	Fact Sheet
Preventing Falls Card .....	Card
Preventing Mold-Related Problems in the Indoor Workplace: A Guide for Building Owners, Managers, and Occupants.	Guidance Document
Preventing the Uncontrolled Release of Anhydrous Ammonia at Loading Station.	Safety and Health Information Bulletin (SHIB)
Psychological First Aid Materials and Information .....	Other Web Products
Quick Start: Construction Module .....	Other Web Products
Quick Start: Health Care Module .....	Other Web Products
Recordkeeping Handbook .....	Guidance Document
Rescue of Animals (Dogs) by Disaster Relief Personnel .....	Card
Respiratory Disease Among Employees in Microwave Popcorn Processing Plants.	Safety and Health Information Bulletin (SHIB)
Respiratory Protection Card .....	Card
Respiratory Protection Guidance for Employers and Workers .....	Safety and Health Information Bulletin (SHIB)
Rodents, Snakes, and Insects Card .....	Card
Safe Driving Quick Card .....	Card
Safeguarding Equipment and Protecting Workers from Amputations .....	Booklet
Safety Hazards of Overloaded Cable Trays .....	Fact Sheet
Safety Pays Advisor .....	eTool
Safety and Health Cheddist for Community Service Organizations Engaged in Disaster Recovery Demolition and Construction Activities.	Guidance Document
Scaffold Quick Card (#2): Supported Scaffold Inspection Tips .....	Card
Scaffolding (Supported) Card .....	Card
Search and Rescue .....	Fact Sheet

Product name	Type
Seasonal Influenza Vaccinations—Important Protection for Healthcare Workers.	Fact Sheet
Shipyard .....	Directive (with outreach component)
Shipyard Employment: Fire Protection Module .....	eTool
Shipyard eTool: Barge Cleaning module .....	eTool
Shipyard eTool: Best Practices for Marine Hanging Staging Module .....	eTool
Shipyard eTool: Ship Breaking module .....	eTool
Shipyard eTool: Ship Building module .....	eTool
Silicosis Card .....	Card
Teen Worker Bookmark (OSHA/WHDD) .....	Other
Tips for Improving Workplace Safety and Health .....	Fact Sheet
Traffic Safety in Marine Terminals .....	Guidance Document
Tree Care Industry .....	Safety and Health Topics Page
Tree Trimming .....	Fact Sheet
Tree Trimming Card .....	Card
Trenching and Excavation Safety .....	Fact Sheet
Use of Blunt Suture Needles to Decrease Percutaneous Injuries to Surgical Personnel.	Safety and Health Information Bulletin (SHIB)
Use of Blunt Tip Suture Needles to Decrease Percutaneous Injuries to Surgical Personnel.	Safety and Health Information Bulletin (SHIB)
West Nile Virus .....	Fact Sheet
West Nile Virus Card .....	Card
Whistleblower Protection for Employees in the Aviation Industry .....	Fact Sheet
Whistleblower Protection for Employees in the Transportation Sector .....	Fact Sheet
Whistleblower Protection for Employees of Public Transportation Agencies.	Fact Sheet
Whistleblower Protection for Railroad Employees .....	Fact Sheet
Whistleblower Protection for Trucking Employees .....	Fact Sheet
Whistleblower Protections and the Environment .....	Fact Sheet
Work Zone Safety .....	Fact Sheet
Work Zone Safety Card .....	Card
Worker Protection Matrix for Hurricane Response and Recovery Workers ...	eTool
Working Outdoors in Warm Climates .....	Fact Sheet
Young Worker Fact Sheet (Update) .....	Fact Sheet

#### ENHANCED ENFORCEMENT PROGRAM

**Question.** For each of the past 5 years, please provide the number of enhanced enforcement program cases and the associated number of major enforcement outcomes.

**Answer.** If an inspection is classified as an Enhanced Enforcement Program (EEP) case, it may receive additional enforcement efforts such as: an enhanced follow-up inspection to verify that both the cited conditions and other, similar, hazards have been corrected; in cases that can be settled, more comprehensive abatement requirements in the settlement agreements; and potential Federal court contempt enforcement of the citations or settlement provisions pursuant to Section 11(b) of the Occupational Safety and Health Act. In addition, other workplaces of the employer may be inspected through the following mechanisms:

**SST-Related Inspections in General Industry.**—When other establishments of the same corporate employer (other than construction employers) are included on OSHA's current Site-Specific Targeting (SST) primary or secondary inspection lists, they will be moved to the current SST inspection cycle.

**Related Inspections.**—Additional establishments of the same employer in both general-industry and construction may be inspected if there is evidence of showing that the safety and health problems identified in the initial EEP inspection are part of a broader company-wide problem.

The following chart shows data for OSHA's original Enhanced Enforcement Program, which was initiated October 1, 2003.

Fiscal year	EEP 1 inspections	Follow-up inspections	SST-related inspections	General industry-related inspections	Construction-related inspections	Enhanced settlement agreements	11(b) court actions to SOL
2004 .....	314	54	1	2	10	60	5
2005 .....	589	108	19	9	7	88	2
2006 .....	473	128	8	12	12	49	2

Fiscal year	EEP 1 inspections	Follow-up inspections	SST-related inspections	General industry-related inspections	Construction-related inspections	Enhanced settlement agreements	11(b) court actions to SOL
2007 .....	717	174	18	3	6	84	1
2008 <sup>1</sup> .....	277	46	8	4	1	33	1
Totals .....	2,370	510	54	30	36	314	11

<sup>1</sup> From 10-1-07 thru 5-22-08.

On January 1, 2008, OSHA issued its revised Enhanced Enforcement Program. The revision changed the EEP criteria to place greater emphasis on those employers that have a history of violations with OSHA (including history with State Plans).

Because there are significant differences between the original EEP (EEP 1) program as implemented in October 2003, and the revised EEP (EEP 2) program initiated in January 2008, the data from the two programs are not directly comparable and are reported separately.

The following chart shows data for OSHA's revised Enhanced Enforcement Program, which was initiated January 1, 2008:

Fiscal year	EEP 2 inspections (number of fatalities)	Follow-up inspections	SST-related inspections	General industry-related inspections	Construction-related inspections	Enhanced settlement agreements	11(b) court actions to SOL
2008 <sup>1</sup> .....	<sup>1</sup> 13	.....	.....	.....	.....	.....	.....
Total .....	<sup>1</sup> 13	.....	.....	.....	.....	.....	.....

<sup>1</sup> From 1-1-08 thru 5-22-08.

#### WHISTLEBLOWER ACTIVITY

*Question.* What is OSHA's experience to date in terms of workload numbers and time involved in carrying out new whistleblower/anti-discrimination protections provided for in recent legislation, such as the 9/11 Commission bill? What does the budget assume for these workloads in fiscal year 2009?

Answer. To date, cases filed under the Federal Rail Safety Act (FRSA) and the National Transit Security Systems Act (NTSSA), the whistleblower provisions of which were assigned to OSHA in the Implementing Recommendations of the 9/11 Commission Act of 2007, constitute less than 2 percent of OSHA's caseload. Based on past experience, the cases can be expected to increase as public awareness of the laws increase. The new statutes require a great deal of deliberation, as the agency works to address novel jurisdictional and coverage issues, develops implementing regulations, establishes working relationships with the agencies that enforce the substantive provisions of those laws, and develops and plans to deliver comprehensive training to investigators and supervisors.

OSHA's fiscal year 2009 budget includes a total workload estimate of 2,055 whistleblower-case investigations and a discussion of the challenges of administering these new whistleblower statutes, but individual workload estimates are not established for each statute administered by the agency.

#### OSHA INFORMATION SYSTEM

*Question.* Please provide more detail on the major steps, timeline, and costs for fiscal year 2008 and 2009 associated with the OSHA Information System. What are the outcomes expected to be achieved under this new information system?

Answer. When fully implemented, OSHA's Information System (OIS) will replace the agency's current data system, the Integrated Management Information System (IMIS). The current project timetable for the OIS schedules full deployment by the end of fiscal year 2010. During fiscal year 2008 and 2009, work will be continued in three major areas: system design, a pilot to test approximately 20 percent of the total function for the new system, and completion of system development. OSHA estimates that OIS will cost \$24 million to fully implement by September 30, 2010.

When OIS is fully implemented, the agency will have an enhanced ability to more quickly identify local trends unique to States or counties, and to predict emerging trends such as new hazardous chemicals affecting workers. Unlike the current system, the analytical tools employed by OIS will have the capacity to recognize and detect events and occurrences that are unique to specific industry sectors and geographical areas, allow improved targeting and utilization of resources for both en-



forcement and compliance assistance activities, and more accurately set and monitor progress towards reaching performance targets.

#### SUSAN HARWOOD TRAINING GRANTS

*Question.* The budget once again proposes to eliminate funding for the Susan Harwood Training grants and Institutional Competency Building grants programs. What proportion of the grantees under these programs met their performance goals, based on a review of the most recent grant periods for which data are available?

*Answer.* The most recent period for which Susan Harwood Training grant data are available for grantees that completed their programs is fiscal year 2007. This activity reflects grants awarded in fiscal year 2006. The data indicate that 82 percent of Susan Harwood Training grantees met or exceeded their performance goals. Current Institutional Competency Building grantees are operating several years beyond the initial period designed for their development and 100 percent of them met or exceeded their performance goals originally established for them.

#### RECORDKEEPING AUDITS

*Question.* During the budget hearing, Secretary Chao stated that OSHA completes inspections of employer recordkeeping of workplace injuries. Please describe specifically the steps involved in these recordkeeping audits. How many have been done for each of the last 5 years and what specifically did these audits find? Do these audits include a specific and effective attempt to identify injury cases missing from the employer logs? What follow-up actions were taken in response to findings of inaccurate logs?

*Answer.* OSHA collects injury and illness data from a universe of approximately 130,000 employers in high-rate industries for the purpose of identifying individual high-rate establishments for potential OSHA interventions. The program for conducting recordkeeping audits involves (1) onsite visits to a statistically valid sample of establishments that submitted data to OSHA; (2) a sample of employees within the establishment selected for inspection; (3) a comprehensive review of documentation concerning any injuries or illnesses for each employee file selected; and (4) a comparison of recordable cases discovered from the employee files compared with the establishment's original OSHA 300 log to determine if any cases discovered were (or were not) properly recorded on the log. The audit program also entails (1) an interview of the recordkeeper; (2) comparison of the log summary data found onsite and the data the employer submitted to OSHA for the agency's Data Initiative; and (3) employee interviews.

The following table reflects the number of audits completed over the past 5 years and their findings:

Year	Reference year data	Number of audits	Percent of establishments classified with accurate recording for total recordable cases (at-or-above the 95 percent threshold of accuracy)
2003 .....	2001	246	95.53
2004 .....	2002	252	94.84
2005 .....	2003	251	92.43
2006 .....	2004	256	95.70
2007 .....	2005	245	( <sup>1</sup> )

<sup>1</sup> Analysis pending.

Accuracy data pertain to the number of establishments recording correctly and does not attempt to estimate the actual number of instances where cases may have been under or over reported. The audit protocol was specifically designed to detect unrecorded cases as well as mis-recorded and over-recorded cases. This is done through a comprehensive onsite review of multiple record sources including medical records, workers compensation records, first-aid logs, and employee interviews. The sampling methodology was independently developed by the National Opinion Research Center at the University of Chicago to allow estimates of recordkeeping accuracy. Since these audits are conducted as part of an OSHA inspection, violations discovered are cited and require abatement by the employer.

## CRANES AND DERRICKS STANDARD

*Question.* Nearly 4 years after labor and management reached consensus on a safety standard for cranes and derricks, a proposed rule has yet to be issued. In the meantime, workers continue to be hurt and killed. On March 6 workers and one member of the public was killed in a crane collapse in New York City. Several days later two more workers lost their lives in a crane collapse in Miami, Florida. What is OSHA's timeline for completing action on this issue? Why has there been such a delay in moving forward based on the consensus reached 4 years ago?

*Answer.* The cranes and derricks proposed rule will comprehensively address the hazards associated with the use of cranes and derricks in construction. As a consequence, this complex rule has required extensive time to conduct the required analyses and reviews. Pursuant to requirements enacted by Congress, OSHA is required to conduct a regulatory flexibility analysis, small business review, and paper-work burden analysis of the proposed rule. In addition, OSHA is required to explain the basis and purpose of the rule. OSHA anticipates issuing a notice of proposed rulemaking for this standard in Fall 2008.

## EMPLOYEE BENEFITS SECURITY ADMINISTRATION

*Question.* As you may know, I have long been involved in maximizing retirement security for Americans. I am deeply concerned by the growing shift from secure defined benefit pensions to 401(k) plans. That is why I appreciate the Department's focus on fees associated with these plans, and as you know I have also introduced legislation on this critical issue. Studies show a small percentage increase in fees can have a dramatic impact on overall retirement security. I have a couple of questions for you on this front.

Clearly, there are a number of parties that need to be made aware of plan fees. Of most interest to the press and public is the information that participants receive, since most plans are participant-directed and they pay most of the fees. However, the plan sponsor actually bears fiduciary responsibility in selecting plans that best serve the participants' interests and as they select plan options with reasonable fees, the participant ends up being in the happy position of choosing from several favorable options. And finally, in order to keep an eye on these plans, the Government needs information on fees.

So far the Department has issued regulations on the information that the Government and plan sponsors receive—when do you plan to issue regulations on the information that participants get?

*Answer.* The Department has developed proposed regulations concerning the disclosure of plan fee and expense information to plan participants and beneficiaries which are now in the final stages of review. We anticipate publication of our proposal in the Federal Register in early summer.

## DISCLOSURE TO PLAN SPONSOR REGULATIONS

*Question.* With regard to the proposed regulation on disclosure to plan sponsors, I have sent a comment letter detailing all of my concerns with the proposed rule. I have also heard from plan sponsors and providers who have commented to DOL about this rule.

Can you discuss how these comments are being integrated and what the timeline currently is anticipated in issuing a final rule?

*Answer.* In December 2007, the Department published a proposed regulation and related prohibited transaction class exemption concerning the disclosure of service provider compensation and conflicts of interest information to plan sponsors. To date, the Department has received over 100 public comments on this regulatory initiative. Further, the Department conducted 2 days of administrative hearings on March 31 and April 1 of this year to further develop the public record and to provide Department representatives an opportunity to obtain additional information concerning the many issues raised by public commenters.

The Department currently is reviewing these comments, as well as testimony presented at the public hearings, and analyzing the proposed regulation and class exemption in light of the legal, technical, and practical issues that have been raised. We have been and continue to pursue the goal of transparency for plan sponsors who are engaging service providers and selecting investment products for their plans, and we intend to finalize this regulatory initiative by November 2008.

## ADMINISTRATIVE FEES

*Question.* I want to clear up specifically a debate that seems to be raging about bundled services. I keep hearing that it doesn't matter if plan sponsors understand

all of the various kinds of fees that participants are being charged as long as the overall level is competitive. However, that doesn't take into account things like whether some costs are reasonable over time. For example, the cost per participant to administer a plan for 100 people is going to be significantly higher than the per participant costs for a plan covering five times as many people.

So how is a plan sponsor to gauge the reasonableness of administrative fees as their plan grows if they only know the overall fee level that includes asset-based fees and investment fees? Don't you think that insuring reasonable administrative costs is inherent to fiduciary responsibility?

Answer. ERISA prohibits the payment of fees to service providers unless the plan pays no more than reasonable compensation. Plan fiduciaries have an obligation to make sure that the plan is getting its money's worth whenever it makes an investment or enters into a contract with a service provider. To do so, the fiduciary needs to understand how much the plan is going to pay and what it is going to get in return. In order to make a judgment about whether fees are reasonable, the fiduciary needs to understand precisely what services are being rendered, the quality of those services, and whether the fees are structured in such a way that the interests of the service provider run counter to the interest of the plan.

When administrative and investment fees are "bundled" together, for instance when they both are assessed through asset-based fees, a fiduciary needs to have the information necessary to make these assessments. Whether or not the fiduciary needs to look at the pricing of a particular component, for example administrative expenses, is likely to depend on the facts and circumstances. For example, in many instances, it may be relatively easy for the fiduciary to assess the benefits of purchasing each service separately or in a bundle simply by looking at the competitor's prices for the individual services. In such cases, if the contract does not give the service provider any improper incentives, the aggregate price may be all that matters to the plan. The fact that fees are bundled does not necessarily mean that the services and fees are hidden or that the plan is paying more for bundled services than if services were selected individually.

#### PENSION BENEFITS GUARANTY CORPORATION

*Question.* I am very interested in movement by the PBGC as mentioned in the fiscal year 2009 budget request to modify investment policy more aggressively to reduce the long-term shortfall in obligations. I ask that you keep Congress fully apprized of such strategies as you move forward. I see that there could be some benefit in this approach, as reserves can be shored up without further increasing the strain on employer contributions, which in turn strains their ability to provide guaranteed benefit plans to their workers. However, this must be balanced with the investment policy that will not increase risk unduly. On a related note, I am hearing rumors of activity by the PBGC to examine whether to allow third-party financial institutions to purchase assets in frozen pension plans. I find this concept deeply troubling. ERISA of course requires that plan fiduciaries manage pensions solely in the interest of the participant. I fail to understand how adding another profit motive to the equation is accomplishing that requirement. Furthermore, I believe that an employer has more interest in protecting participant assets than a third party financial institution.

Can you please comment on the PBGC's activity with regard to examining such plan asset sales?

Answer. The three ERISA agencies have been approached by several financial institutions interested in assuming sponsorship of frozen pension plans from employers. The various proposals would transfer sponsorship and all aspects of plan administration and plan asset investment from the employer to a newly created subsidiary of the financial institution, which would become the new plan sponsor. Because the proposals involve ongoing plans that will not terminate, primary regulatory responsibility for these proposals rests with the Internal Revenue Service and Department of Labor. The IRS is actively examining whether such transactions are consistent with the requirements of the Internal Revenue Code. PBGC has asked the financial institutions to clarify the possible risks and benefits to plan participants and the pension insurance program.

#### WAGE AND HOUR DIVISION

*Question.* Please provide the information requested in last year's 2008 Senate committee report related to the misclassification of workers and enforcement efforts in low-wage industries.

Answer. ESA is working to finalize the requested report, and expects to transmit the full report to the Congress in the near future.

*Question.* Staffing for the wage and hour division has fallen by 20 percent from 2001 to 2008. What has been the impact of this reduction on the mission of the wage and hour division?

*Answer.* The Wage and Hour Division's (WHD) mission is to promote and to achieve compliance with labor standards to protect and to enhance the welfare of the Nation's workforce. The President's fiscal year 2007 budget requested an additional increase of \$6 million to hire 39 FTE for WHD. The fiscal year 2008 budget requested an additional increase of \$5 million to hire 36 FTE for WHD. The fiscal year 2009 budget request includes funding to hire an additional 75 Wage and Hour enforcement staff to target resources on industries and workplaces that employ low-wage, immigrant workers.

As has long been its mission, WHD is committed to protecting workers, particularly in low-wage industries. To make the best use of resources, WHD employs complementary strategies—enforcement, compliance assistance, and partnerships—that strengthen the agency's ability to protect the employment rights of workers in low-wage industries and to promote compliance by covered employers.

We believe the ultimate impact of the resources we are given is shown in the enforcement results that WHD has achieved, rather than in the number of FTEs. In fiscal year 2007, WHD recovered more than \$220 million in back wages, the largest amount ever, for over 341,600 employees, the second largest number since 1993. Since fiscal year 2001, WHD has recouped more than \$1.25 billion for nearly 2 million workers.

*Question.* For each of the past 10 years, what share of wage and hour resources has been dedicated to self-directed investigations versus employee complaint-initiated actions?

*Answer.* WHD has the following data for the past 10 years relating the percent of concluded cases that are self-directed and the percent of concluded cases that are initiated as a result of a complaint.

Fiscal year	Self-directed cases as a percent of concluded cases	Complaint-based cases as a percent of concluded cases
1998 .....	29.1	70.9
1999 .....	27.9	72.1
2000 .....	27.5	72.5
2001 .....	30.7	69.3
2002 .....	25.7	74.3
2003 .....	26.7	73.3
2004 .....	23.4	76.6
2005 .....	22.6	77.4
2006 .....	22.7	77.3
2007 .....	23.3	76.7

*Question.* What has the impact been on wage and hour's ability to respond effectively to employee wage and hour complaints?

*Answer.* In fiscal year 2007, WHD investigators concluded complaint cases in 97 days on average. This is less than the 108 average numbers of days that it took to conclude complaint cases in fiscal year 2003. WHD has also improved the effectiveness of its complaint intake strategies and this has increased the percent of WHD complaint investigations that find violations of WHD laws. In fiscal year 2003, 72 percent of WHD complaint investigations, excluding conciliations, found violations. By the end of fiscal year 2007, 79 percent of complaint investigations found violations.

#### BUDGET JUSTIFICATION OF SPENDING FOR SPECIAL PERSONAL SERVICES PAYMENTS AND OTHER PERSONNEL COMPENSATION

*Question.* The Employment Standards Administration (ESA) budget justification (page ESA-19 for 2009 and page ESA-17 for 2008) shows a significant increase in the 2008 estimate of spending for special personal services payments and other personnel comp. The 2008 spending on such activities increases from \$3.6 million under the president's 2008 request (which ESA did not receive) to \$6.6 million, an increase of more than 80 percent. What is the explanation for such a dramatic increase in this category of spending? Specifically, how does this proposed spending support the goals of ESA?

*Answer.* After further review, we realize that our initial response to an informal question from the committee was incomplete. The appearance of a significant in-

crease in the fiscal year 2008 estimate of spending for “special personal services payment and other personnel comp” is the result of the Employment Standards Administration’s (ESA’s) inconsistent use of some of the detailed budget object classes for personnel compensation. This issue, which became known when the Department implemented its new budget system that displayed a more detailed object class breakout, has been corrected.

Although the fiscal year 2008 funding for object class 11.5 was included in the requested funding level for 11.0 (Total Personnel Compensation, which includes funding for regular salaries, as well as awards, overtime, and other personnel costs), it was not displayed in detailed object class 11.5 as it should have been. It was, unfortunately, displayed in other object classes within 11.0. With the implementation of the Department’s new budget system, ESA is now providing a more accurate object class breakout.

Moreover, in fiscal year 2008, ESA requested a total amount of \$267.879 million for total personnel compensation (11.0), but was appropriated only \$253.264 million—\$14.615 million less than requested. The actual amount enacted for fiscal year 2008 for total personnel compensation was reflected correctly in the fiscal year 2009 submission.

#### OFFICE OF LABOR-MANAGEMENT STANDARDS

*Question.* According to the Department’s evaluation of the Labor Management Reporting and Disclosure program, OLMS technology creates a problem for timely filing of required reports, as do difficulties with understanding LM form instructions and recordkeeping. What steps is OLMS taking in 2008 and planning in 2009 to address these findings? What level of resources will support these actions?

*Answer.* In fiscal year 2007, DOL contracted with Eastern Research Group (ERG) for an analysis and evaluation of the OLMS reporting and disclosure program. In its October 31, 2007 report, ERG stated that, in general, “OLMS has well established, organized, and documented policies and procedures in place to assist union officers in complying with LMRDA reporting requirements, to encourage compliance, and to rectify compliance problems with individual unions.” The report also noted that issues with electronic filing and difficulties with understanding LM form instructions represent obstacles to union compliance with LMRDA reporting.

To obtain further information on electronic filing difficulties, DOL commissioned ERG to perform a cost benefit analysis regarding potential improvements to the OLMS Electronic Labor Organization Reporting System (e.LORS). The e.LORS system provides labor organizations with the capability to electronically submit their reports, enables OLMS personnel to secure and analyze reported data, and provides a means for public disclosure of LM reports filed by labor organizations through an Online Public Disclosure Room.

In its March 14, 2008 report, ERG noted four concerns with the current e.LORS system and recommended that OLMS replace the Adobe Forms and Adobe Server components of e.LORS with a Web-based alternative that would alleviate all of the business and technical gaps. ERG also suggested that an alternative “pin and password” process could replace the existing electronic signature requirement, and that the existing date query system could be replaced with a more versatile web-based application.

OLMS has been reviewing ERG’s recommendations and expects to develop a plan to implement selected ERG recommendations. Congressional assistance will be important to implementing this plan, as fiscal year 2009 budget considerations will affect the extent to which ERG recommendations can be implemented. Meeting the President’s budget level is critical to improving e.LORS.

OLMS is also focusing on compliance assistance to help union officers better understand the LM Form instructions. At mid-year fiscal year 2008, OLMS field offices had completed 50 compliance assistance sessions to over 1,300 attendees. These sessions assist attendees on how to understand the LM forms and instructions.

OLMS’ existing metric of “percent of union reports meeting standards of acceptability” was created in 2003 prior to the advent of substantial numbers of unions filing reports electronically. At that time only 73 percent of paper reports met the criteria of “acceptability,” meaning that the form was facially compliant with the LMRDA (i.e., that required information fields were filled out) but not measuring accuracy or otherwise evaluating the filing. Thus, a report that meets the minimum level of “acceptability” may nevertheless contain serious deficiencies. Consistent cooperation with unions and extensive compliance assistance along with free software developed by OLMS and provided to unions, which assists in ensuring acceptability by pointing out facial inaccuracies or missing information, has allowed OLMS to increase the “acceptability” measure to 95 percent. As noted in the 2007 Performance

and Accountability Report, OLMS plans to replace the acceptability measure with a new performance measure—increased electronic filing—which would drive continuing improvements in LMRDA reporting compliance, provide more timely disclosure of reports and improve agency efficiency in managing reports and public disclosure.

A new baseline for electronic filing is being developed this year and future reports will use that baseline to measure OLMS performance. Acceptability remains a component of the new metric because as more unions file electronically, the percentage of reports meeting standards of acceptability also will rise.

*Question.* How does the OLMS track who uses the Union Reports.gov website and how is the information used to support the purposes of the LMRDA? Please provide the number or share of hits by different types of visitors, such as union members, employers, academics, etc.

Answer. OLMS does not collect information on who uses the union reports disclosure site and, therefore, has no way of determining the number or share of hits by different types of visitors. In calendar year 2006, OLMS recorded 79,319 visits to its Online Public Disclosure Room ([www.unionreports.gov](http://www.unionreports.gov)) home page, and in calendar year 2007 there were 228,154 visits.

The following chart provides more specific information with regard to 2007.

Month	Union/trust Search	Payer/payee Search	Officer/employee Search	Yearly
Jan .....	41,071	1,917	4,548	1,274
Feb .....	36,814	1,608	4,290	1,184
Mar .....	34,353	1,521	3,987	1,168
Apr .....	27,745	1,065	2,777	839
May .....	44,454	1,986	5,202	1,674
Jun .....	43,207	2,062	4,646	1,790
Jul .....	43,227	2,233	4,579	1,842
Aug .....	36,378	1,598	4,330	1,456
Sep .....	35,228	1,376	3,419	1,311
Oct .....	31,766	1,358	3,597	1,262
Nov .....	19,406	770	2,053	761
Dec .....	16,351	724	1,654	591
Yearly total .....	410,000	18,218	45,082	15,152

The first column shows the number of union financial disclosure reports retrieved or searched from the disclosure site. The second column shows the number of queries seeking to retrieve data on payments from a union to a particular individual or company, or vice versa. The third column shows the number of queries concerning transactions involving union officers or union employees. The fourth column shows the number of times the contents of the database were downloaded.

The number of searches exceeds the number of visits to the disclosure home page because a single visit may involve multiple searches and individuals may access the disclosure site through a bookmarked page or by other means that circumvent the disclosure home page.

One of the primary purposes of the LMRDA is to publicly disclose the financial conditions and operations of labor organizations. See 29 U.S.C. § 435 (Reports Made Public Information). “By such disclosure, and by relying on voluntary action by members of labor organizations, abuses can be eradicated effectively.” Senate committee report, S. Rep. No. 187 (1959), at 15. Publicly disclosed information empowers union members to become educated about their labor organization, to express knowledgeable opinions at membership meetings, and to cast informed votes at union officer elections.

#### FAMILY AND MEDICAL LEAVE

*Question.* Family and Medical Leave Enforcement: I frequently hear from constituents the hardships they are having because their FMLA claims are denied, many of them incorrectly, but in some cases, in ways that would become legal under this new regulation. I have heard the following complaints:

- The employer requires diagnosis of health condition on FMLA form.
- The employer contacts the worker’s medical provider directly and demands more medical information than required under regulations.
- Multiple employers are refusing to approve completed FMLA paperwork or they frequently ask employees to return to health care provider for more information

- at great inconvenience to workers who are already spending a great deal of time coping with a chronic health condition.
- Employers fail to inform employees of rights to FMLA when they ask for medical leave.
- The employer issues attendance points for absences that should have been covered under FMLA.
- The employer asks for recertification more often than allowed under regulations.
- The employer attempts to limit the amount or frequency of intermittent leave for a serious health condition.
- The employer uses FMLA absences to downgrade an employee's performance rating or evaluation.

I would like to know if the Department has considered the complaints they have received from the field about employers engaging in the very same activities that the regulations would permit.

Answer. On February 11, 2008, the Department of Labor published proposed revisions to certain regulations implementing the Family and Medical Leave Act of 1993 (FMLA). The public comment period closed on April 11, 2008, and the Department is carefully reviewing all of the 4,500 comments that it received from workers, employers, health care providers, and other stakeholders.

#### AMERICAN TIME USE SURVEY

*Question.* The American Time Use Survey provides critical information on Americans' work and commuting schedules, the time they spend taking care of children and sick adults, the time teenagers spend doing homework and all of the other activities that make up Americans' days. The survey costs only \$4.3 million per year. Over 1,500 researchers (including 4 Nobel Prize winners) signed a statement requesting that the Congress restore funding for the American Time Use Survey.

Why does the Department's budget propose eliminating this critical survey?

Answer. The administration made the decision to eliminate the ATUS in order to partially offset the rising costs of the Current Population Survey (CPS), a Principal Federal Economic Indicator. Eliminating the ATUS—one of BLS's newest and lowest priority surveys—allows BLS to focus its resources on higher priority programs that protect the accuracy and reliability of the monthly data on the Nation's labor force. Also, it is worth noting that not all industrialized countries that conduct time use surveys do so on an annual basis. On the other hand, CPS data—most notably the monthly unemployment rate—are among the Nation's most critical and widely used economic indicators in setting economic and social policies, and the preservation of the survey's sample size is most critical.

#### DOCUMENTING MISSING INJURY CASES

*Question.* According to the Bureau of Labor Statistics website, BLS is taking a number of steps to learn more about research results documenting missing injury cases in individual firms, as determined by comparisons between BLS and State workers' compensation data, and to address any deficiencies in its survey operations.

Please describe the efforts planned or underway in fiscal year 2008 and planned for fiscal year 2009 to address the documents underreporting?

Answer. The annual DOL reports of occupational injury and illness estimates come from the BLS annual Survey of Occupational Injuries and Illnesses (SOII). The survey captures data from Occupational Safety and Health Administration (OSHA) logs of workplace injuries and illnesses maintained by employers. Recent outside research has indicated that both SOII and workers' compensation programs missed cases. Beginning in fiscal year 2008 and continuing into fiscal year 2009, the BLS is examining and extending the results of this research to better understand the research methodology and the nature of the comparisons to determine if any changes in BLS survey operations are needed. In addition, the BLS conducted its own "follow-back" study in fiscal year 2007, with final results tabulated in fiscal year 2008. The results indicate that the survey correctly captured the data that employers recorded on their OSHA logs.

In fiscal year 2008, the BLS began interviewing a small number of SOII respondents to learn about the decisions they make about reporting cases to workers' compensation programs and on the OSHA log. The purpose is to understand situations where workers' compensation cases might not be recorded on OSHA logs and vice versa. These interviews are being conducted by a BLS cognitive survey methodologist. At the request level, the BLS plans to expand the number of these interviews conducted in fiscal year 2009. Finally, the BLS has documented much of its analysis

of the undercount issue to date, and its plans for future research, and will publish a research note in an upcoming issue of the Monthly Labor Review.

The BLS has updated its "Frequently Asked Question" (FAQ) on this topic at <http://www.bls.gov/iif/peoplebox.htm#faqaa>.

*Question.* How much is being spent or planned to be spent in fiscal year 2008?

*Answer.* The BLS plans to spend approximately \$240,000 on these activities in fiscal year 2008.

*Question.* How much is requested in the BLS 2009 budget for these activities?

*Answer.* At the 2009 request level, the BLS expects to spend approximately \$300,000 for the activities described above relating to potential underreporting.

*Question.* The BLS website also indicates that BLS is developing its own "follow-back" study to ensure the survey correctly captures the data that employees have recorded in the OSHA logs and that further research is still being planned as well.

Please describe the follow-back study as well as future research plans?

*Answer.* In 2007, the BLS conducted a quality assurance recontact survey that indicated that BLS survey processes were not responsible for an undercount. A sample of 3,600 establishments who participated in the 2006 survey were recontacted and asked to submit their OSHA logs, used in filling out the SOII survey form, to the BLS. The BLS then compared the OSHA logs to data for the SOII. There was no systematic evidence that the data in the SOII undercounted cases recorded on OSHA logs. This study did not attempt to ascertain whether the OSHA logs were correct or complete; the BLS is not responsible for ensuring the accuracy of OSHA logs from which the survey data is derived.

*Question.* What resources are being allocated to the study or research on this issue in fiscal year 2008?

*Answer.* In fiscal year 2008, BLS completed the final tabulations and the final report on the fiscal year 2007 recontact survey, with minimal staff time used. Under \$90,000 was spent to conduct the study in fiscal year 2007.

*Question.* How much is being requested in 2009 for these areas?

*Answer.* The BLS has no current plans to conduct another recontact survey related to the SOII undercount issue. Therefore, the BLS request includes no funding related to the SOII recontact survey.

#### OFFICE OF DISABILITY EMPLOYMENT POLICY

*Question.* The Department's performance goal for the Office of Disability Employment Policy is to "build knowledge and advance disability employment policy that affects and promotes systems change." The performance targets developed by DOL for this goal include:

- The number of policy related documents issued by ODEP, which falls from 34 in fiscal year 2008 to 8 under the DOL budget request for fiscal year 2009; and
- The number of effective practices developed or validated by ODEP drops from 24 in fiscal year 2008 to 15 under the DOL budget request for fiscal year 2009.

Does DOL believe that ODEP's mission has been completed and there is less of a need for developing effective practices or issuing policy-related documents?

*Answer.* ODEP's mission, "to provide national leadership by developing and influencing disability-related policy and practice affecting the employment of people with disabilities" continues to be an important component of the Department's overall mission. From fiscal year 2004, when it began tracking the number of effective practices it developed, through fiscal year 2007, ODEP's investments resulted in the development and dissemination of 79 effective practices. Since fiscal year 2006, when it began counting the number of policy documents produced as a measure of its performance, ODEP's efforts have produced 54 policy documents. In fiscal year 2009, ODEP will focus its efforts on developing and implementing disability employment policy to increase the recruitment, retention and promotion of people with disabilities, and eliminate duplicative grant making activities. The requested funding level will allow ODEP to develop national policy related to and affecting employment of people with disabilities; foster the implementation of effective policies and practices within State and local workforce systems and with employers; conduct research and analysis that identifies and validates effective disability-employment strategies; and provide technical assistance on implementing effective disability employment policies and practices throughout the workforce development system, its partners and employers. The Department believes that ODEP's mission continues to support the agency's efforts to develop and influence the implementation of policy that reduces barriers to employment.

*Question.* Please explain the goals, operations and outcomes achieved under the ODEP Alliance? How much has been allocated to this Alliance over the past 3 years and the 2009 request?



Answer. The purpose of the Alliance initiative is to increase voluntary collaboration between ODEP and other public entities, including employers, organizations, and institutions. The operations of the Alliance initiative include formalizing the collaborative agreement with the Alliance entity, conducting outreach of the Alliance initiative, and managing specific Alliances. The goals of the Alliance initiative are to promote training and education, disseminate best practices, promote outreach and communication, and advance dialogue that promotes the employment of people with disabilities. Alliances are currently in place with the Society for Human Resources Management (SHRM) and CVS/Caremark.

Since the Alliance initiative began in 2007, the following results have been achieved:

- February 27, 2007: Presentation describing the ODEP/SHRM Alliance to Salisbury (Maryland) Chamber of Commerce members. The Salisbury Chamber is host to the Eastern Shore Business Leadership Network and is a 2003 New Freedom Initiative (NFI) Awardee.
- October 5, 2007: At the 2007 Virginia State SHRM Conference, Driving Competitive Advantage, in Arlington, Virginia, ODEP presented a paper that describes resources being developed to assist employers in hiring, employing and advancing people with disabilities.
- ODEP, together with Job Accommodation Network (JAN) and Employer Assistance & Recruiting Network (EARN) staff, welcomed conference attendees to ODEP exhibits at SHRM Conferences and shared information on ODEP policy initiatives, disability employment practices, and JAN and EARN services. Various ODEP policy advisors attended conference sessions and networked with SHRM members:
- April 23, 2007, Staffing Management Conference and Exposition (750 attendees), New Orleans, Louisiana;
- June 24, 2007, Annual Conference and Exposition (22,000 attendees), Las Vegas, Nevada;
- October 3, 2007, Virginia SHRM Conference (700 attendees), Arlington, Virginia;
- October 18, 2007, Diversity Conference (500 attendees), Philadelphia, Pennsylvania; and
- April 14, 2009, Staffing Management Conference and Exposition (1,200 attendees), Nashville, Tennessee.

As part of a comprehensive outreach effort, since 2007, ODEP has allocated \$100,000 toward its Alliance initiative, and the fiscal year 2009 budget provides \$50,000.

#### LEGAL SERVICE/SOLICITOR'S OFFICE

*Question.* The 2009 budget indicates that the request level for legal services will allow the office to handle 36 percent fewer regulatory projects. Please identify by DOL agency the number of projects completed in fiscal year 2007, planned/completed in 2008 and planned in 2009.

Answer. Because regulatory initiatives vary widely in complexity and the time and resources necessary to complete them, and reflect policy decisions made outside the Office of the Solicitor (SOL) rather than merely workload capacity in SOL, workload projections are based on an average amount of time spent on regulatory projects rather than the number of actual regulations. Assuming each "regulatory project" required the same expenditure of resources, SOL estimates that at the funding level requested in fiscal year 2009, it would be possible to work on approximately 36 percent fewer such projects than fiscal year 2006. The 36 percent decrease was derived by comparing the actual hours spent by SOL attorneys on all regulatory matters in fiscal year 2006 and fiscal year 2007 with the hours that are projected to be available for such work with the resources requested in fiscal year 2009. It should also be noted that some SOL regulatory work includes reviewing non-DOL proposed regulations for their potential impact on DOL-administered laws and regulations. Because these estimates reflect average times spent on average regulatory projects, rather than actual projects, DOL's Semi-Annual Regulatory Agenda (available at [http://www.dol.gov/asp/regs/unifiedagenda/spring\\_2008\\_agenda.pdf](http://www.dol.gov/asp/regs/unifiedagenda/spring_2008_agenda.pdf) and at Regulations.gov) should be consulted for an accurate prediction of the regulatory projects that DOL will complete in the next 12 months.

#### OFFICE OF JOB CORPS

*Question.* During the hearing, Secretary Chao stated that the 2009 budget request maintains a level of service currently offered by the Job Corps. I have heard from

a number of my constituents that the Denison Center in Iowa has had to reduce teaching staff, which means greater class sizes; defer replacement of high school textbooks and aging computers; and a reduction of a daycare provider for their solo parent program.

How is it possible to maintain services at the President's budget level, when I have heard that the last couple years of funding have resulted in program service reductions? What has been the impact of relatively flat funding over the past 2 years on the level of service offered by the Job Corps program?

Answer. Current budgetary constraints require us to make difficult choices with the resources available. The Job Corps program will continue its efforts to find cost efficiencies to offset increases in health, energy and transportation so that we can maximize the number of students served. The 2009 budget request for Job Corps will enable us to maintain the same level of service to its students and keep high levels of performance with respect to job placement, diploma attainment, and numeracy and literacy gains.

*Question.* Additionally, Secretary Chao stated that the Department is "very focused to keep Job Corps a strong program" that serves young people and further stated that a reason for the cut was the unused beds within Job Corps.

If the Department is focused on keeping Job Corps a strong program why wouldn't the Department enhance its investment in recruitment of students?

Answer. Job Corps continues to maintain and develop our recruitment and outreach efforts. Job Corps consistently spent \$6 million for each PY from 1999 through 2005 on its recruitment campaign; Job Corps spent \$5 million in PY 2006 and \$6 million in PY 2007. The recruitment budget for PY 2008 will not be less than PY 2007 funding levels.

In October 2006, all Job Corps recruitment efforts were consolidated under the National Office. Previously, the National Office and each of the six regions had separate outreach support contracts. While the separate regional outreach efforts allowed for regional and center-specific outreach and recruitment approaches, having materials produced by different contractors had the unintended effect of diluting the Job Corps brand and duplicating efforts.

Under this centralized plan, the National Office oversees the creation of Outreach & Admissions (OA) and CTS materials such as brochures and posters for distribution to Regional Offices and OA and CTS project directors. This plan resulted in better utilization of resources by providing economies of scale and allowing the program to have consistent name brand recognition.

*Question.* Why hasn't the Department responded to Congress' directive to develop and implement a national plan to increase enrollment?

Answer. Job Corps has responded to Congress' directive to develop and implement a plan to increase enrollment. Highlights of that report are as follows:

In October 2006, Job Corps' Consolidated Outreach and Recruitment Plan was launched, which combined the outreach efforts of the National Office and its six Regional Offices into a single contract. This allows Job Corps to take advantage of economies of scale and ensures that a single message is communicated to our target audience. With this consolidated plan, OJC rolled out new recruitment materials and television outreach segments as of May 1, 2007. All OA contractors, Regional Offices, and the Job Corps National Call Center are being provided with these national materials.

In May 2007, Job Corps launched the Youth Ambassador program, a program that serves as a student speakers' bureau to introduce Job Corps to potential workforce and recruitment partners. The ambassadors' goals are to: share their Job Corps experiences and success stories to select groups/organizations; help recruit new students; educate target audiences about the benefit of Job Corps; and serve as mentors. Each Job Corps region has two student ambassadors: one primary and one alternate. The first ambassador public speaking training conference was conducted January 7–10, 2008.

Job Corps is also in the process of developing a national recruitment Web site that provides a single portal for prospective students, their parents and other adult influencers; an online application process to further streamline the enrollment process will also be added to the new site. This site will be a public site which will be linked to the primary Job Corps Public website as well as Job Corps Center websites. Users will be able to navigate between the various sites at their discretion.

In addition to the national outreach and recruitment strategies OJC coordinates regional activities as well. Each Regional OJC administers and oversees several Outreach and Admissions (OA) contracts that are responsible for both recruiting and enrolling students in Job Corps centers. Each Region develops a Geographic Assignment Plan (GAP) using a national GAP planning template to ensure consistency across all regions, which assigns specific arrival goals to each OA contractor by spe-

cific Job Corps centers. Regional Offices monitor the success of the OA contractor in reaching these goals and review regional-level data to make adjustments to the GAP as necessary.

It is important to note that the number of students enrolled in the program is not solely a function of recruitment and admissions. In addition to student arrivals, the number of student separations and students' average length of stay also factor into the program's On Board Strength (OBS). A vital component of increasing Job Corps' on board strength (OBS) is student commitment, or the willingness and readiness of a student to remain in the program through graduation. To improve performance in this area, Job Corps has implemented the Speakers, Tutors, Achievement, Retention, and Success program (STARS), offering structured tutoring and mentoring to provide those students at risk of leaving early the encouragement and support necessary to remain longer in the program, thereby increasing the number of program graduates. Furthermore, OJC implemented Career Success Standards (CSS), which incorporates employability and social skills development into all aspects of the program, leading to a more personalized relationship between staff and students, improving center culture, and students' willingness to remain in Job Corps.

To further focus on improving student commitment, retention and to reduce the number of students who leave the program due to drugs or violence, Job Corps implemented a small drug test pilot program in the Philadelphia region. Applicants are tested for drug use prior to admission to further ensure that the program is enrolling students who are committed to their education and ready for the rigor and demands of the program. This pilot will allow Job Corps to determine the effect of pre-enrollment drug screening on retention, early program separation due to drugs and or violence and student outcomes.

The preliminary results of Philadelphia drug screening pilot and the program's early separation analysis provides support that students who enter the program drug-free are more likely to remain in the program beyond 60 days.

Thus, Job Corps is addressing challenges with recruitment and retention throughout the program in order to implement a more holistic solution.

*Question.* Please describe the specific steps the department has taken to strengthen the interaction between outreach/admission contractors and center operators, and to ensure that outreach/admission contractors are effectively carrying out their responsibilities?

*Answer.* Job Corps has historically taken definitive steps to strengthen the interaction between outreach/admissions contractors (OA) and center operators and to ensure that OA contractors are effectively carrying out their responsibilities.

Job Corps' performance management system, entitled the Outcome Measurement System (OMS), is one of the major factors encouraging collaboration between all Job Corps operators and ensuring that each are effectively carrying out their respective responsibilities.

Job Corps' performance management system is comprised of four outcome measurement systems:

- Outreach and Admissions (OA) Report Card
- Center Report Card
- Career Transition Services (CTS)
- Career Technical Training Report Card

Each outcome measurement system assesses performance in specific areas of responsibility with respect to serving students throughout the Career Development Services System (CDSS). Combined, these outcome measurement systems provide a comprehensive picture of performance throughout all phases of students' Job Corps experience. Thus, it is critical that the systems be closely aligned to both encourage collaboration in delivering quality services to students and provide an accurate reflection of efforts towards meeting clearly defined program goals.

Each component of the program's (Outreach Admissions [OA], Center and Career Transition Service [CTS]) report cards contains elements that are impacted by the performance of the other program components. The interdependence is such that one component of the program can not perform well overall if other components are performing poorly.

Additionally, a recent, yet significant, step to hold OA providers accountable and strengthen the interaction between OA contractors and center operators was the implementation of performance based contracts (PBSC) for Outreach and Admissions. Previously only center and career transition operators' contracts were performance based. Effective February 7, 2008, all new OA contract awards have the appropriate performance based contract language added to the contracts.

## VETERAN'S EMPLOYMENT AND TRAINING ADMINISTRATION

*Question.* Approximately 200,000 service members and 90,000 Reserve and National Guard Members are discharged from active duty annually.

Specifically, how is the 2008 appropriation used to ensure their employment rights are being protected and transition and training programs are effective and available?

*Answer.* Regarding the protection of employment rights, the fiscal year 2008 appropriation will be used to train and maintain a corps of over 100 trained investigators in our Regional and State offices throughout the country, six Senior Investigators (one in each Region) and a team of compliance and investigations specialists at the National Office. The fiscal year 2008 appropriation will support our aggressive outreach program to ensure employees and employers understand their respective rights and obligations under the statute. VETS national and regional staff will continue briefing deploying and returning military units, State Chambers of Commerce, State Bar associations and professional associations, and conduct information sessions through a variety of electronic media. We are hopeful that our outreach program will result in fewer USERRA complaints and violations. However, when we receive a USERRA complaint, we thoroughly and promptly investigate to ensure compliance with the law. Under the Transition Assistance Program (TAP) the appropriation supports the delivery of TAP employment workshops and provides VETS with the flexibility to provide targeted funding in response to exigent circumstances, such as an increased demand for TAP Employment Workshops. The number of TAP Employment Workshop participants is expected to continue to increase during fiscal year 2008 and fiscal year 2009 as TAP Employment Workshops are being extended overseas to serve Guard and Reserve units and individuals; and as DOD works to meet its goal of an 85 percent participation rate in TAP Employment Workshops. As demand for TAP Employment Workshops increases, VETS will coordinate with DOD to provide additional workshops while working to maintain optimal class sizes. The additional TAP Employment Workshops would be delivered through a combination of Disabled Veterans' Outreach Program (DVOP)/Local Veterans' Employment Representative (LVER) staff and/or contracted facilitator support.

*Question.* Does the fiscal year 2009 request provide sufficient funds to address VETS' responsibilities?

*Answer.* Yes, the fiscal year 2009 request provides sufficient funds to address VETS' responsibilities.

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 QUESTION SUBMITTED BY SENATOR DANIEL K. INOUE

## STATE OF HAWAII NATIONAL EMERGENCY GRANT

*Question.* On March 20, 2008, Aloha Airlines shut down its passenger operations. This is the largest mass lay-off in Hawaii's history. It has put approximately 1,900 employees out of work. Hawaii has recently filed a National Emergency grant to assist with the job retraining and placement of these workers. Madame Secretary, this application is pending your review, and I would greatly appreciate your swift and favorable review. Time is of the essence so many of these former employees can look to new career opportunities as they struggle to get their lives back on track. Your review of this is much appreciated. Can you inform us of where you are in this process?

*Answer.* The Department is in the final stages, working with the State of Hawaii, of developing its decision to award a National Emergency Grant (NEG). The State's request identified approximately 710 workers needing services, including 146 pilots who would need training on aircraft other than those they flew for Aloha Airlines.

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 QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

## PROVIDING ADDITIONAL WORKERS WITH SERVICES

*Question.* In light of the Department's fiscal year 2009 proposed budget cuts to programs under the Workforce Investment Act and the elimination of Employment Services, how do you propose to accommodate the additional workers who are likely to need employment and training services during these turbulent economic times?

*Answer.* The fiscal year 2009 budget request complements the administration's proposal for job training reform, which seeks to provide services in a more cost-effective way. This reform proposal would consolidate the Employment Service and the Workforce Investment Act (WIA) Adult, Dislocated Worker, and Youth funding

streams into a single funding stream to be used for Career Advancement Accounts and employment services. In addition to eliminating the duplication between the Employment Service and WIA One-Stop delivery system that still exists in a number of States, it would replace the current siloed system of separate training programs, reduce administrative and overhead costs, and, most importantly, significantly increase the number of individuals who receive job training. Approximately 200,000 individuals receive training through the public workforce investment system each year. However, these reforms would increase the number of workers trained to over 600,000.

Overall, the fiscal year 2009 budget request makes a substantial investment in job training. Government-wide, the budget invests more than \$13 billion in training and employment programs. Including Pell Grants for students pursuing training at technical or community colleges brings this total to \$23 billion.

#### ASSISTANCE TO LOW-INCOME, OUT-OF-SCHOOL YOUTH

*Question.* This is the final budget that you will present for the Department of Labor as Secretary of the Department. It comes at a time when the United States has the highest proportion of students who drop out of secondary schools in the world—our teens ages 16 to 24 have the lowest annual average employment rates since World War II—and the employment rates for young adults ages 20 to 24 with no 4-year college degrees were substantially below those of 2007—especially for young men.

What have you done over the past 7 years as Labor Secretary that addresses the needs of the millions of young people who are low-income, out-of-school, and out of work in a significant and meaningful way—beyond Job Corps, which was a service for disadvantaged young people before you became Secretary and will continue to be so when your term ends?

*Answer.* In 2004, the Department adopted and announced its new strategic vision to more effectively serve those youth most in need of services: out-of-school youth and at-risk youth. Recognizing the necessity of involving other Federal agencies that serve other groups of neediest youth in this collaborative effort, the Department's outreach and recruitment strategy led to the creation of a national cross-agency group, which evolved into the Shared Youth Vision Federal Partnership. The Federal Partnership now includes nine Federal agencies. This group serves as a catalyst at the national, State, and local levels to promote the Shared Youth Vision by strengthening the coordination, communication, and collaboration among youth-serving agencies to support the neediest youth in acquiring the talents, skills, and knowledge necessary for their healthy transition to successful adult roles and responsibilities.

The Federal Partnership has been actively involved in sponsoring numerous activities to promote the Shared Youth Vision to State and local agencies serving youth. These activities have included: (1) a series of Shared Youth Vision technical assistance forums nationwide for State teams; (2) the selection of 16 Shared Youth Vision Pilot Project State teams to develop and implement strategic approaches that leverage their State-level coordination at the local service delivery level; (3) the development and implementation of a comprehensive technical assistance plan for infusing the collaborative vision in all States throughout the country; and (4) funding a Shared Youth Vision Implementation Study.

Beginning 3 years ago, the Department's Youth Vision began to address the problems created by the large number of youth leaving high school without a diploma. The increased national focus on the impact of high drop-out rates on regional economic development, as well as the lessons learned through DOL-sponsored Alternative Education Listening Sessions, has driven the development of a multiple education pathways strategy that will increase the quality and quantity of alternative education opportunities and post-secondary opportunities for formerly out-of-school youth. The Department has demonstrated its leadership through the support of seven cities (Brockton, Massachusetts; Des Moines, Iowa; Fall River, Massachusetts; Gary, Indiana; Metairie, Louisiana; Mobile, Alabama; and Pittsburgh, Pennsylvania) in their efforts to develop a blueprint to create high quality, innovative multiple education pathway systems through our Multiple Education Pathway Blueprint (MEPB) initiative (funded at \$3.4 million). MEPB addresses talent development and the very real need to address the high costs of increasing numbers of drop-outs and their negative impact on regional and State economic development.

The Department is continuing to develop bridges between One-Stop Career Centers and offender-focused youth programs in local communities to improve services to young offenders. The co-enrollment of youth offenders in Workforce Investment

Act-sponsored programs, Temporary Assistance for Needy Families, and Average Daily Attendance funds offer other examples of utilizing funds more effectively and leveraging resources. Some of the benefits of these arrangements include cost sharing and improved communication among participating programs.

The Department of Labor also is providing leadership in serving out-of-school youth through our investments in YouthBuild and Youth Offender initiatives and focusing efforts on reconnecting the neediest youth to high-quality alternative learning environments that lead to a diploma and to post-secondary training.

#### UNDERREPORTING OF INJURIES

*Question.* I continue to hear the administration's claims that worker injuries and illnesses on job are on the decline; yet, I also continue to hear about the problem of underreporting workplace injuries.

Last year, in my first oversight hearing on OSHA in my Employment and Workplace Safety Subcommittee, Dr. David Michaels told us that the "true incidence . . . is far higher than reported by the Bureau of Labor Statistics since these data do not include approximately two-thirds of occupational injuries and illnesses." (testimony for Dr. Michaels can be found at [http://www.help.senate.gov/Hearings/2007\\_04\\_26/2007\\_04\\_26.html](http://www.help.senate.gov/Hearings/2007_04_26/2007_04_26.html)).

The problem goes beyond inadequate data collection. Experts cite various reasons for underreporting, including OSHA's failure to issue new regulations, employer disincentives to report these incidents, and workers' fear of retaliation.

I believe that underreporting is a real problem and that is why I initiated a GAO investigation into OSHA efforts to ensure that employers are reporting injuries and illnesses accurately.

What steps is the Department taking to proactively address the problem of underreporting workplace injuries and illnesses, particularly as it relates to areas under the jurisdiction of OSHA and BLS?

*Answer.* The Department's annual injury and illness statistics are derived from the BLS Survey of Occupational Injuries and Illnesses (SOII). The survey captures data from Occupational Safety and Health Administration (OSHA) logs of workplace injuries and illnesses maintained by employers. While recent studies by outside researchers have reported that both SOII and workers' compensation programs undercount cases, these studies do not necessarily provide a definitive answer on the presence or size of any potential undercount, and thus do not provide an adequate basis for revising current BLS survey operations. The BLS is examining and extending the results of this kind of matching research to better understand the methodology and the nature of the comparisons.

In fiscal year 2008, the BLS began interviewing a small number of SOII respondents to learn about the decisions employers make that might lead to workers' compensation cases not being recorded on OSHA logs or workers' compensation claims not being filed for cases recorded on the logs. BLS plans to expand the number of interviews conducted in fiscal year 2009.

Finally, the BLS has documented much of its analysis to date of the purported undercount and its plans for future research, and will publish a research note in an upcoming issue of the Monthly Labor Review.

OSHA is responsible for ensuring that employers accurately record work-related injuries and illnesses on their logs. OSHA collects data from employers in industries with high rates of injuries and illnesses to identify individual high-rate establishments for potential OSHA interventions. Each year OSHA conducts approximately 250 recordkeeping audits of employers in high-rate industries to estimate the accuracy of the logs. These audits include a comprehensive review of documentation concerning actual injuries and illnesses, and a comparison of these cases to those recorded on the employer's log to determine if the log is accurate. These audits indicate that over 90 percent of the establishments accurately recorded injuries and illnesses.

*Question.* What steps has the Department taken in the past?

*Answer.* In fiscal year 2007, the BLS began efforts to expand the scope of the SOII to include State and local government workers in all States. With the expansion of the survey, the BLS will include these public sector workers in its National estimates, including those in such high hazard occupations as police, fire-fighters and public health workers. In fiscal year 2007, the BLS also conducted a quality assurance survey that indicated that BLS survey processes were not responsible for an undercount. A sample of 3,600 establishments that participated in the 2006 survey were contacted and asked to submit their OSHA logs to the BLS. The BLS then compared the OSHA logs to data for the SOII. Though this study did not attempt to ascertain whether the OSHA logs were correct or complete, there was no system-

atic evidence that the data in the SOII undercounted cases recorded on OSHA logs. OSHA has conducted yearly audits of the OSHA logs as described above.

#### OSHA STATE PROGRAMS

*Question.* State OSHA programs now cover more than half of all States or territories (26), yet Federal funding for these programs has not kept up. My home State of Washington is one such State that continues to do more with less but is constantly getting the short end of the stick from Federal OSHA. Funding increases over the last 7 years have been negligible or non-existent, although in fiscal year 2006 alone States issued 43,000 more violations and assessed millions of dollars more in penalties than Federal OSHA. Too many State programs have been forced to cut their operations budget, lay off inspectors or ask their overworked employees to forgo cost of living increases.

Why doesn't OSHA adequately fund the 26 State-run safety and health programs required under the law? Please provide me with detailed data concerning of the number of inspections performed, violations cited, and penalties collected in both Federal and State run programs, and a cost-benefit analysis of the resources allocated on both levels.

*Answer.* Section 23(g) of the Occupational Safety and Health Act provides for funding of State programs at a level which "may not exceed" 50 percent. Annual appropriations language also provides for funding "up to 50 percent of the costs required to be incurred." Of the 26 approved State Plans, 22 cover both the private and public (State and local government) sectors and four operate plans limited in scope to the public sector. Although no State Plan is required to contribute more than a 50 percent match of the available Federal funds, many States have chosen to contribute additional funding above their Federal match funding. Washington is one of those States.

The fiscal year 2008 Consolidated Appropriations Act provided \$1.6 million less than the President requested to fund these State Plan grants. This reduction exacerbated the difference between the Federal funds that were available and the amount that States were contributing to their safety and health programs. However, that gap has existed throughout the history of the program. This reflects, in part, the differences among the various States in the scope of their programs as well as the sources and availability of State funding compared to that made available from the Federal side.

Attached is a chart showing inspection, citation and penalty data for Federal OSHA and State Plans. OSHA has not conducted a cost-benefit analysis due to the wide disparity among the various State Plans as well as between the State and Federal programs. The differences among the various approved State plans would make a cost-benefit analysis very difficult to construct. Further, the results of such a study would be of limited value given the difficulty in assessing and interpreting the different State and Federal approaches with any reasonable or meaningful degree of validity. It is clear, however, that Federal penalties far exceed those remitted in the States while the number of State inspections and violations issued are greater than those shown in the Federal data.

#### FISCAL YEAR 2003–FISCAL YEAR 2007 FEDERAL OSHA ENFORCEMENT DATA

Federal data only	Fiscal year				
	2003	2004	2005	2006	2007
Total inspections conducted .....	39,931	38,286	38,828	38,604	39,400
Total violations issued .....	82,422	85,586	84,266	82,909	88,170
Total penalties remitted .....	\$59,557,998	\$59,765,326	\$80,533,951	\$61,146,763	\$56,708,502

#### FISCAL YEAR 2003–FISCAL YEAR 2007 18(b) STATE PLAN OSHA ENFORCEMENT DATA

18(b) state plan data only	Fiscal year				
	2003	2004	2005	2006	2007
Total inspections conducted .....	60,868	58,990	57,481	58,567	51,545
Total violations issued .....	138,293	132,263	126,097	125,753	124,429
Total penalties remitted .....	\$36,833,975	\$36,243,306	\$33,291,121	\$31,171,361	\$25,342,236

## FAMILY AND MEDICAL LEAVE

*Question.* Working families continue to face more and more challenges when it comes to balancing the needs of work and home. Fifteen years ago, Congress recognized a need to protect a worker's right to job-protected leave and did so by enacting the Family and Medical Leave Act of 1993. Since then, we know that more than 60 million people have benefited from this law, enabling them to care for their families or their own medical needs without the fear of losing their jobs.

Despite this fact, earlier this year, the Department proposed sweeping changes to the act in an administrative rule change. I joined a number of my colleagues from both Chambers in expressing our concern that collectively, these rule changes unnecessarily restrict a worker's access to their job protected leave and they upset the delicate balance between employers and employees carefully established in the original act. I believe that we should be proactively looking to expand FMLA to help working families better balance the needs of home and work, not restricting it even further.

I am most concerned that the Department proposed these changes without current, sound, and objective data to justify them. In fact, the last comprehensive survey completed by the Department was 8 years ago.

What prompted the Department to propose these sweeping changes without first conducting a comprehensive survey as many of us recommended in our response to last year's Request for Information?

*Answer.* The proposed changes are based on a careful examination of the Department's experience of nearly 15 years administering the law, several U.S. Supreme Court and lower court rulings on the FMLA, enactment of the new military caregiver leave provisions (Public Law 110-181), and the more than 15,000 public comments the Department received from workers, employers, health care providers, and other stakeholders in response to a Request for Information that was published on December 1, 2006.

*Question.* Will you commit to conducting such a survey before implementing final rule changes? If not, why?

*Answer.* In response to the RFI, the Department received a significant amount of data on FMLA leave usage. The RFI was a useful information collection method that yielded a wide variety of objective survey data and research, as well as a considerable amount of company-specific data and information from employers, both large and small, in a wide variety of industries.

As explained in the RFI Report, despite the criticisms and limitations of the 2000 Westat Report, the Department believes that it provides a great deal of useful information and data on FMLA leave-takers. Moreover, the Department has significantly supplemented and updated its knowledge of the impacts of FMLA leave, particularly intermittent FMLA leave based upon the information received in response to the RFI.

The targeted updates in the proposed rule are well-supported by the available data, the Department's enforcement experience, case law developments, and the more than 15,000 public comments the Department received from workers, employers, health care providers, and other stakeholders in response to a Request for Information that was published on December 1, 2006.

*Question.* During your tenure as Secretary, what proactive steps have you taken to expand job protected leave for workers?

*Answer.* The Wage and Hour Division employs complementary strategies—enforcement, compliance assistance, and partnerships—to promote compliance with the FMLA by covered employers.

## OFFICE OF APPRENTICESHIP

*Question.* In December 2007, the Department of Labor issued a Notice of Proposed Rulemaking to update the regulations for the National Apprenticeship Act of 1937. I heard from a number of organizations in my home State that these proposed changes would reduce the effectiveness and weaken the high standards that the Washington State's Apprenticeship Council has maintained since its establishment in 1939. Washington's apprenticeship programs have developed safety and training standards that are a model for other States. In March of this year I joined many of my congressional colleagues from Washington State in sending a letter to your agency, detailing our concerns about your proposal and the negative effect it will have on our State's apprenticeship programs. What prompted the department to propose these changes?

*Answer.* The main impetus for updating the regulations was to develop a more flexible, adaptive and responsive national apprenticeship system that could continue to be strong and relevant in the 21st century. The existing regulations were origi-



nally published in 1977 and have not been revised in 30 years. These regulations have not kept pace with the changing work environment, technology, or the rise of the global economy. Many of the changes defined and clarified in the Notice of Proposed Rulemaking were, in fact, already put into effect administratively because the existing rule was silent on the subjects. Additionally, many of the changes are intended to provide the kind of flexibility needed to serve the demands of industries that have not traditionally used, but could benefit from, the registered apprenticeship model. Finally, the proposed regulations ensure that registered apprenticeship keeps pace with technological changes, particularly in the delivery of related technical instruction.

The Advisory Committee on Apprenticeship, which consists of equal representation from employers, labor, and the public sector, contributed to the development of the proposed regulatory framework that will align registered apprenticeship with the realities of the 21st century economy and changes in the workplace. Throughout the development of the proposed revisions, the Department has focused on maintaining the integrity of the key components of registered apprenticeship that have made it such a successful and useful model for addressing the needs of industries and employers that have sponsored registered apprenticeship programs for many decades. These key components are on-the-job learning, related instruction, incremental wage increases, and mentoring.

*Question.* Who if any stakeholders expressed concern about the current regulations?

*Answer.* Over the past several years, the Department received numerous concerns from employers, employer associations, and labor organizations about the existing regulations. Many of these concerns are reflected in our purposes for updating the regulations, including the need for improved accountability, opportunities to incorporate technological advances, and more flexible options for program sponsors and apprentices. Additionally, concerns arose from the need to develop consistency for the registration of programs across the national apprenticeship system. Finally, many stakeholders, including labor unions, as well as oversight entities, including the Office of Management Budget and the Government Accountability Office, have asserted that the Department should strengthen accountability for quality and successful outcomes across all registered apprenticeship programs.

*Question.* What exactly does the agency hope to accomplish with these proposed changes?

*Answer.* With the proposed changes, registered apprenticeship will have the regulatory framework to: (1) continue to expand into new industries and occupations that are critical to maintaining a globally competitive workforce, (2) strengthen outcomes through an emphasis on program quality and accountability for all program sponsors, and (3) accommodate for technological advances in delivery of related technical instruction.

Any and all proposed changes to the regulatory framework remain rooted in the fundamental tenants of the National Apprenticeship Act, which authorizes the Secretary of Labor to “formulate and promote the furtherance of labor standards necessary to safeguard the welfare of apprentices.” These changes also maintain the integrity of the original regulatory framework developed for industries that created and sustained the American apprenticeship system, particularly those in the construction and manufacturing industries.

#### REAUTHORIZATION OF TRADE ADJUSTMENT ASSISTANCE

*Question.* The Department of Labor’s Trade Adjustment Assistance program provided critical assistance to hundreds of thousands of workers who have lost their jobs due to increased imports and offshore shifts in production for more than 40 years. The program’s authorization expired at the end of 2007, but assistance continues to be provided until Congress funding runs out at the end of fiscal year 2008. TAA could cease to exist in just 4 months.

What specific steps does the administration intend to take in order to reauthorize TAA by 10/1/08?

*Answer.* The administration strongly supports Trade Adjustment Assistance (TAA) reauthorization that includes needed reforms to help workers adversely impacted by trade access the training and re-employment services they need to return to work quickly. The administration will continue to work with Congress to make TAA a more flexible and beneficial program for workers.

*Question.* I am working closely with Senator Max Baucus to not only reauthorize the program, but to also improve access to training and make assistance more accessible and flexible.

Please provide your comments on the various proposals included in Senator Baucus' legislation?

Answer. The administration has not taken positions on specific proposals in S. 1848.

*Question.* One of the glaring holes in the program is that all trade-impacted service workers are not currently eligible for assistance. How does the administration propose to fix this problem? What other proposals might the administration put forward to ensure that TAA provides adequate assistance to all eligible workers?

Answer. The administration believes there are several flaws in the Trade Adjustment Assistance (TAA) program as it is currently designed. These flaws include: (1) TAA is an "all or nothing" program, where participants lose access to benefits by choosing to return to work; (2) Training options are limited and the process of applying for training is lengthy and bureaucratic; (3) Services cannot be provided until after the worker is laid off, even when the layoff is announced well in advance; and (4) There is no requirement that "wrap-around" services, such as career counseling, assessment and job placement assistance, are to be provided.

The administration believes any reauthorization of the TAA program should reflect the following priorities: (1) Workers must have increased choice to combine employment with training and "earn while they learn;" (2) Training options should be flexible and easy to access; (3) Services should be available prior to layoff, in order to reduce the length of time workers are unemployed; and (4) Integration with the public workforce investment system should be improved to ensure workers have access to the full range of services available through the One-Stop Career Centers.

#### EMPLOYMENT SERVICES TO UNEMPLOYMENT INSURANCE CLAIMANTS

*Question.* The public Employment Service serves Unemployment Insurance claimants. Employers pay for the administration of Employment Service in part because they assume that workers receiving UI will seek new jobs. From August 2006 through September 2007, about 4.5 million individuals received services under both the unemployment insurance and employment service.

What are your plans for serving these UI claimants when there is no Employment Service under your 2009 budget proposal?

Answer. Under the fiscal year 2009 budget proposal, Unemployment Insurance (UI) claimants would receive employment services through the Workforce Investment Act (WIA) One-Stop Career Center system. We propose to consolidate the Employment Service and WIA Adult, Dislocated Worker, and Youth funding streams into a single funding stream to be used for Career Advancement Accounts and employment services. It is estimated that 600,000 individuals would receive training and an additional 10.4 million individuals, including UI claimants, would receive other employment services under this approach.

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#### QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

##### MENTORING

*Question.* Secretary Chao, the statistics on youth violence are staggering. Philadelphia has the fifth highest homicide rate of all major U.S. cities, and juveniles account for 38.5 percent of all arrests in Philadelphia County. To help address this issue, in fiscal year 2007, I included \$25 million within your Department for grants to school districts to discourage youth in high-crime urban areas from involvement in gangs. In fiscal year 2008, \$50 million was included for persistently dangerous schools. Madame Secretary, I believe mentoring is one of the answers to this Nation's youth violence problem. What more can be done by your Department to address the crime and violence problems facing many of our Nation's youth?

Answer. The Department of Labor will continue to work closely with the Department of Justice and its Office of Juvenile Justice and Delinquency Prevention (OJJDP) in the coordination of resources and activities that address the crime and violence young people face. Specifically, the Department anticipates working closely with OJJDP on its current Solicitation for Grant Applications, which focuses on gang prevention and coordination assistance.

The Department will also continue its efforts to fully integrate mentoring strategies in existing and new projects. This includes the Department's current focus on school districts and the discouragement of youth involvement in gangs. The Department is presently making a concerted effort to ensure that existing apprenticeship, alternative education, and expansion projects incorporate mentoring as a key component in program design and service delivery.

Planned grant solicitations, such as those that focus on persistently dangerous schools, will have a required mentoring component for which extensive technical assistance will be provided. The Department also anticipates an opportunity to prepare and distribute to the public workforce investment system a "Mentoring" Training and Employment Notice that will highlight the importance and positive impact of mentoring that, together with other proven models of success, will foster desired employment outcomes. Lastly, the Department will continue its support and active involvement in the Federal Mentoring Council and its focus on foster youth, continue the involvement of Federal staff in direct mentoring activities, and include mentoring as an expressly allowable activity within the Department's grant solicitations.

#### ELIMINATION OF EMPLOYMENT SERVICE STATE GRANTS

*Question.* The budget proposes to eliminate the \$703.4 million employment service State grant program. Your rationale for this decision is that it is duplicative of Workforce Investment Grants (WIA). The number of people served by the Employment Service is 13 million annually. WIA grants service 900,000. How do you plan to serve the 12 million people who would be receiving services under the Employment Service grants?

*Answer.* The fiscal year 2009 budget proposes to consolidate the Employment Service and the Workforce Investment Act (WIA) Adult, Dislocated Worker, and Youth funding streams into a single funding stream to be used for Career Advancement Accounts and employment services. It is estimated that 600,000 individuals would receive training and an additional 10.4 million individuals would receive other employment services under this approach.

Our workforce system reform proposals will allow us to significantly increase the number of people trained. Therefore, many participants who would have been previously constrained to employment services due to the limited availability of training will be able to continue their professional development and acquire the skills and abilities sought by employers. Additionally, the labor exchange services traditionally provided by the employment service, such as resume posting and job search assistance, have largely been privatized and job seekers now have free access to Internet job boards that allow them to search for jobs and often post their resumes. While we believe there is an important role for the workforce system to play in providing employment services, these services should be provided exclusively through the One-Stop Career Centers.

#### EMPLOYMENT AND TRAINING SERVICES IN PENNSYLVANIA

*Question.* Pennsylvania State officials claim that the Employment Service and the Workforce Investment Act programs are not duplicative and that eliminating these funds will cut staff and resources that make up at least half of the one-stop system in Pennsylvania. Officials also claim that almost no training will occur, that critical career counseling will be unavailable, and efforts to help veterans with specialized veterans counselors in the Employment Service will be hurt. What is your response to these claims Madame Secretary?

*Answer.* The fiscal year 2009 budget proposes to consolidate the Employment Service and the Workforce Investment Act (WIA) Adult, Dislocated Worker, and Youth funding streams into a single funding stream to be used for Career Advancement Accounts and employment services. In addition to eliminating the duplication between the Employment Service and WIA One-Stop delivery system that still exists in a number of States, it would replace the current siloed system of separate training programs, reduce administrative and overhead costs, and, most importantly, significantly increase the number of individuals who receive job training.

We disagree with the statement by Pennsylvania officials that almost no training would occur. Our proposed reforms to the public workforce investment system will ensure that 600,000 individuals receive training nationally at the requested funding level for fiscal year 2009, three times the current number. An additional 10.4 million individuals will receive other employment services, such as career counseling. Current law provisions relating to services to veterans will continue to apply, except that those services will be provided through the VETS-funded and WIA-funded services offered in the One-Stop Career Centers.

#### OFFICE OF JOB CORPS

*Question.* The budget proposes to cut the Job Corps program by \$45.8 million. The cut would result in 4,097 fewer student training slots than in 2008, a reduction of 9.2 percent. Do you plan to close any of the existing 123 Job Corps centers or to operate them below capacity?

Answer. Job Corps does not intend to close any of the existing 123 centers. At the President's fiscal year 2009 budget level Job Corps will be able to support 40,394 student slots.

*Question.* If Congress were to provide funding to fully utilize the capacity of Job Corps centers, how would you improve recruitment aimed at a segment of the 1 million youth who drop out of high school each year?

Answer. Job Corps will continue its outreach and recruitment efforts through our national campaign, consolidated outreach and recruitment plan and continued collaboration with high school counselors and local school districts. Job Corps is also placing greater emphasis on expanding the use of technology to promote the program such as the implementation of a National Job Corps recruitment website including an online application, as well as the using You Tube and other Web based portals for program promotion campaigns.

*Question.* Each year 1.2 million youth drop out of high school. We need to do all we can to find new programs and expand existing program, such as Job Corps to address this problem. Your budget would result in a substantial reduction in Job Corps capacity. Our Nation's dropout statistics disprove your assertion before the House that there is insufficient demand or need for the program. Why do you continue to propose reducing Job Corps' capacity?

Answer. Maintaining enrollment levels is always a top priority for the Office of Job Corps. The Department is not reducing capacity, rather we are no longer allocating funding for training slots which do not have participants. In doing so, we maintain the funding for student activities in those training slots that do have participants and more closely align with the consistent level of on-board strength in the program.

JOB CORPS OBS DATA PY 2003–2007 YTD <sup>1</sup>

	Program year				Current OBS
	2003	2004	2005	2006	
Average on board strength .....	43,178	42,441	40,760	40,512	40,569

<sup>1</sup> Program Year (July 1–June 30).

*Question.* Historically, the Department of Labor has always been able to implement national plans that boosts Job Corps enrollment. Two years ago we requested that you submit a national plan to the subcommittee. To date, no such plan has been received. When can we expect to receive this plan?

Answer. Job Corps submitted the plan to Congress on May 20, 2008. This reflects the consistent message that Job Corps has provided to Congress over the past 2 years through numerous means to include formal hearings and questions from the committees. This message communicates a comprehensive enrollment plan which includes a consolidated outreach and recruitment strategy implemented in 2006, the Speakers, Tutors Achievement and Success (STARS) program and Career Success Standards in 2007 as well as the Youth Ambassador Program and a pre-enrollment drug test pilot. This comprehensive plan is designed to not only boost enrollment but improve student commitment and retention.

#### OSHA PENALTIES

*Question.* A recent report by the Senate Health, Education, Labor and Pensions Committee showed that the median final OSHA penalty in cases where workers are killed is only \$3,675. Many companies treat such low penalties as just the cost of doing business. Would you agree that corporate accountability is enhanced when OSHA imposes meaningful penalties for serious safety and health violations?

Answer. OSHA agrees that employer accountability is enhanced when meaningful penalties are imposed for serious safety and health violations. However, OSHA does not agree with the HELP Committee's conclusion that the median penalty is the most appropriate measurement of penalties. Using the same data provided to the HELP Committee, and using only closed fatality investigations, which by definition are those investigations where citations have been issued and final payment made, the average penalty per fatality investigation is actually \$6,035. More importantly, it should be noted that 62 percent of OSHA fatality investigations between 2004 and 2007 were conducted at companies with fewer than 25 employees, where penalties must statutorily be adjusted based on the employer's size. In fiscal year 2007, OSHA's significant enforcement actions included more than 100 inspections that each resulted in a total proposed monetary penalty of over \$100,000.

When proposing penalties for violations, the Occupational Safety and Health (OSH) Act requires the agency to take into consideration: (1) the gravity of the alleged violation, (2) the size of the employer's business, (3) the good faith of the employer, and (4) the employer's history of previous violations. Proposed penalties are calculated for each violation, with the initial statutory penalties adjusted based on these statutory factors. The act does not provide for enhanced civil penalty amounts for an employee fatality, except to the extent the statutory factors address the factors contributing to the accident. Moreover, even where violations are found in fatality investigations, those violations may not have contributed to the fatality.

#### CRIMINAL PROSECUTIONS

*Question.* There is essentially no criminal enforcement of our Nation's safety and health laws. In the past 5 years, there have been only 10 prosecutions under the Occupational Safety and Health Act and only 68 cases in the entire 38-year history of the OSHA. What role do you think criminal prosecutions should play in enforcing the law? Do you think 10 prosecutions in 5 years or 68 cases in almost 40 years is enough to have a deterrent effect on employers who don't take their workers' safety and health seriously?

*Answer.* OSHA believes that criminal prosecutions are a vital enforcement tool and provide a powerful deterrent effect for employers who do not take their workers' safety and health seriously and show indifference to compliance with workplace safety and health regulations.

Since the passage of the OSH Act in 1970, OSHA has referred 210 cases to the Department of Justice for consideration of criminal prosecution. This administration has referred 65 OSHA cases to the Department of Justice since 2001—31 percent of all criminal referrals made by OSHA and more than any other administration. The Department of Justice's decisions on whether to prosecute these cases reflect its own further evaluations of the evidence and other appropriate issues.

The primary criminal provision in the Occupational Safety and Health Act is section 17(e), which makes it a misdemeanor for an employer to willfully violate a standard that causes the death of any employee. It is the Department of Labor's policy to evaluate all willful OSHA violations that contribute to workplace fatalities for potential referral to the Department of Justice for prosecution. The Department's Office of the Solicitor has issued specific instructions to its attorneys to evaluate all such cases for criminal referral.

#### MINE SAFETY AND HEALTH ADMINISTRATION

*Question.* Report by the U.S. Department of Labor, Office of Inspector General, Office of Audit: On March 31, 2008, the OIG issued their report regarding MSHA's roof control plan approval process for the Crandall Canyon Mine, which concluded that "MSHA was negligent in carrying out its responsibility to protect the safety of miners." Specifically:

- MSHA could not show that it made the right decision in approving the [roof control] plan or that the process was free from undue influence by the mine operator.
- MSHA did not have a rigorous, transparent review and approval process for roof control plans consisting of explicit criteria and plan evaluation factors, appropriate documentation, and active oversight and supervision by Headquarters and District 9 management.
- MSHA did not ensure that inspections assessed compliance with, and the effectiveness of, approved plans in continuing to protect miners.
- Finally, requirements related to surface rescue operations and non-rescue activities need to be clarified.

*Answer.* That while the report "points to several shortcomings in MSHA's documentation . . . and identified missed opportunities to proactively enhance safety protections," it "does not provide evidence that MSHA negligently breached its duty to protect miners".

*Question.* Madame Secretary, the report found serious deficiencies in the review and approval of the Crandall mine plan—can you assure me that MSHA is taking all steps necessary to make sure that no other unsafe mining plans have been approved by this deficient process? Please provide the subcommittee a list of the safeguards that you have implemented regarding the approval of mine plans.

*Answer.* In response to improving the roof control plan approval process, MSHA has conducted specialized training and has taken specific actions, as described below.

- An evaluation was made of all underground coal mines in the United States to identify mines that may have a "bump" or "burst" potential. This initiative

began in late August 2007 and was completed in December 2007. Seventeen mines were identified. Each one of these mines has been visited by MSHA's Technical Support roof control experts and reports have been submitted to Coal Mine Safety and Health (CMS&H). MSHA will revise the roof control plans accordingly, as well as requesting for Technical Support to review select plans at mines with bump potential.

- MSHA roof control supervisors and specialists received additional training on various computer modeling software that can be used to evaluate complex and non-typical roof control plan proposals.
- A Program Information Bulletin (PIB) was recently issued by MSHA providing guidance on the proper use of the National Institute for Occupational Safety and Health's (NIOSH) Analysis of Retreat Mining Pillar Stability (ARMPS) program. The PIB alerts the mining community about the availability of an updated version of the program.
- A list of Best Practices addressing "Ground Control for Deep Cover Coal Mines" was developed. The Best Practices, which covered topics such as geology, pillar design, multiple seam mining, and retreat mining, were posted on MSHA's website, [www.msha.gov](http://www.msha.gov).
- MSHA and the Bureau of Land Management developed a Memorandum of Understanding to facilitate communication and information sharing about geological conditions or mining practices that impact the health and safety of miners.
- MSHA and NIOSH technical experts in roof control are working together to develop safer retreat mining guidelines. (see addendum below on MSHA/NIOSH Cooperation on Retreat Mining)
- A Procedure Instructional Letter has been issued that provides uniform guidance to CMS&H Districts on which roof control plans are to be sent to MSHA's Technical Support for further review.

In addition, MSHA developed the following procedures, which were sent to the District Managers on June 6, 2008, with a memorandum from the Administrator for CMS&H describing each procedure and its intended use:

New procedures:

- Roof Control Plan Approval Process*.—Incorporates the specific steps involved in the plan approval review process, and identifies the responsible parties for each step. Responsible parties include the roof control specialist and supervisor, mine inspector and supervisor, Assistant District Manager for technical programs, Assistant District Manager for enforcement, and the District Manager. Each of the MSHA personnel reviewing the plan must initial approval/concurrence, and any identified deficiencies must be addressed.
- Roof Control Plan Review Form Checklist*.—Ensures that review items are included in the plan, such as: detailed accident and injury data, violation history, requirements of Title 30 CFR sections 75.204, 75.215, 75.221, and 75.222, software applications related to development, and/or retreat stability factors.
- General Safety Precautions Checklist*.—Addresses Automated Temporary Roof Support systems, removal of loose material, installation of timbers, adverse roof conditions, temporary supports, continuous mining machine breakdown in unsupported area, remote control operation, and distance for first coal mined out of crosscuts. A "breakdown in an unsupported area" occurs when a continuous miner begins mining, advances into the coal seam and breaks down. There is no roof support in this area thus is considered an unsupported area. Mining machines are now equipped with a remote control feature that allows the miner to remotely operate the machine from a safe distance. This document will supplement the Roof Control Plan where applicable.
- Retreat Mining Precautions Checklist*.—Addresses intersection supplemental support, marking pillar cut locations, certified person on working section, equipment operator positioning, training, drilled test holes, and pillar extraction sequence. A certified person is someone who has received additional training and received a certification by the State in which they are working. The concept in this case would be that a certified person would be better trained to determine the adequacy of the roof and make a determination if supplemental support would be needed. This document will supplement the Roof Control Plan where applicable.
- Mobile Roof Support Checklist*.—Addresses safety items directly related to the use of Mobile Roof Support (MRS) units during retreat mining. Some of the items addressed are training, operator positioning, manual and remote operation, procedural limits for lowering and setting MRS, pressure gauges and lights, and breakaway cable hangers. This document will supplement the Roof Control Plan where applicable.

- Deep Cut Safety Precaution Checklist.*—Specific to extended cuts of up to 40 feet in depth. Some of the precautions include place changing, operator positioning, time allotment for unsupported cut, reflective markers on second full row of roof bolts, and conspicuous marking on the continuous miner to indicate depth of cut. This document will supplement the Roof Control Plan where applicable.
- A memorandum has been sent to the District Managers from the Administrator for CMS&H stating that all complex and non-typical roof control plans proposed by mine operators shall contain an assessment of the basis on which the operator has determined the plan is appropriate and suitable to the mining conditions. Data and engineering evaluations shall be included with the assessment. MSHA shall not approve the proposed plan until the operator has provided the data and evaluation supporting the proposal and a confirming evaluation(s) have been completed. On June 3, 2008, a letter was sent from the Administrator to all underground coal mine operators of MSHA's intentions pertaining to complex and non-typical roof control plans.

#### ADDENDUM—MSHA/NIOSH COOPERATION ON RETREAT MINING

NIOSH and MSHA Technical Support are working together to improve safety for miners working in retreat mining operations. In response to language in its fiscal year 2008 budget allocation, NIOSH is conducting, in collaboration with the University of Utah and West Virginia University, a major study of the recovery of coal pillars through retreat room and pillar mining practices in underground coal mines. The study is focusing on mines operating at depths greater than 1,500 feet, but it will address issues that are important to all retreat mining operations. This report will be delivered by December 31, 2009, and will include:

- A detailed description of the retreat mining segment of the industry, including the geologic conditions encountered and the mining practices employed;
- Suggested guidelines for maintaining global stability during retreat mining through proper design of production and barrier pillars. The appropriate use of ARMPS, additional computer-modeling software known as LAMODEL, and other pillar design tools will be covered in detail, as well as specific designs to minimize the risk of bumps;
- Suggested best practices and procedures to ensure local stability during retreat mining, including cut sequence, roof support, and the application of seismic monitoring, and;
- Remaining research needed to develop improved technologies to protect miners during deep cover retreat mining.

MSHA and NIOSH have established a Working Group, consisting of ground control experts from both agencies, to review progress on the NIOSH project and facilitate transfer of information on retreat mining. Personnel from MSHA in Technical Support's Pittsburgh Safety and Health Technology Center's Roof Control Division (RCD) will participate in the MSHA/NIOSH Working Group on retreat mining. RCD personnel will review progress on the NIOSH project and facilitate transfer of information on retreat mining. Based on the findings of the NIOSH project, the Working Group will develop recommendations for establishing methods, requirements, and parameters for technical analyses of retreat mining plans.

Although a project of this scope requires 2 years for completion, RCD's involvement will assure that significant interim results and conclusions of immediate benefit to miner safety are made available to MSHA enforcement personnel and the mining industry as quickly as possible.

Also, RCD, in collaboration with NIOSH, previously developed a pillar recovery risk factor checklist which was published in a December 2005 technical paper. The checklist can be used by MSHA Districts and the mining industry to identify potential problems for specific retreat mining plans. The risk factors listed on the checklist include: production pillar design, barrier pillar design, final pillar stump design, mobile roof supports, supplemental roof support, geologic hazards, equipment operator locations, intersection spans, multiple seam interaction, depth of cover, age of mine workings, and type of coal haulage system.

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#### QUESTIONS SUBMITTED BY SENATOR LARRY E. CRAIG

##### LABOR-MANAGEMENT REPORTING AND DISCLOSURE ACT

*Question.* Until last year the Office of Labor-Management Standards (OLMS) has received steady increases in funding from this committee. I am supportive of the mission of OLMS to ensure that union funds are being handled in a responsible

way. What results can you cite that would support your fiscal year 2009 request to increase funding for OLMS?

Answer. OLMS has responsibility for enforcement of the Labor-Management Reporting and Disclosure Act (LMRDA) of 1959. After years of inadequate funding to carry out this mission effectively, we have requested resources to re-establish an effective program to ensure union financial integrity and compliance with the LMRDA.

OLMS' union audit program verifies compliance with the law, investigates potential violations and allows OLMS to provide compliance assistance to help unions meet statutory requirements. The audit program had substantially waned since the mid-1980s because of the steady erosion of resources. For example, in 2000, OLMS was able to perform only 204 audits for out of well over 20,000 unions, which was the equivalent of a union being audited once every 133 years. With gradual funding increases for the audit program until fiscal year 2008, the number of audits rose from 238 in 2001 to 775 in 2007—an increase of 226 percent.

The additional resources also have supported investigations into criminal activity. During fiscal year 2007, OLMS secured 100 indictments and 118 convictions against union officials and related parties for crimes, such as fraud and embezzlement. Since 2001, OLMS investigations have yielded a total of 842 indictments with 802 convictions and returned more than \$88,000,000 in restitution to rank-and-file union members. In cases of organized crime and labor racketeering, OLMS has referred cases to the Office of Inspector General (OIG) and has worked cooperatively with the OIG on a number of successful investigations, some of which are described in the Inspector General's semi-annual report.

It is clear that providing OLMS with appropriate resources yields results for rank-and-file union members. The program results from fiscal year 1998 to fiscal year 2007 are set forth below.

	Fiscal year									
	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Actual FTE usage .....	289	287	274	290	260	262	290	314	327	331
Compliance audits .....	302	289	204	238	277	255	532	612	736	775
Criminal cases processed .....	367	386	464	371	410	317	303	332	340	406
Indictments .....	143	119	204	99	166	131	110	115	121	100
Convictions .....	130	131	191	102	89	152	111	97	133	118
Compliance audits .....	302	289	204	238	277	255	532	612	737	775
International compliance audits .....	.....	.....	4	1	2	.....	1	7	5	7

A recent example of OLMS's work can be seen in a case starting in 2006 when a compliance audit by the OLMS Detroit District Office of Steelworkers Local 1358 revealed that, during the period from November 1999 through July 2006, the Secretary-Treasurer had embezzled a total of \$274,262.38 from Local 1358 by cashing checks to himself. He forged the signature of another officer to further his scheme, created false union records, and destroyed union records to conceal his embezzlement. In addition, he caused the union to file false LM reports by omitting the embezzled amounts when he prepared the reports. On July 11, 2007, he pled guilty to one count of embezzling union funds. He made restitution of \$128,438.46 prior to the discovery of the embezzlement, resulting in a net loss to the local of \$145,823.92. On November 14, 2007, he was sentenced to 24 months in prison and 2 years of supervised release. He was ordered to pay restitution of \$145,823.92 and a special assessment of \$100. He was also ordered to participate in the Bureau of Prisons Inmate Financial Responsibility Program.

Another example of OLMS's compliance audit program concerns the 2007 audit of the Federated Independent Texas Union Local 900 in Fort Worth. Based on issues raised during this audit, OLMS opened a criminal investigation into a potential embezzlement. Subpoenaed bank records revealed that 63 union checks, endorsed by the then-treasurer, had been deposited into her personal bank accounts. The treasurer also made withdrawals of union funds amounting to \$35,850 for personal use. The treasurer pled guilty before trial to one count of embezzlement of union funds totaling \$164,268.

Since 2001, the Department has also worked to improve the enforcement of the LMRDA by updating the 40-year-old financial disclosure forms required by the law. With the first significant update of the annual union financial disclosure report used by the Nation's largest unions (Form LM-2) in over 40 years, the Department increased the usefulness of the Form LM-2 and empowered rank-and-file union members to easily access clear and concise information on how their dues money is spent



and on the financial condition of their unions. Although the reforms were challenged in court, they were upheld in a significant U.S. District Court decision and affirmed in large part by the U.S. Court of Appeals for the D.C. Circuit.

OLMS has also updated Form LM-30, the report filed by union officers and employees to disclose possible conflicts of interest between their personal financial interests and their duty to the union and its members, and has stepped up compliance with Form LM-10 Employer Report filing requirements.

In order to provide rank and file union members with better accountability and transparency, OLMS has established a public disclosure Web site at [www.unionreports.gov](http://www.unionreports.gov). This Web site contains union annual financial disclosure reports and reports required to be filed by employers, labor relations consultants, and union officers and employees, as well as copies of collective bargaining agreements.

The OLMS 2007 Annual Report can be found at the following website: [www.dol.gov/esa/olms/regs/compliance/highlights\\_07.pdf](http://www.dol.gov/esa/olms/regs/compliance/highlights_07.pdf).

#### SENIOR COMMUNITY SERVICE EMPLOYMENT PROGRAM

*Question.* Your fiscal year 2009 request for the Senior Community Service Employment Program (SCSEP) is the same as the amount appropriated in fiscal year 2008. In your testimony you cited the ineffective rating that this program received by the Program Assessment Rating Tool (PART). What steps are being taken to improve the efficiency of SCSEP?

*Answer.* Although the 2003 PART evaluation gave the Senior Community Service Employment Program (SCSEP) an ineffective rating, the Department has actively addressed deficiencies identified by that evaluation through several administrative actions and the 2006 reauthorization of the Older Americans Act. The deficiencies included inadequate competition in the grants process, lack of data on program performance and impact, and duplication of other Federal programs. Program improvements since the 2003 evaluation include:

- Development of a comprehensive on-line data collection and performance management system (known as SPARQ).
- Completion of three competitions, including one for national grantees (which account for 78 percent of all SCSEP participant positions); one for grants to create employment opportunities with private businesses; and one for pilot and demonstration grants.
- Provision of extensive technical assistance and training for all grantees on programmatic, fiscal, and performance issues.
- Improved grantee planning instructions on collaboration and coordination with other entities to minimize duplication and to allow SCSEP to serve those with the more significant barriers to employment.

#### SUBCOMMITTEE RECESS

Senator HARKIN. Well, thank you, Madam Secretary. You are very generous with your time. I appreciate it very much.

The subcommittee will stand in recess.

[Whereupon, at 11:38 a.m., Wednesday, May 7, 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 2009**

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**WEDNESDAY, JULY 16, 2008**

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

The subcommittee met at 9:47 a.m., in room SD-138, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Murray, Durbin, Reed, Specter, and Cochran.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**NATIONAL INSTITUTES OF HEALTH**

**STATEMENT OF HON. ELIAS A. ZERHOUNI, M.D., DIRECTOR, NATIONAL  
INSTITUTES OF HEALTH**

**ACCOMPANIED BY:**

**FRANCIS S. COLLINS, M.D., Ph.D., DIRECTOR, NATIONAL HUMAN  
GENOME RESEARCH INSTITUTE**

**ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF AL-  
LERGY AND INFECTIOUS DISEASES**

**ELIZABETH G. NABEL, M.D., DIRECTOR, NATIONAL HEART, LUNG,  
AND BLOOD INSTITUTE**

**JOHN E. NIEDERHUBER, M.D., DIRECTOR, NATIONAL CANCER IN-  
STITUTE**

**OPENING STATEMENT OF SENATOR TOM HARKIN**

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

Welcome to our hearing on the fiscal year 2009 budget for the National Institutes of Health. Last year you'll recall that this subcommittee held six hearings. I promise we'll do it in 2009, because I want to get back to that system of having all of the Directors back again, just—this year was just—a lot of things happening this year.

Senator COCHRAN. You think you're going to be chairman again?

Senator HARKIN. Well, let me put it this way—even if I'm not chairman, I'll bet the—the way we pass this gavel back and forth, it won't make any difference. He'd let me have them anyway, even if I wasn't chairman.

Anyway, we'll move on, here.

Before I begin, I do want to take a moment to thank Dr. Collins, for his extraordinary service as a Director of the National Human Genome Research Institute. Dr. Collins has been teaching me about genomics since 1993 when he first came to NIH, and I'd like to think that, at times during those 15 years, I almost understood what he was talking about.

In fact, that's one of the things I admire the most about you, Dr. Collins. As brilliant as you are, you never talk down to your audience, you can converse as easily with the layman as with the Nobel Prize winner. In all the years that I've known you, I've ended entered a conversation with you without feeling smarter and more hopeful about the future.

So, I think that that kind of a quality helps explain, again, why you were so successful in leading the Human Genome Project. An effort that, I believe, will go down in history as one of mankind's greatest achievements.

This has also served you well during your 13-year crusade to pass the Genetic Information Nondiscrimination Act, which finally became law in May. They call it GINA, for short, we think it should have been called "Francis", for short.

So, this will be Dr. Collins' final appearance before this subcommittee as the Director of the Genome Institute, but I strongly suspect that we'll see you here again in some other capacity, once you decide where and how you're going to apply your talents next.

Until then, Dr. Collins, on behalf of this subcommittee, and I think I can speak for every person on this subcommittee, thank you for all you've done, at NIH and throughout your career, to help improve people's lives. You will be greatly missed.

As for the matter at hand this morning, the NIH budget, we got some good news 2 weeks ago, when the President signed into law the supplemental that included \$150 million for NIH. That's enough to award an additional 246 new research project grants, bringing the total for fiscal year 2008 to more than 10,000.

Even with that increase, however, fiscal year 2008 marks the fifth year in a row that NIH funding failed to keep up with the cost of inflation. In fact, since the end of the doubling period, in fiscal year 2003, NIH funding has dropped by about 10 percent in real terms. The average investigator now has a less than 1-in-5 chance of receiving an NIH grant. As Dr. Zerhouni has frequently lamented, the average age at which a researcher gets his or her first—R01 grant, is now 42.

It should be no surprise, then, that many young people are deciding against a career in biomedical research, putting this Nation at risk of losing a generation of talented investigators.

Regrettably, the President responded by freezing NIH funding in his fiscal year 2009 budget. Under his plan, the success rate for research project grants would fall to 18 percent, the lowest level on record. But, rest assured, Congress will not accept this approach.

Last month, the Senate Appropriations Committee marked up the fiscal year 2009 bill. It includes an increase of \$875 million over last year for NIH, on top of the \$150 million in the recent supplemental.

Today, Senator Specter and I will introduce another supplemental appropriations bill that would add \$5.2 billion for NIH.

This would be enough to restore the purchasing power of NIH that was lost to inflation since the end of the doubling period, plus provide \$1.2 billion specifically for the National Cancer Institute, in line with the NCI's professional judgment bypass budget.

To elaborate, perhaps, on this or anything else, I now turn to my distinguished ranking member and great friend, Senator Arlen Specter.

#### OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Well, thank you very much, Mr. Chairman, and thank you for convening this important hearing.

At the outset, Dr. Collins, I join the chairman in thanking you for extraordinary service. I thank all of you. I thank NIH, other medical professionals for the excellent care that I'm getting. As you can tell from my Telly Savalas look, I've had a recurrence of Hodgkin's. Had the last of 12 chemotherapy treatments on Monday. I'm constantly asked how I'm doing, and my slogan is tough, but tolerable. Good to have distractions so that I don't think about myself, and around here there are a lot of distractions.

Senator HARKIN. Why are you looking at me?

Senator SPECTER. Senator Harkin and I—well, if I look at Senator Harkin, it's an attraction, it's not a distraction. Not as decisive as an attraction as looking at Senator Bettilou Taylor but also an attraction.

Senator Harkin and I will be on the floor later today, as he's noted, with a supplemental appropriations bill for \$5.2 billion. Regrettably, the prospects are that it's confederate money, and we have to do something about it, it's just a scandalous situation to have seen the NIH budget cut in recent years, with across-the-board cuts, which we can't control, at all, out of the subcommittee.

With the cost of living adjustments not maintained—again, which we can't control, because we've gone through the fat, the muscle and the bone, and there just isn't anything left in the subcommittee budget, when you have to compete with Headstart and worker safety and job training—the three departments which this subcommittee has. But we were determined, if I have a way, to do better.

As you know, we have asked for projections as to what it would cost to cure cancer. Now, I hear everybody talk about cure, which is in quotation marks, but really make a major assault—a major assault.

In 1970, President Nixon declared a war on cancer and had that war been pursued with the intensity of other wars, I wouldn't have gotten Hodgkin's and—we all have good friends who have died from breast cancer or prostate cancer, ovarian cancer—just rampant. We can do better. A lot better.

Of course, you can't just move for the National Cancer Institute, there has to be parity with other NIH funding.

We're taking a look at a collateral line, which may have some overlap on a funding stream, or may not. That is the issue of advanced directives. For some time now, Senator Harkin and I, in our subcommittee, have included in the request to Medicare to put in information on advanced directives. It hasn't worked out too well,

and obviously, nobody should tell anybody else what ought to be done on that situation.

I talked to the Secretary of Health and Human Services, Mike Leavitt, about it, and projecting the savings that might be obtained from advanced directives, the thought is there might be an incentive with a discount on part B payments. One of my colleagues, Senator Johnny Isakson, has an idea to make an advanced directive mandatory before coming into Medicare—maybe that's too strong, but which way you go, it doesn't matter, if you take an advanced directive for life support, or not.

We're trying to get a projection as to what we're doing—we just had a bloody political battle on Medicare, as you all know. Regrettably, we got it behind us, not with a lot of blood on the ground on the Senate chamber and from here to the White House, with condemnatory statements coming from the President yesterday about nine people who shifted their votes.

I was asked about it, and what did I think about the President's veto, and the President's statement. I said, "Well, I respect the statement, I hope he would respect the Senators." We all have our constitutional role to play.

But these are big, big issues which this committee is in the center of, and we've got the greatest experts around.

As I told the chairman a few moments ago, I'm ranking on Judiciary, and there was a hearing that's going to start in 2 minutes, and I have to be there for the opening part of it, but I will return very, very shortly for this important hearing.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you.

Senator Durbin.

#### STATEMENT OF SENATOR RICHARD J. DURBIN

Senator DURBIN. I'm anxious to hear the testimony, but I wanted to be here today, first to thank Senator Harkin and Senator Specter—it really is hard to imagine that any of us could go home to our States and explain to the people of this country that we can not afford medical research.

Yet, the fact is that after a dramatic increase in NIH funding, during the period when a Congressman from my State, John Porter, was chair of the appropriate House subcommittee, we have seen this whole area of medical research fall under this administration—not keeping up with medical inflation—let alone, inflation—in most instances. I think that that is shameful. I don't believe it's defensible, morally or politically.

I want to thank Senator Specter and Senator Harkin for continuing their battle to fund this important agency.

The major reason I'm here, and the questions I'll go to comes down to something that virtually every Senator faces, almost every day. When somebody comes in our office and says, "My son is dying, why aren't you spending more in research to find a cure for his disease? Why is the NIH spending so little for the research to spare him, and so many others who can die?"

We sit here—I sit here—wondering—is that person right? Are we doing the right thing for medical research? Are we putting the money in the right places? I don't know the answer to that ques-

tion, having been around Capitol Hill for a long time. I'm going to ask them that later.

Thank you, Mr. Chairman.

Senator HARKIN. Senator Reed.

STATEMENT OF SENATOR JACK REED

Senator REED. Mr. Chairman, I too am here to thank and commend you and Senator Specter for your extraordinary leadership over many years. You've never let go of this issue, and you're responsible, collectively, for some of the vast improvements in NIH over many years.

Let me also echo the concerns that Senator Durbin expressed, and one other, which is that it's not just about the relatively new therapeutic techniques. It's also maintaining a new generation of researchers and scientists. As this funding decreases we're seeing more and more of these very talented, young academic researchers go elsewhere.

I had a chance to visit a Brown University researcher, Dr. Teresa Serio. She related to me that she was one of 30 Ph.D. students at Yale University—she's the only one now still in academic research, because the grants weren't there to support the applications to go forward, to get tenure, to do all the things you have to do. So, this is about the infrastructure of our research endeavor, and how it's also critical.

Thank you.

Senator HARKIN. Thank you very much, Senator Reed.

Senator REED. I have a statement for the record, too, Mr. Chairman.

Senator HARKIN. Okay, it will be made part of the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR JACK REED

Research to prevent debilitating diseases has the potential both to ease patient suffering and lessen the burden on our health care system. For this reason, I was proud to support the historic doubling of funding for the NIH from 1998 to 2003. Unfortunately, since then our Nation's commitment to this critical research has wavered.

Recently, a group of concerned universities and research institutions—including Brown University in my State—released a report that documents how flat funding for the NIH puts a generation of science at risk. Since 2003, the purchasing power of the NIH has eroded by 13 percent. As a result, only 24 percent of research projects are funded, and the average age of first-time grant recipients is 43. The report finds that there is a real risk that we will lose aspiring scientists to other industries or overseas.

Of course, flat funding puts at risk not only the development of scientists, but also their science—cures and treatments for chronic diseases that exact a costly human and economic toll. Rhode Island ranks 44th in the prevalence of chronic diseases such as cancer, diabetes, and heart disease. In 2003, the cost of treating these conditions was \$1.2 billion and the economic cost in lost work and productivity was \$4.5 billion. Obviously, an investment in research on these conditions would improve both the health of Rhode Islanders and the health of the Rhode Island economy.

To show the real-life impact of stagnant funding, I want to tell you about Dr. Tricia Serio, a researcher at Brown University. Dr. Serio is ready to research ways to reverse the spread of proteins that damage the brain in several devastating diseases, including Alzheimer's, Huntington's, and Parkinson's. For years, the NIH said that her ideas were very innovative, but too risky. The NIH did not award her a grant until 4 years after she joined Brown.

Dr. Serio has directly observed the effect of flat funding on her generation of scientists. She says that when she was at Yale, there were 30 Ph.D.s in her program;

but she believes that she is the only one who is still pursuing a career in academic science.

The NIH should not be forced to make the difficult decision to turn down research that is innovative, but risky. We did not send a man to the moon by being overly cautious. Nor will we discover a cure for cancer unless we make a significant investment.

Mr. Chairman and Ranking Member, I am pleased that your bill increases funding by 3.5 percent to keep pace with biomedical inflation for the first time in 6 years. This is an increase of over \$1 billion over last year and the President's request, which was extraordinarily shortsighted.

I hope that we will pass this bill soon and that the President will reconsider his priorities. He should consider the stories of researchers like Dr. Serio, who are on the cusp of scientific breakthroughs, but desperately need our support.

Thank you.

Senator HARKIN. Senator Murray.

Senator MURRAY. I would just submit my statement for the record, I apologize for being a few minutes late. I really look forward to the testimony and opportunity to hear from all of you. I agree with everything I've heard this morning, that the investment's critical, the research is critical and just, to all of you, a lot of Americans, and people around the world's hope lands right in your lap as they are hoping that something that you discover or something that one of the scientists does changes their lives.

So, we really appreciate the tremendous work you do, and are very proud of the support of this community, Mr. Chairman, I want to thank you personally for your attention to this.

[The statement follows:]

#### PREPARED STATEMENT OF SENATOR PATTY MURRAY

Thank you, Senator Harkin and Senator Specter, for holding this hearing.

I appreciate your long-time support for the National Institutes of Health. And I'm proud of this committee's leadership supporting research and other important health care issues.

For more than a century, NIH has played a vital role in improving the health of our Nation.

By conducting and supporting research on everything from breast cancer to autism, NIH is helping to improve our understanding of what causes diseases—so we can predict when they will occur and develop the tools to better fight them.

Its work gives tremendous hope to the many Americans who suffer from a number of devastating diseases. And I believe that every dollar invested can save money later in reduced health care costs and economic productivity.

That is why I have been extremely discouraged by President Bush's proposed funding levels for NIH.

If President Bush's budget becomes reality, fiscal year 2009 will be the sixth year in a row that funding for the NIH was frozen at \$29.3 billion.

That fails to keep up with biomedical inflation, and it would cause the projected success rate for research grant applications to fall to the lowest level since 1970.

Fortunately, this year, we are taking steps to turn the tide.

The Senate's Labor-HHS Appropriations bill increases NIH's budget by 3.5 percent, enough to keep up with inflation.

While I wish we could do more, this is a step in the right direction.

It has been almost 6 years since we increased NIH funding. In fiscal year 2003, when we doubled the budget, we enabled NIH to advance into new areas of science and to support far more promising research than ever before.

Our continued investment will ensure that there are enough trained professionals ready to turn today's research advances into tomorrow's treatments, diagnostics, vaccines, and cures.

And I look forward to working with my colleagues to continue support its progress.

Senator HARKIN. Thank you very much, Senator Murray.

Again, Dr. Zerhouni, thank you very much, and thank all of you for being here today. Like I said, just because of schedules, this



year I was unable to do what we did last year, and so I thought it was at least important to have you here to go over the budget and to respond to some of our inquiries, perhaps on what's happening at NIH, with the panel that you have in front of you, which represents the—perhaps the largest of the institutes at NIH.

So, Dr. Zerhouni, again, welcome. Thank you for your great leadership, and please proceed as you so desire.

#### SUMMARY STATEMENT OF HON. ELIAS A. ZERHOUNI

Dr. ZERHOUNI. Thank you, Mr. Chairman, and members of the subcommittee. My colleagues and I are really pleased to be here, and we have submitted written testimony for the record, but what I'd like to do in my oral presentation is to really give you perspective about what has been the return investment which was testified to, over the years at NIH, in terms of benefits to the public.

But today, what I'd like to stress is, in parallel to the difficulties we have to sustain momentum, there is an incredible opportunity that is facing us, that has come from the work of my colleagues, in particular, from the completion of the human genome.

I would like to spend a few minutes with you, to describe for you what is it that NIH faces in terms of scientific challenge—you have the core issues that, from the scientific standpoint we see, that members of the subcommittee should focus on, and help us address.

So, what I'd like to do, first and foremost is give you, if you'll allow me, a little lesson on the complexity of biology and where we're going.

First and foremost, over the past 10 years, we have discovered methods, ways, approaches, ideas, technologies, and methodologies, that tell us that we can do four things we couldn't do before.

One, we can be a lot more predictive about exactly how a disease develops, in whom it develops, and what are the markers that tell us that someone is susceptible to a disease process—that's predictive.

The second, we can be much more personalized about how we treat an individual, because we do realize today that none of us are exactly made like anyone else—we're individuals, and individual variability means that we have to tailor therapies to the individual.

The third, for the first time in history, we can foresee an era where we can be preemptive, where we can act years before the disease strikes a patient, and basically keep the patient healthy, rather than wait for the disease to affect the patient, and for the doctor to intervene.

So, we're moving from what we call a late intervention, reactive paradigm, to an early intervention, proactive paradigm, which will require the fourth P, which is participation.

Now, participation is essential—Senator Specter is a fire—he really participates in his own care, and this is key to the success he's had in battling cancer.

We see this as the future of medicine. Without understanding that, and I understand the future paradigm is very difficult to understand, but the strategies at NIH have been to advance our knowledge and to benefit the American public. See Figure 1.

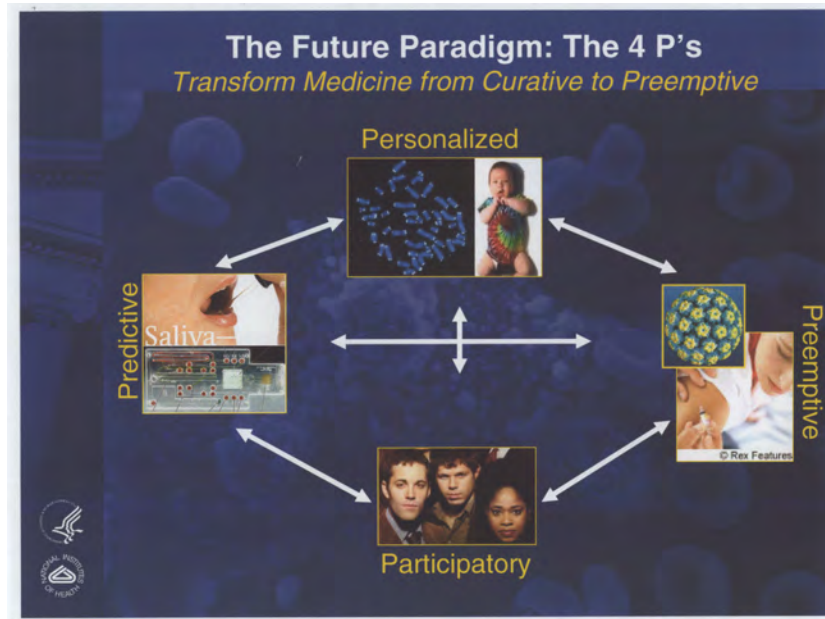


FIGURE 1.

So, let me just go forward here, and tell you the concept that is essentially emerging in front of us, and that is, the concept of complexity of disease processes.

It is our understanding today that there's no disease that can—that comes from any one particular molecule in the body being diseased. In fact, most of us are a combination of a network of molecules, as described on the side, that interact constantly.

#### NORMAL GENE FUNCTION—HEALTHY STATE

For example, here I have described five proteins—A, B, C, D, and E—all of these proteins are related to each other in the complex network. Over the past 50 years, since the discovery of the structure of DNA, what we have done is to try to understand how these proteins are interacting with each other. See Figure 2.

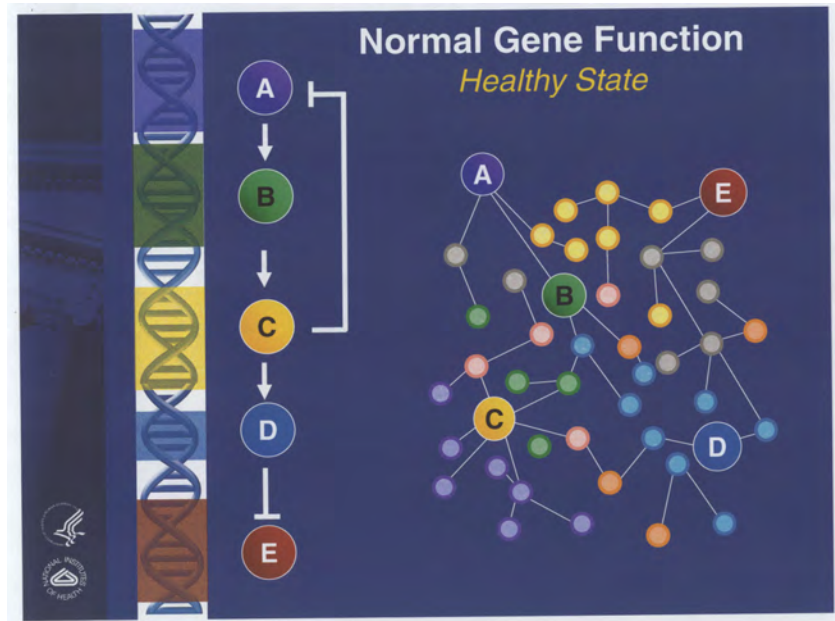


FIGURE 2.

As we discover the genetic code, and we discover that, in fact, every protein in our body is really made through—by instructions that are embedded in our genetic code through a process of transcription and translation—then they understand that fundamentally to understand the healthy state, and the disease state, we need to understand the components.

So, for example, in this case, A, B, C, D, and E are proteins that are encoded by DNA. So that, if you look at each one of them, you know that they are made upon instructions by DNA, and each one of them is made in a certain amount, a certain shape, and each one of them interacts with the other.

#### DISRUPTED GENE FUNCTION—DISEASE STATE

So, what happens when a disease process occurs? One of the theories that we have worked on, over the past 25 years is that, perhaps, instead of having a concept of disease that is related to one protein creating one disease, perhaps what is more important is to understand how they all interact.

But when we observe a disease process, we need to know which part of the code is abnormal? Where we do that, where we find, for example, what we have discovered over the past 5 years, in great part due to the work of Dr. Francis Collins, is that when there is a bad instruction in our genetic code. For example, as I showed here with that little mark, what happens? Well, that instruction translates itself into a protein that, instead of being shaped normally, as a round circle, is now abnormal.

So, what happens downstream in all of these molecules that keep us healthy, one of them will be abnormal, as you will see, that molecule now is completely misshapen. But that C molecule does not act by itself—it acts by interacting with A, and by repressing, for example, the amount of A, so the amount of A will increase. So on, we can see decreases in others. This is the disease state. See Figure 3.

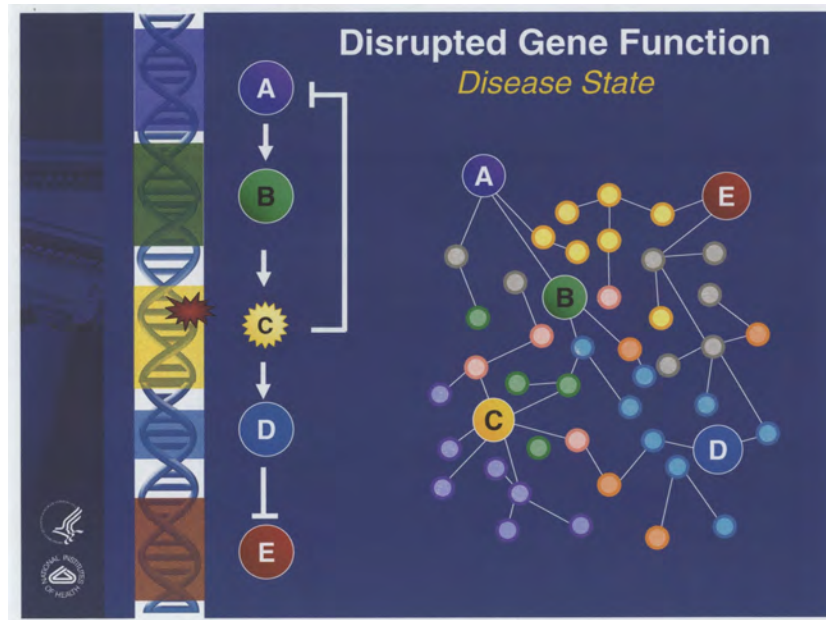


FIGURE 3.

So, the question we have faced over the past 15 years is, how can we discover all these code abnormalities, the things that we carry with us, that make us susceptible to disease, and how do we understand the environment interacting with it, in the context of a much more complex biology than we even thought in 1971. In 1971, we thought we would find silver bullets for cancer. Now we know that cancer is not one disease, not one pathway, not one interaction, but many. We need to understand them to be able to cure them.

#### GENOME-WIDE ASSOCIATION DISCOVERIES

So, let me tell you, then, what happened in my tenure here as Director of the NIH since 2002—and in a slide provided to me by Dr. Francis Collins in 2005—how much we knew about these abnormalities in the genetic code that may have an impact on a particular molecule, or a disease process. See Figure 4. This is, basically, the discovery panel that I have in my office, trying to get the reports from everyone about what I was discovering in disease processes, according to that template that I showed you. That template is essential to comprehend, and it is essential to understand that, this is where the battle is, today, and this is where the re-

sources need to be put in, and we do not have the resources to pursue all of these hints, if you will.

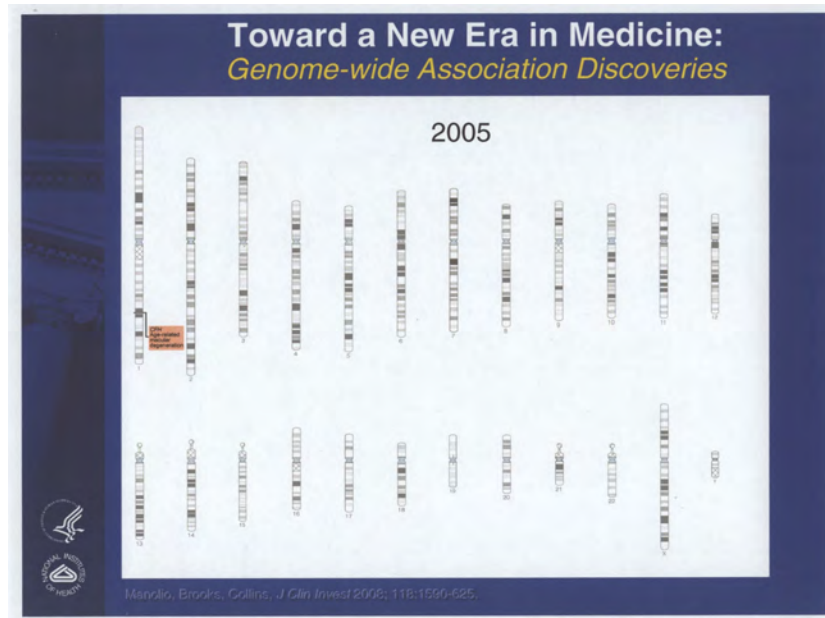


FIGURE 4.

In 2005, what you see here are all of the chromosomes of the human body—all of these marks here are chromosomes. All of these chromosomes, essentially, are the genetic code. So, when you make a discovery, somebody puts a little flag on the chromosome and says, “Gee, we made a discovery, here.” Patients who have this disease, had this abnormality right there.

In 2005, we found that in age-related macular degeneration, which is a major cause of blindness in our seniors, for years we thought it was a degenerative disease. Then, all of a sudden, someone discovered that the gene that was abnormal was an inflammatory gene, that led to the inflammation.

So, all of a sudden, now, we have new treatments, because we have a completely new understanding of that complex network that I described.

Look at what happens in 2005, and this is 2006: three more discoveries. See Figure 5. I was really elated, I thought this was great. Finally, we’re breaking the code, we’re going to be able to find some leads—then look what happens. First quarter of 2007, I had more discoveries reported to me than in the entire years of 2005 and 2006—that’s the first quarter of 2007. See Figure 6. Second quarter of 2007, I had even more discoveries than all of the cumulative discoveries that were made in my 5 years as NIH Director, just in the second quarter of 2007. See Figure 7.

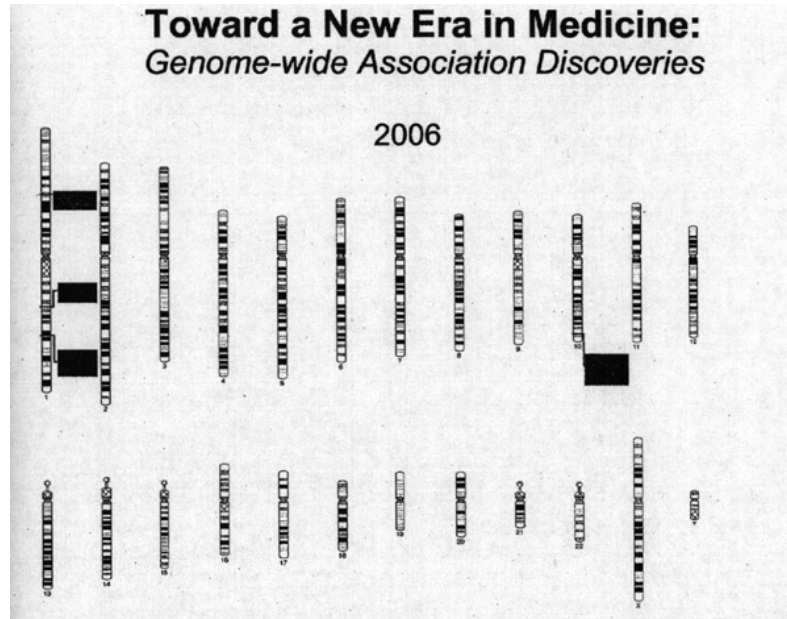


FIGURE 5.

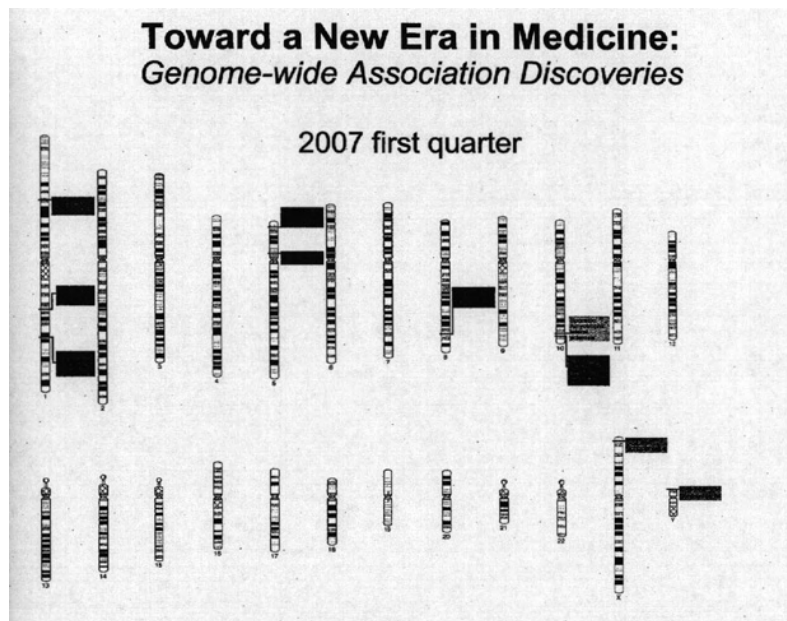


FIGURE 6.

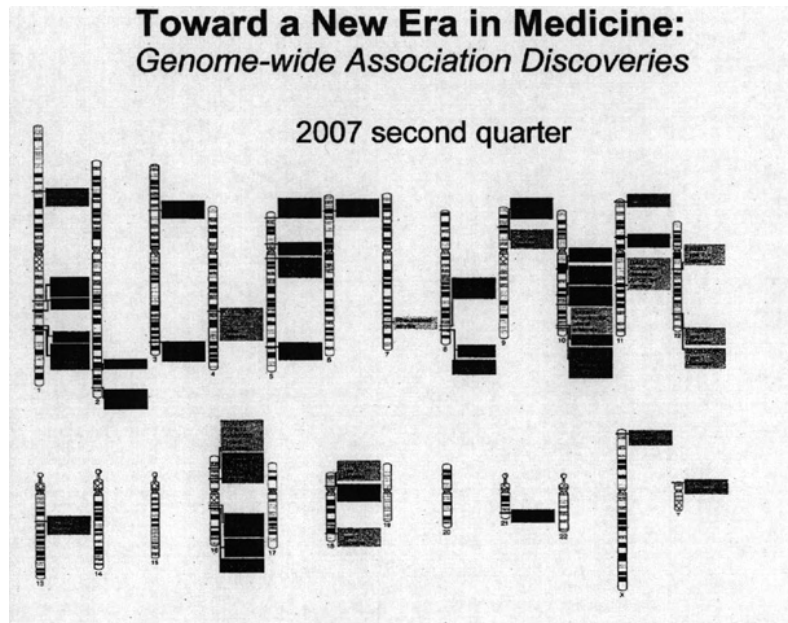


FIGURE 7.

In the third quarter of 2007, fourth quarter 2007, first quarter of 2008, and the second quarter of 2008. See Figures 8, 9, 10, and 11. This is nothing short of an explosion of knowledge. This is not something that we can drop, this is not something that we can just leave on the floor and say, “Our job is done.” These are clues that tell us about dozens of diseases.



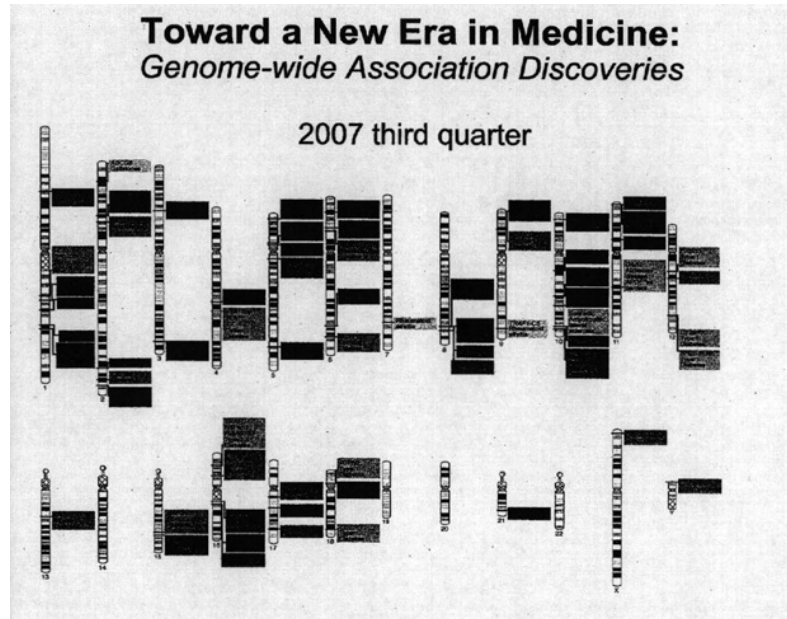


FIGURE 8.

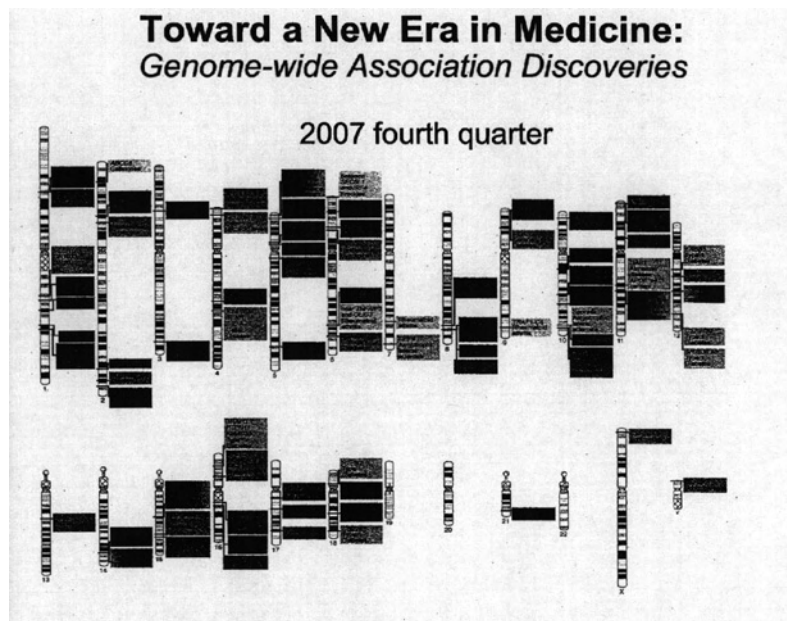


FIGURE 9.



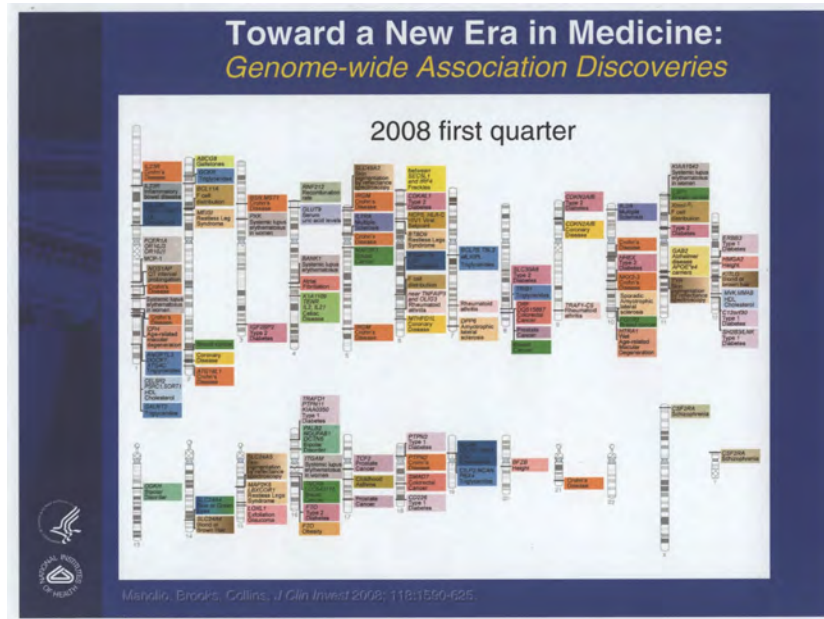


FIGURE 10.

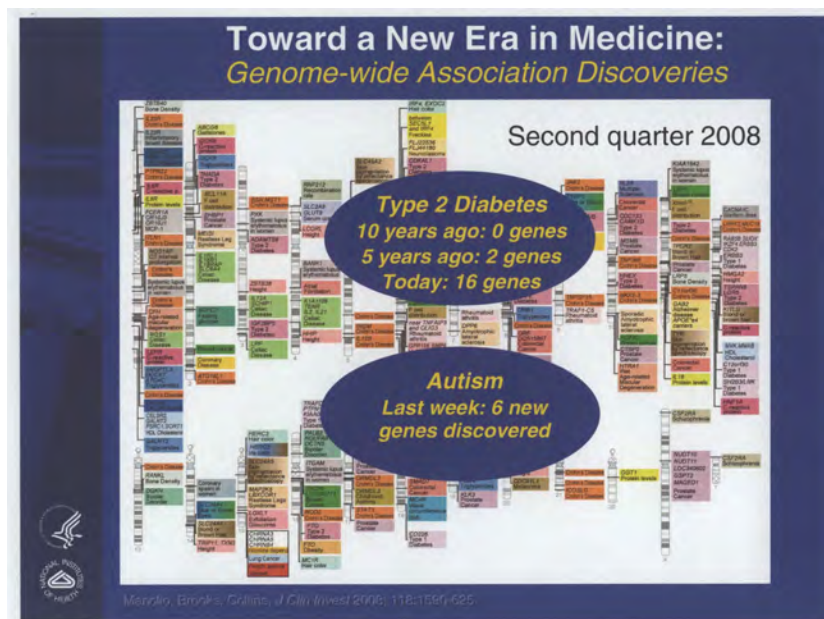


FIGURE 11.

For example, Type 2 diabetes—10 years ago, we knew about nothing, we knew zero genes that were important in diabetes. Many people had worked on it, couldn't find them. Five years ago, we have two genes, today 16 genes. I'm told in the next few days or weeks, a new paper is going to come up, identifying 14 essential genes that underlie that network that I described, that is abnormal in diabetes.

If you look at autism, last week—only last week, we received a report, a landmark report—identifying six new genes, and telling us something about this disease we didn't even know 3 years ago. So, the explosion is enormous, but does that mean our work is done?

Actually, let me show you what we, as scientists, believe are great opportunities. I showed you genetic abnormalities in what we call our inherited genome, things that we're born with. But cancer is a different process. The genome of cancer can become abnormal during our lifetime.

#### OPPORTUNITIES IN CANCER RESEARCH: NEW GENOMIC CLUES

So, the National Cancer Institute and the National Human Genome Research Institute engaged in a program, a pilot project called the Cancer Genome Atlas, and guess what? Two weeks ago, they reported the first finding in one of the most deadly cancers, brain cancer, glioblastoma, and we reported three new genes, we had absolutely no idea that they were critical to the development of glioblastoma. See Figure 12.

**Opportunities in Cancer Research:**  
*New Genomic Clues*

**THE CANCER GENOME ATLAS**

**Goal:** To systematically explore the entire spectrum of genomic changes involved in human cancer

**Current study:** Lung, glioblastoma, and ovarian cancers

**Finding:** Three new genes discovered mutated in glioblastoma

**Glioblastoma**

Credit: Arthur Toga/UCLA/Photo Researchers Inc.

NATIONAL CANCER INSTITUTE  
NATIONAL HUMAN GENOME RESEARCH INSTITUTE

FIGURE 12.

This is happening in front of our eyes. Members of the subcommittee, I cannot tell you that the feeling I have is that we're witnessing, right in front of us, a revolution in knowledge. The question is, are we going to be able to take advantage of it? To take advantage of it is a rigorous process, that requires NIH to be extremely proactive, dynamic, flexible, and adaptive. But how?

#### THE NEXT STEPS IN UNRAVELING THE MYSTERY

Let me just show you with this slide what the process is. See Figure 13. Once you have a clue, like the many clues that I described, the first thing that you have to do is invest immediately in analyzing more populations and more genes, so that that clue becomes a real lead, so that you confirm it—not just one lab reporting a finding, you need two, three labs reporting that finding, so we can follow that lead. Just like a detective, you go after that lead. That's step one.

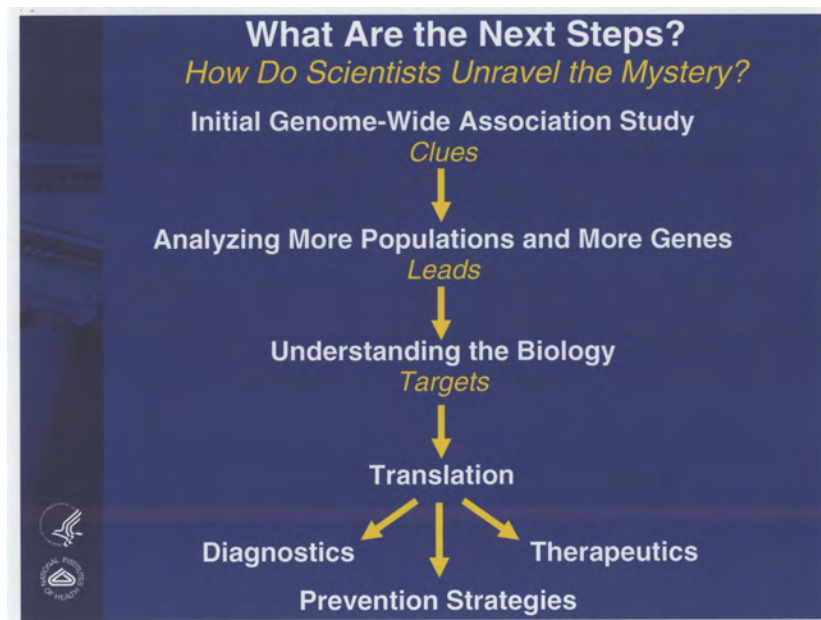


FIGURE 13.

Once you have that lead, you need to understand, where does it fit in that complex network that I described—how does the biology work? Once you have understood the biology, now we have a real target to go after. So, you go from clue to lead to target, and then you have to make the investment to translate that into either diagnostics, a prevention strategy, or a therapeutic strategy, and we have done that in many diseases—now we have a way to do it systematically in almost every common disease that we know.

So, this is really the challenge, are we going to drop these clues? Drop these leads? Are we going to have the new next generation of scientists that are going to dedicate their lives in exploring what

has come up through the 10 years of very hard work that all of us at NIH have done?

The game is to transform medicine. We cannot practice medicine in 20 years the way we do today. It will have to change, otherwise, we will not sustain the cost of healthcare that is facing us. It can only be done through renewed discovery, through renewed investments and trust that, in fact, only knowledge, only discovery will provide the solutions.

#### PREPARED STATEMENTS

So, with that, I'd like to thank you, and again, repeat my admiration for Chairman Harkin, and ranking member Specter, and all members of the subcommittee, you've shown a deep understanding of the challenges in front of us, and we appreciate it very much.

We're ready to answer your questions.

[The statements follow:]

#### PREPARED STATEMENT OF DR. ELIAS A. ZERHOUNI

Good afternoon, Mr. Chairman, and distinguished members of the subcommittee. It is a privilege for me to appear before you today to present the National Institutes of Health (NIH) budget request and to discuss the priorities of NIH for fiscal year 2009 and beyond.

Before I begin, please allow me this opportunity to express my appreciation to you and your staffs for your continued support of the National Institutes of Health.

As you are aware, research is the basis of virtually every improvement in health and medicine. The impact of scientific research, however, extends far beyond disease. Throughout history, advances in science and technology strengthened our economy, raised our standard of living, enhanced our global leadership, and lengthened and improved our lives.

To sustain these achievements, the flow of new scientific knowledge must be both continuous and substantive. Despite monumental progress, science remains a difficult frontier to explore. In this century, our society faces even greater challenges to the human condition that will require innovative and unprecedented scientific and technological advances across all fields of science, but most particularly in the life sciences. NIH's investment of \$29.5 billion in fiscal year 2009 will be used to support such advances.

NIH plays a significant role in the extension of life, and the prevention and treatment of many diseases, transforming modern research, and medicine in countless ways. For example, not long ago, acute, short-term, and lethal conditions such as heart attacks, stroke, acute infections, and cancers were the dominant causes of early mortality. Today, life expectancy has markedly increased due to progress made in reducing death from such acute conditions. However, these advances indirectly led to a major rise in the burden of chronic long-term conditions. It is estimated 75 percent of today's healthcare expenditures relate to chronic diseases. The emergence and consequences of chronic conditions—like obesity, diabetes, or Alzheimer's disease—are examples of the challenges we face. Healthcare costs are rising exponentially. We must continue our focus on not only how we best deliver healthcare, but more importantly, what healthcare we deliver.

#### A NEW STRATEGIC VISION FOR MEDICINE

Given this dramatic shift from acute to chronic disease, the strategies for preventing and treating diseases are beginning to shift. Today, we intervene late when the patient exhibits symptoms of disease. Our research is changing this approach, so that we may intervene much earlier in the natural cycle of diseases, years before they strike their victims. We must now develop a much more pre-emptive approach that manages disease over its entire life cycle, from identifying an individual's susceptibility to a disease, to prevention, early diagnosis, reduction of complications, and smarter therapies.

This shift from a late curative paradigm to an early pre-emptive one is becoming increasingly possible, thanks to the avalanche of recent discoveries funded by NIH. For example, in 2002, when I became NIH Director, we knew of one important gene abnormality in type 2 diabetes. In the last year alone, researchers uncovered seven

new genes or genetic regions that provide new clues to how this disease may develop. Remarkably, I now receive about one report a week of a significant discovery in the field of genomics. Recent discoveries apply to a broad spectrum of chronic diseases, ranging from mental disorders to autism. We now can see a clear path to what we call “the 4 P’s of Medicine”: medicine that will be more Predictive, Personalized, Pre-emptive, and Participatory.

To reach these key long-term goals, NIH is strategically investing in research to further our understanding of the fundamental causes of diseases at their earliest molecular stages. However, individuals respond differently to environmental conditions, according to their genetic endowment and their own behavior. In the future, research will allow us to predict how, when, and in whom a disease will develop. We can envision a time when we will be able to precisely target treatment on a personalized basis to those who need it, thereby avoiding treatment to those who do not. Ultimately, this individualized approach will allow us to pre-empt disease before it occurs, utilizing the participation of individuals, communities, and healthcare providers in a proactive fashion, as early as possible, and throughout the natural cycle of a disease process.

This prospective management approach to disease is vital to the transformation of medicine of tomorrow. Today’s discoveries are paving the way to make this future a reality. NIH continues its research efforts to search for cures to alleviate the suffering of the millions already affected by disease—and is greatly expanding the scope of research to discover entirely novel ways to stop disease in its tracks before it cripples us. This entails investing in completely new areas of investigation, while sustaining the level of our current efforts and supporting talented scientists using novel methodologies to explore new ideas and concepts that were impossible to envision only a few years ago.

#### TODAY’S SCIENTIFIC ADVANCES ARE TOMORROW’S MEDICINE

Consider how more predictive and personalized treatments could improve the safety and effectiveness of medications. The same medication can help one patient and be ineffective, or toxic to another. With the emergence of a field of research called pharmacogenomics, we will increasingly know which patients will likely benefit from treatment and which will not benefit, or worse, be harmed. Good examples of the present usefulness of pharmacogenetics are for cancer chemotherapy and use of the anticoagulant Coumadin.

Research on viruses is improving the lives of Americans and people around the world. NIH supported the early research that led to the discovery and development of antiretroviral therapies for HIV/AIDS. Today, antiretroviral therapies are benefiting millions of Americans as the most effective means of treating HIV infections. These therapies are also helping millions of people in Africa and the Caribbean through the President’s Emergency Plan for AIDS Relief.

Current HIV/AIDS therapies focus on the virus itself. Researchers are trying to understand how the virus enters the human cell and hijacks the cellular machinery, so it can replicate and spread. In a recent experiment, researchers made significant progress toward reaching this goal. Their new approach is based on a process called RNA interference discovered in 1998 and recognized with a Nobel Prize in 2006. Using RNA interference, the researchers suppressed the activity of every single gene in a type of human cell. They discovered more than 276 human proteins that seem essential to the replication of the HIV virus in human cells. This experiment, unthinkable a few years ago, can now be exploited to develop new ways of disabling this deadly virus.

Fundamental research can unexpectedly lead to revolutionary breakthroughs. Scientists at the National Cancer Institute, for example, developed a virus-like particle technology that formed the basis for new commercial vaccines that target specific cancers. In June 2006, the U.S. Food and Drug Administration approved the vaccine Gardasil, which is highly effective in preventing infections from the four types of human papilloma virus (HPV) that cause the majority of cervical cancers in women. Worldwide use of this vaccine could save the lives of 200,000 women each year. This is the first example of a truly pre-emptive strategy in cancer.

More often than not, it is the sustained combination of multiple approaches—from the most basic science to epidemiological and behavioral research—that makes advances in science effective. One important public health success story is the reduction in tobacco use and related diseases. In the last decade, overall cancer death rates dropped for the first time in a century, driven largely by the dramatic reduction in male smoking from 47 percent in the 1960s to less than 23 percent today. This reduction, along with more effective early screening tools like mammography and colonoscopy, is changing the landscape of cancer mortality. These successes re-

flect the outcome of significant research investments made by many NIH Institutes and Centers (ICs) and our sister agencies over the last 50 years.

Our ability to predict and pre-empt disease also hinges on the development of new diagnostics based on recent discoveries in genomics, proteomics, systems biology, and imaging. Among the diagnostic capabilities currently being explored are:

*Point of Care Diagnostic Testing.*—NIH supports research that has and will develop technologies that offer instant diagnosis in the emergency room or physician's office, or at home, including rapid analysis of blood for assays such as chemistry, electrolytes and blood gases; biosensors that instantly detect signs of heart disease or infections; and biochips that detect disease processes at the molecular level.

*Salivary Diagnostics.*—Scientists identified genes and proteins expressed in salivary glands that we believe will replace some forms of urine or blood analysis in the detection of cancer, heart disease, diabetes, and other conditions.

*Optical Imaging.*—NIH-supported researchers are developing imaging techniques that seek to reduce the need for invasive diagnostic procedures. These new tools include fiber optic probes to detect malignant tissues, with the potential of avoiding invasive biopsies with a more accurate method of analysis; optical coherence tomography to identify heart disease; and multiphoton microscopy to study living cells and tissues.

*Brain-Wiring Diagrams.*—NIH-supported researchers developed a way to reveal connections made by a single nerve cell in living tissue. We hope one day to construct a wiring diagram of the billions of nerve cells that constitute the brain's visual centers that might allow us to diagnose and treat vision loss with far more success—an advance that has implications for many other brain diseases as well.

*Autism Genes.*—Research into autism discovered clues that rare genetic changes represent a risk for autism. With this preliminary result, we are on at least one path to understanding methods of predicting autism risk in infants.

#### THE CHALLENGES THAT LIE AHEAD

We are optimistic about recent discoveries. However, there are challenges that lay ahead of us. We still need to focus much of our efforts on fundamental research, because new threats and diseases constantly emerge. For example, soldiers suffering from blast injuries highlight the importance of additional knowledge on traumatic brain injuries. Infectious diseases remain among the leading causes of death worldwide. More than 30 newly recognized infectious diseases and syndromes emerged in the last three decades alone, including HIV/AIDS and SARS. Infectious diseases that once seemed to be fading, such as tuberculosis and malaria, have resurged. New drug-resistant forms of once-easily treated microbial infections are emerging at a rapid pace. New strains of influenza occur each year. There is concern that a new influenza virus may emerge with the capacity for sustained human-to-human transmission, possibly triggering a pandemic similar to what occurred in 1918, 1957, and 1968.

The tragic events of September 11, 2001, and the deliberate release of anthrax in the Nation's capital, drove home the realization that certain deadly pathogens, such as smallpox or anthrax, could be used deliberately as agents of bioterrorism against the civilian population—similar to radiological, nuclear, and chemical threats. Research in these arenas is critical to meeting these threats, and \$1.7 billion is included in fiscal year 2009 budget for such NIH-supported research.

Efforts to prevent, detect, and treat disease require better understanding of the dynamic complexity of the many biological systems of the human body and their interactions with our environment at several scales—from atoms, molecules, cells, organs, to body, and mind. As the questions become more complex, and even as knowledge grows, research itself becomes more multi-faceted. We recognize that to effectively push science/new knowledge forward, researchers and scientists must begin to work more collaboratively to develop unifying principles that link apparently disparate diseases through common biological pathways and therapeutic approaches.

Today, and in the future, NIH research must reflect this new reality. Advanced technologies, including sophisticated computational tools, and burgeoning databases, need to be more widely shared with easy public access. The scale and intricacy of today's biomedical research problems increasingly demand that scientists move beyond the borders of their own disciplines and apply new organizational and interdisciplinary models for science. One of NIH's most pressing challenges is to help generate and maintain the trained and creative biomedical workforce necessary to tackle the converging and daunting research questions of this century.

Many of our public health problems have a behavioral component. To put evidence-based interventions into place, all of society must participate. To confront obe-

sity, NIH researchers must continue to address a multitude of intersecting factors, from inherent biological traits that differ among individuals, to environmental and socioeconomic factors and behavioral factors that may have molecular and environmental influences. NIH developed innovative intervention programs such as the WE CAN (Ways to Enhance Children's Activity and Nutrition), now in several hundred communities. WE CAN is designed to help children maintain a healthy weight by promoting improved food choices, increased physical activity, and reduced screen time.

NIH's primary mission is to develop new knowledge in biology and behavior and to apply this knowledge for the benefit of all. NIH is taking a more proactive role in helping to translate these discoveries into practice. For example, we have engaged in the most profound reform of translational and clinical research in the United States in over 50 years. The NIH Common Fund (CF), a new clinical and translational science program, now supports 33 academic centers of excellence charged with the dual task of translating research from the laboratory to patients and discovering the most effective ways of implementing what we know best at the community level. Success in these endeavors depends heavily on our ability to train a new generation of clinician-scientists steeped in modern methodologies and concepts of basic and translational research. This new generation of researchers must be able to work seamlessly with basic and applied scientists in an interdisciplinary environment.

Through our ICs, NIH conducts many comparative effectiveness trials that provide evidence for more effective strategies of care. Many similar NIH-supported comparative effectiveness trials are uncovering evidence that shows, for example, that older generic drugs can often be as effective as newer medications in the treatment of high blood pressure (ALLHAT trial), or certain mental health disorders (CATIE trial). In order to disseminate these results, ALLHAT investigator-educators made 1,696 presentations to 18,905 clinicians in 42 States and Washington, DC.

Given the structure of our healthcare system, it is often difficult for providers to implement the evidence from these large NIH trials. This challenge is real and requires that all relevant parties work collaboratively toward a more systemic approach that goes beyond simply conducting more research of this type. All healthcare components must come together to develop clear follow-through mechanisms to implement the evidence generated by these large trials.

#### OUR NATION MUST SPUR INNOVATION

With the NIH Reform Act of 2006 (Public Law 109-482), Congress provided a foundation for the centerpiece of the NIH Common Fund (CF) for Medical Research that provides "incubator space" to spur innovation. The CF supplies a centralized source of funding for trans-NIH initiatives to meet the research and training needs of the 21st century and stimulate innovation. Research initiatives supported by the CF must not only be trans-NIH and fill a gap in our knowledge base but also be potentially transformative. The CF invests in systems biology, interdisciplinary research, biocomputing, and clinical research, all of which are fundamental to moving biomedical research forward expeditiously. The budget request includes \$534 million for such activities.

The Human Microbiome project is one such initiative. It promises to reveal how bacteria and other microorganisms that are found naturally in the human body (the "microbiome") influence a range of biological processes, including development, immunity, and nutrition. This effort will not only improve our understanding of how an individual's microbiome relates to disease, but will also support the development of new technologies and computational approaches—all cross-cutting outputs that can be applied to investigations of other biosystems.

Another new initiative at the biomedical research frontier is the NIH Epigenomics Program. It will scan the human genome to study heritable features that do not involve changes to the underlying DNA sequence, but significantly affect gene expression and inform us about how DNA is regulated. This analysis of epigenetic changes should reveal new cellular pathways and mechanisms that influence disease progression. Also, the CF continues to support other important initiatives, such as the Pioneer Award program for \$36 million in fiscal year 2009 which nurtures high-risk ideas that, if successful, can have unusually high scientific impact.

Nurturing a new generation of innovators is critical to our future research endeavors. NIH makes strategic investments at every point in the pipeline to improve the flow of talent drawn from every part and population of America. We produce teaching supplements to help educators in grades 2 through 12 convey difficult concepts through engaging activities, improving health literacy, and hopefully sparking children's interests in careers in research. NIH offers undergraduate students re-



search experiences, especially geared toward tapping the vast potential of young people from historically underrepresented groups in the sciences.

NIH grants fund graduate students and post-doctoral fellows, who go on to fill most every niche in the American biomedical research enterprise—from academic research to private industry, and from venture capitalists to policy makers. But most importantly, young people need to see, at all stages of the pipeline, that biomedical research is an attractive career. They need to see that there is a stable research enterprise, providing them opportunities to explore their best ideas for improving human health. The budget request includes \$123 million for individual fellowship awards under the Ruth L. Kirschstein program.

NIH-supported scientists continue to discover the fundamental underpinnings of human biology in all of its complexity through investigator-initiated research, the mainstay of creativity in science. Thus, one of the top budget priorities is to sustain the number of competing Research Project Grants (RPGs). The budget funds essentially the same level of competing RPGs in 2009 as estimated in 2008—about 9,760 RPGs at \$3.5 billion. Overall, NIH will support nearly 38,260 RPGs at \$15.5 billion. This was accomplished, in part, by holding down inflationary increases for existing and new grants.

One example of our efforts to sustain the research enterprise is the Director's Bridge Awards, which funded 244 scientists in 2007. It preserves the U.S. investment in investigators, laboratories, and the research projects that support our mission. We expect to continue this successful approach in 2009.

Our priorities continue to focus on maintaining a competitive and viable scientific support system, especially for new and early-career scientists. Our long-term demographic projections show the aging of the Nation's scientific workforce. Unless we take an immediate and substantial proactive stance in protecting early-career scientists, this situation will have a negative and long-lasting impact on our competitiveness and innovation as a Nation. In 2007, we set a goal for the number of new career investigators based on the historic 5-year average of more than 1,500—it was surpassed. This represented a substantial increase in new career investigators over the number in 2006 of 1,353. We plan to continue this commitment in 2008 and 2009.

In 2007 and 2008 we also targeted earlier career stages, such as the Pathway to Independence Awards, supported by all NIH ICs. These awards provide 5 years of support for over 170 postdoctoral trainees a year to encourage risk-taking and independence. NIH plans to fund over 350 postdoctoral scientists by the end of 2008 and continue the program in 2009. The budget request includes \$56 million for the New Innovator Awards, which support newly independent scientists with novel ideas and potentially large scientific impact. Scientists must be within the first 10 years of receiving their doctoral degree to qualify. NIH funded 30 awards in 2007 and plans to maintain this promising program.

#### PEER REVIEW AND TRANSFORMATIVE RESEARCH

Peer review is such a fundamental and critical part of the research process that it requires our constant vigilance. With the increasing breadth and complexity of science, along with the increased number of research grant applications, NIH recognized the need to take a comprehensive look at its review process, and make the necessary changes to strengthen it for applicants and reviewers alike. Although our peer review system is outstanding—and emulated throughout the world—we wanted to make it even better.

In June 2007, NIH launched a comprehensive effort to identify information about the review process that could be used to enhance the agency's review system. Extensive input was sought and received from a wide range of stakeholders across the country and at NIH, which led to a comprehensive report released in February 2008 detailing the challenges facing our current system, and proposals for improvement. In June of this year, NIH announced the initiatives it plans to implement that should improve review efficiency and effectiveness. These can be grouped into four core priorities: (1) engage the best reviewers; (2) improve the quality and transparency of reviews with a greater focus on scientific impact while streamlining the application; (3) provide for fair reviews across career stages and scientific fields with a greater focus on early stage investigators and transformative research; and (4) develop a permanent process for continuous review of peer review.

An important component of the new plan is an increased commitment to investigator-initiated high-risk, high-impact research to prevent a slowdown of transformative research, despite difficult budgetary times. I firmly support the need for NIH to invest in such research, even more so in times of restricted budgets. Exam-



ples are already under way such as the NIH Director's Pioneer award, the New Innovator Award, and the recently piloted EUREKA award program.

To further stimulate this critical arena of research, NIH intends to continue to grow the Transformative Research portfolio. A key element in this portfolio will be the newly established investigator-initiated "transformative" R01 program, funded within the NIH Roadmap. Potential impact and innovation will be the primary criteria for success in a review process that is designed to encourage risk-taking to achieve revolutionary results. At the same time, NIH plans to continue the commitment for NIH Pioneer and New Innovator Roadmap awards and expand the current EUREKA awards to more ICs in the coming year. Taken together, these programs will represent a substantial investment in investigator-initiated transformative research.

#### SUMMARY

At NIH, building toward the future involves innovations in multiple areas. We are in the midst of an explosion of new discoveries and novel opportunities for progress across all areas of science—from the most basic discoveries, such as the sequencing of the human genome, to the development of fields—like nanotechnology—that did not exist a few years ago. These advances have dramatically expanded the scope and capacity of the Nation's research enterprise, a goal and outcome of the doubling of the NIH budget.

This remarkable growth in research capacity was accomplished, in part, by leveraging NIH and private sector resources to nurture more investigators, develop new technologies, and build infrastructure. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, help entrepreneurs, as they translate science to market products to improve health and help maintain American economic leadership. A total of 4,350 new technologies were brought to market by 189 universities, hospitals, and private research institutions from 1998 through 2006. From 1980 to 2006, a total of 5,724 new companies were formed around technologies developed by research institutions, many directly funded by NIH.

The United States is now the pre-eminent force in biomedical research. Our Nation continues to lead the highly competitive biotechnology and pharmaceutical sectors. Yet, we are also the focus of increasing competition from growing research in Europe and Asia. NIH programs produce steady streams of novel discoveries and innovative researchers that flow into our industries, making them more competitive. We must continually sustain the momentum of U.S. biomedical research, or risk losing it. Complacency is unacceptable!

We stand today at a crossroads in our efforts to improve health. Healthcare costs are rising. As a society, we must commit to moving forward and capitalize on the momentum created by advances in science and technology. We need to sustain this momentum. Progress in the life sciences in this century will be a major determinant of our Nation's health, its competitiveness, and its standing in the world. This is truly a race against time—a race that we cannot afford to lose.

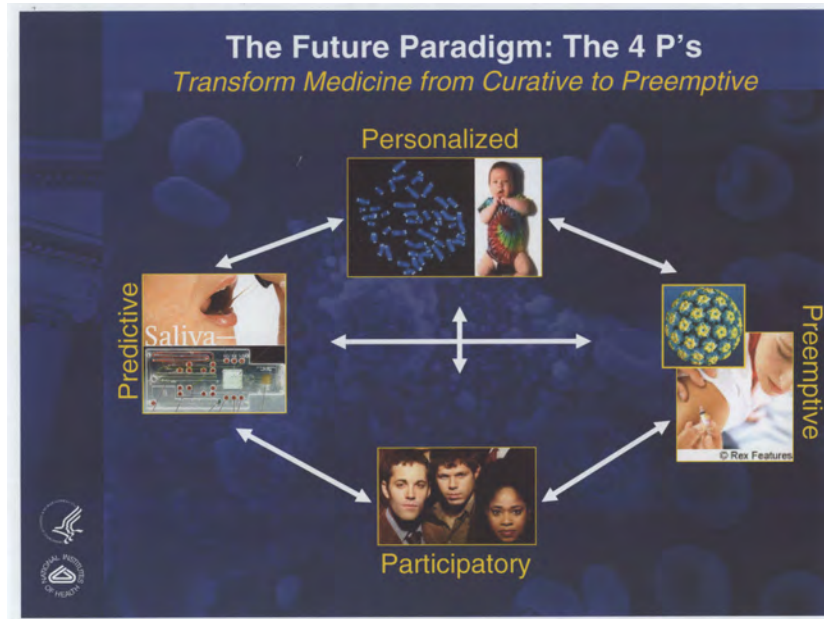


FIGURE 1.

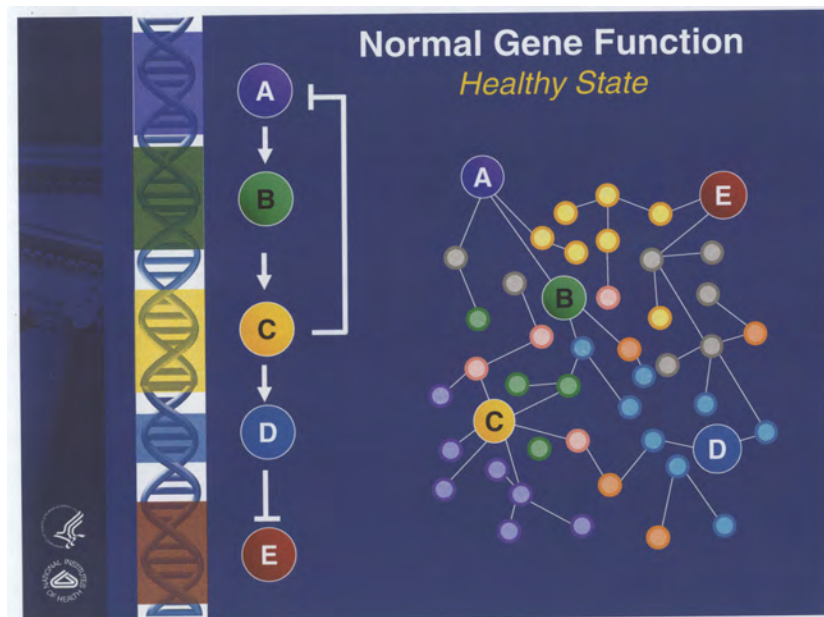


FIGURE 2.

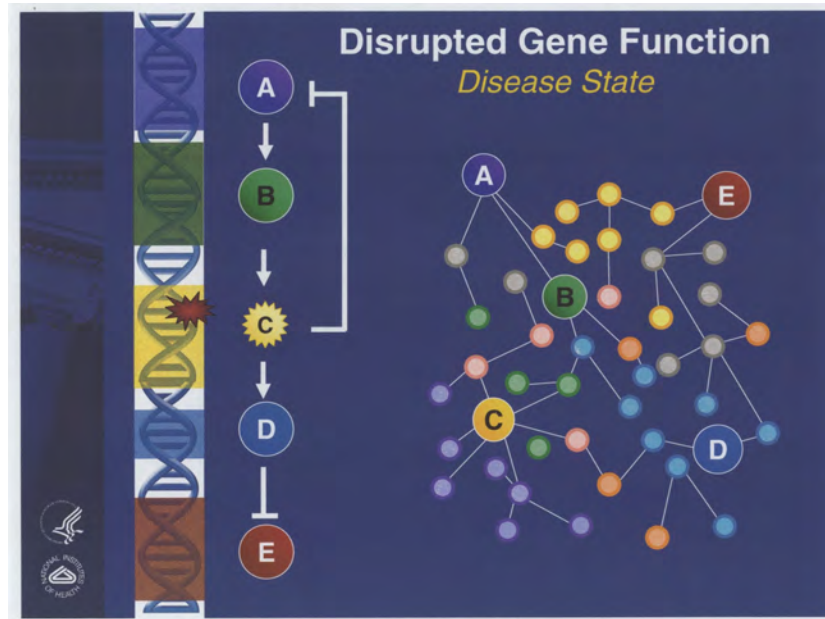


FIGURE 3.

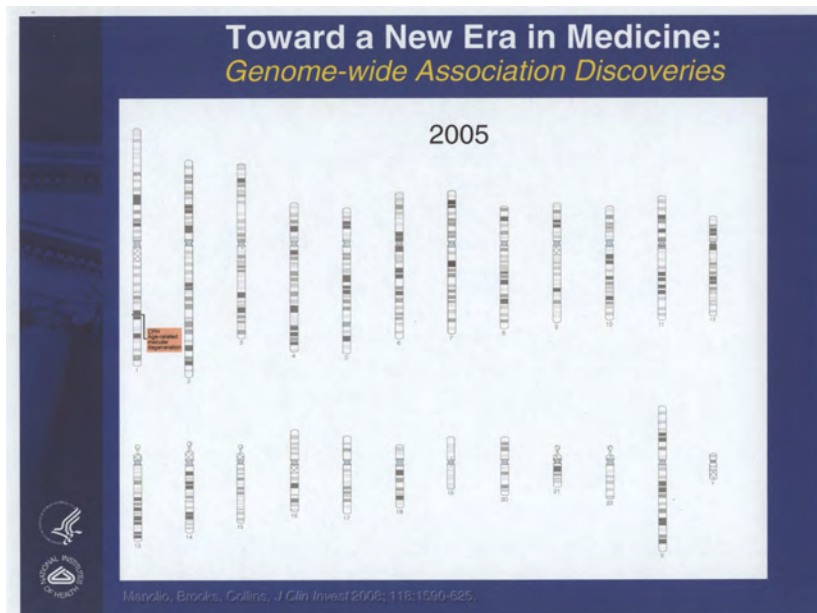


FIGURE 4.

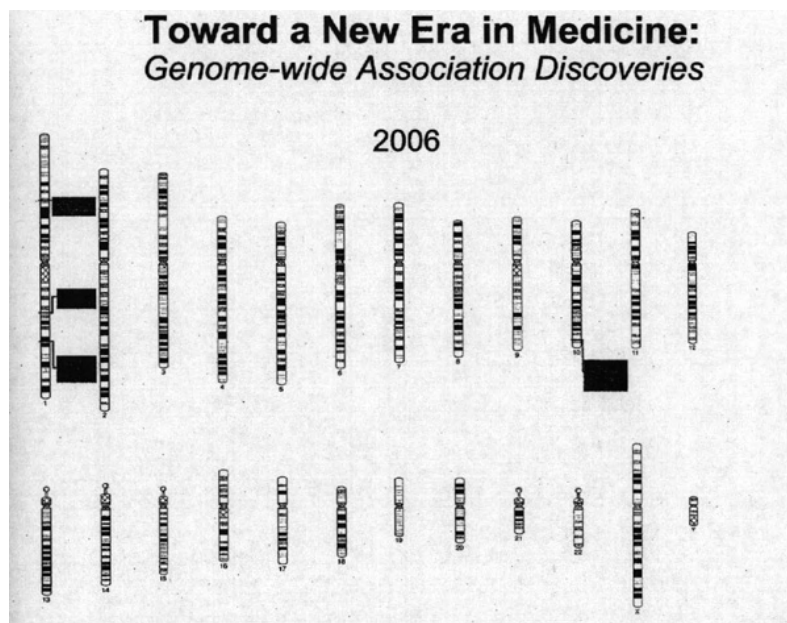


FIGURE 5.

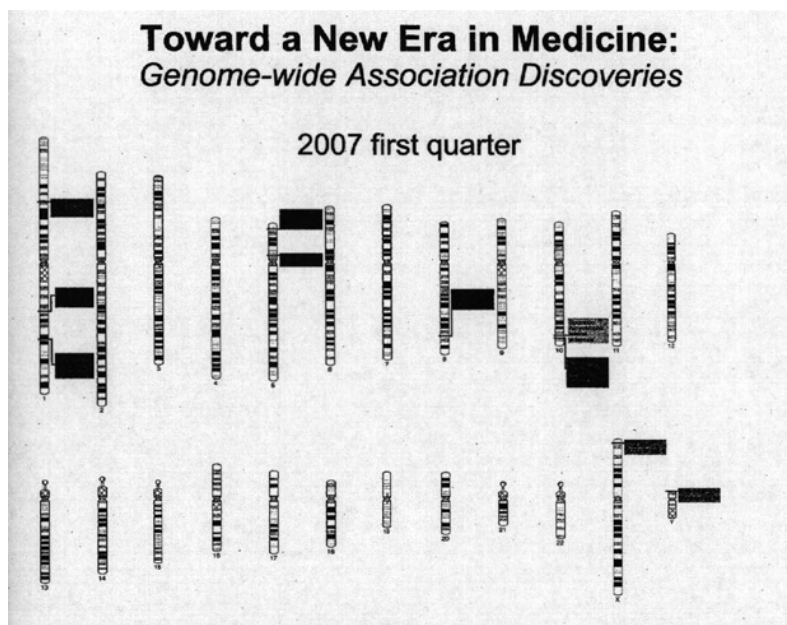


FIGURE 6.

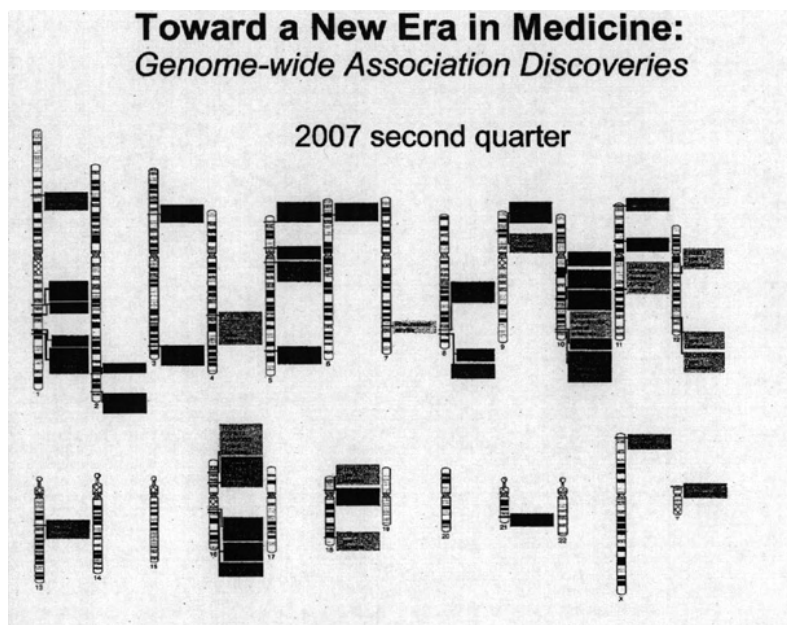


FIGURE 7.

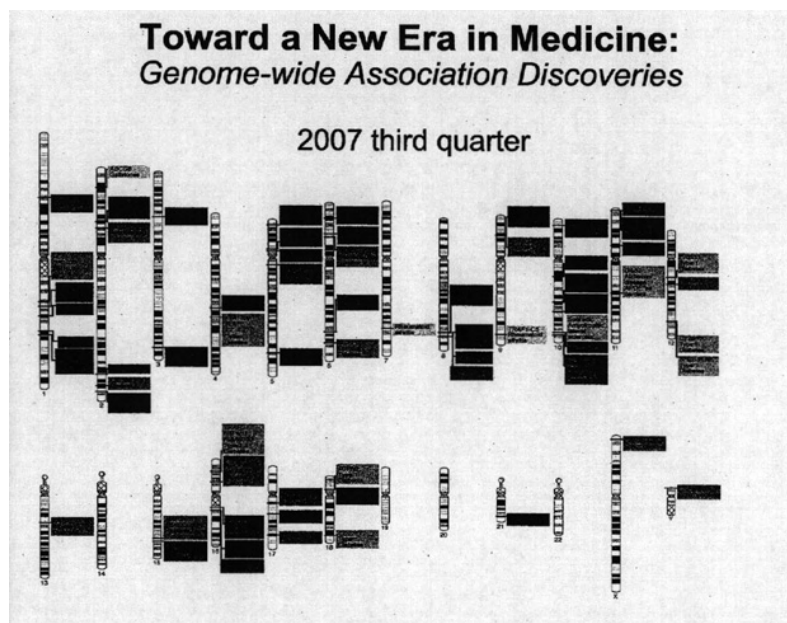


FIGURE 8.

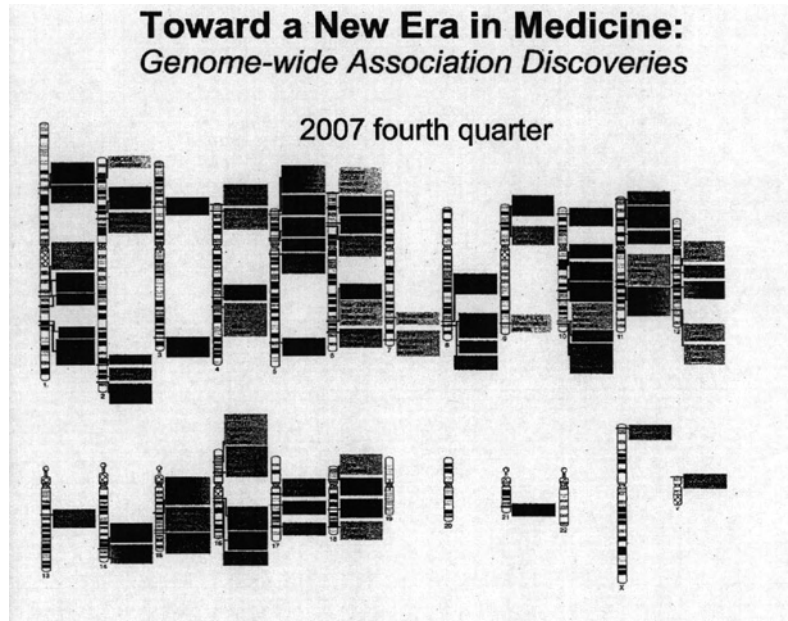


FIGURE 9.

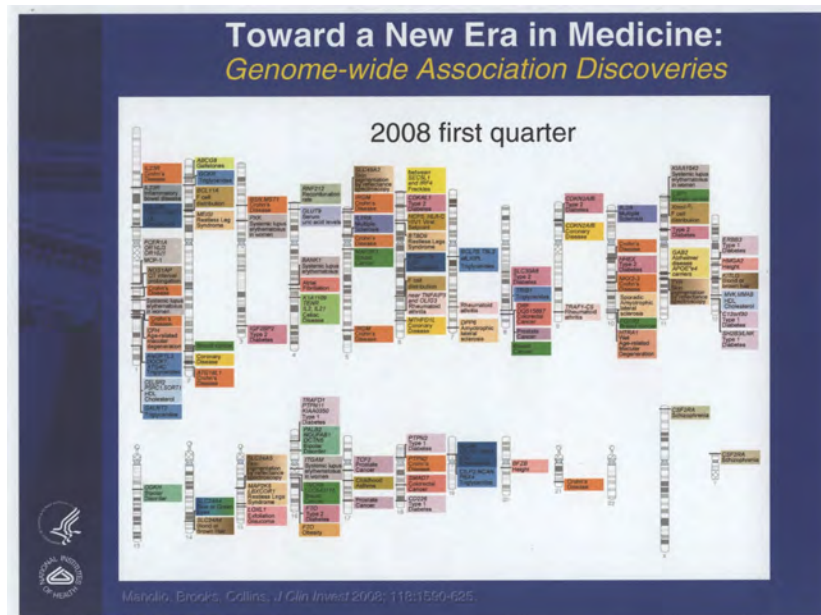


FIGURE 10.



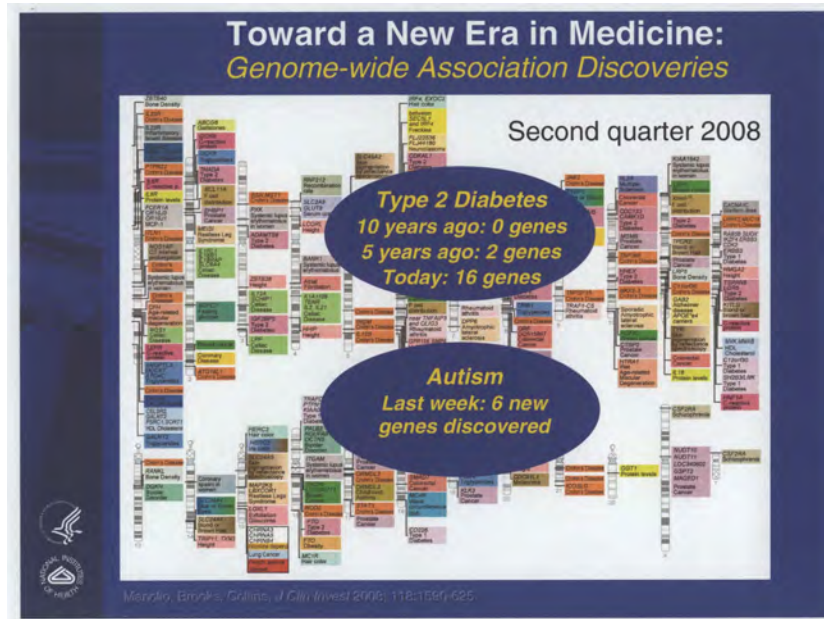


FIGURE 11.



FIGURE 12.

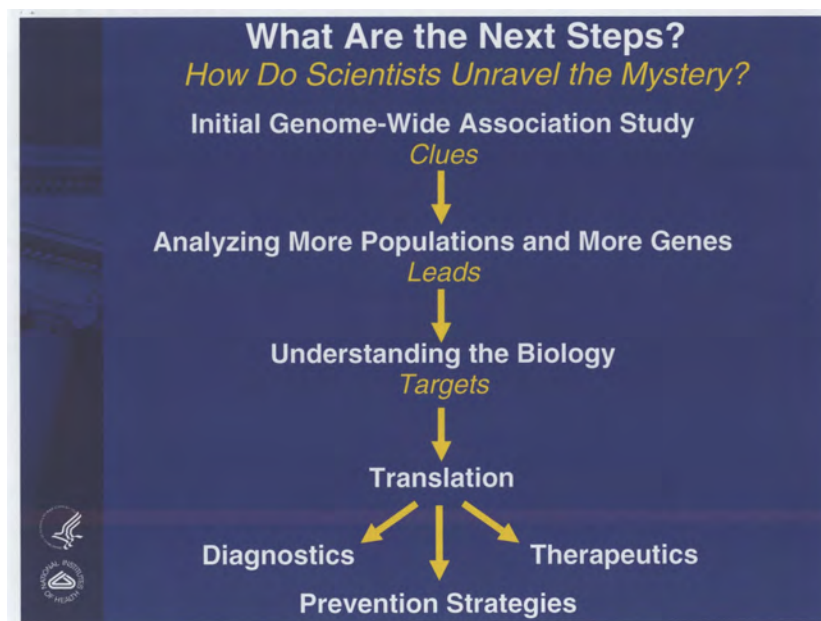


FIGURE 13.

## PREPARED STATEMENT OF DR. ELIZABETH G. NABEL

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 2009 budget of \$2,924,942,000 includes an increase of \$2,830,000 over the fiscal year 2008 appropriated level of \$2,922,112,000. The NHLBI provides leadership for a visionary and highly productive research program in heart, lung, and blood diseases. In December 2007, the Institute announced a new strategic plan to guide its next decade of research, training, and education to reduce the burden of the diseases under its purview. This statement describes the main elements of the plan and then focuses specifically on the Institute's many efforts to forge a scientific basis for a more personalized approach to medicine in the future and to translate research into practice.

## THE NHLBI STRATEGIC PLAN

Thanks to the dedicated involvement of the communities it serves, the NHLBI recently completed development of a scientific working plan to guide its activities and initiatives in the near future. The plan outlines goals that broadly reflect complementary and interactive avenues of scientific discovery—basic, clinical, and translational research. This crosscutting, versus disease-specific, approach highlights areas where the NHLBI is well positioned to make major contributions through investigator-initiated research and through programs that enable and supplement investigator-initiated activities. Shaping the Future of Research: A Strategic Plan for the National Heart, Lung, and Blood Institute is available on the NHLBI Web site at <http://apps.nhlbi.nih.gov/strategicplan/>, and printed copies have been distributed widely.

In the area of basic research, the plan focuses on delineating normal and pathological biological mechanisms and exploiting the emerging understanding of them to identify biomarkers of disease. Such biomarkers—broadly defined as measurable indicators of genotype, normal or pathological processes, or responses to therapeutic intervention—will facilitate identification of disease subtypes and point the way toward new molecular targets for diagnosis, treatment, and prevention.

The plan's clinical and translational research goals emphasize transmission of knowledge between basic and clinical research so that findings in one arena rapidly inform and stimulate research in others. More precise methods of diagnosing disease



and predicting susceptibility and prognosis are expected to arise from application of new approaches from basic science laboratories. A critical challenge will be to develop individualized preventive and therapeutic regimens based on genetic makeup in combination with developmental and environmental exposures. Insights are already emerging, but robust and efficient means of validating both patient-focused and population-based treatments will be needed to establish an evidence base to guide medical practice.

The plan acknowledges the need to enhance understanding of the processes involved in translating research into practice and to use that understanding to enable improvements in public health and stimulate further scientific discovery. It places particular emphasis on conducting research on primary prevention and identifying interventions that work in real-world health-care practice. As well, continued development and evaluation of new approaches to communicate research advances to the public is an important priority for ensuring full and informed participation of individuals in their health care.

#### SETTING THE STAGE FOR PERSONALIZED MEDICINE

Considerable progress has been made in reducing the burden of illness, particularly in the area of cardiovascular diseases, through development of therapeutic and preventive strategies that are broadly applicable to the general population at risk. Now we have advanced to a point where it may soon be possible to develop vastly more sophisticated approaches tailored to individuals. The dream is to be able to prevent disease entirely and, short of that, to be able to offer each patient a precisely targeted drug or other intervention, at a carefully titrated dose, for exactly the proper duration, without risking dangerous or troublesome side effects. One path to realization of this dream lies in developing a more complete and detailed understanding of the genetic basis of individual health and disease.

Technological advances that make it possible to identify millions of DNA sequence variations rapidly and inexpensively, and to correlate them with individual characteristics and health indicators (phenotypes), have fueled an explosion of interest in this area. The NHLBI is investing substantial resources to move the science along, capitalizing on vast amounts of data gathered over many years from cohort studies such as the landmark Framingham Heart Study. In 2007, the Institute conducted genotyping using about 550,000 SNPs (single-nucleotide polymorphisms, which are tiny variations in the DNA code) in over 9,300 people from three generations of Framingham study participants. The genetic data are being linked to an array of phenotypic information, including major risk factors such as blood pressure, serum cholesterol, fasting glucose, and cigarette use; biomarkers such as fibrinogen and c-reactive protein; electrocardiography measures; imaging measures that reveal nascent pathology; and data on clinical cardiovascular disease outcomes. The resulting research resource, known as the Framingham SHARe (SNP Health Association Resource), is being developed and maintained by the NIH National Center for Biotechnology Information in its Database of Genotype and Phenotype (dbGaP). This rich source of data will be made available—with appropriate privacy safeguards—to qualified investigators at no cost.

The Framingham SHARe is only the first of many NHLBI efforts to enable what are known as genome-wide association studies (GWAS)—projects that involve scanning markers across complete sets of DNA from many individuals to find genetic variations associated with diseases or conditions of interest. The Institute is moving rapidly to increase the diversity of its genotype-phenotype data resources. Thus, we have created the MESA SHARe, based on cohorts from the Multi-Ethnic Study of Atherosclerosis, a long-running multicenter study that includes Americans of African, Chinese, Hispanic, and European ancestry. The SHARe-Asthma Resource project or SHARP is conducting a genome-wide analysis in adults and children who have participated in NHLBI's clinical research networks on asthma. The Candidate-gene Association Resource or CARE project includes plans to genotype one million SNPs in African-American men and women and link the results with phenotypic data obtained from eight major epidemiological studies, including the Cooperative Study of Sickle Cell Disease and the Sleep Heart Health Study. The NHLBI has also undertaken genotyping of African-American women who participated in the Women's Health Initiative, a project of great interest to many NIH components and the communities they serve.

The GWAS approach offers a powerful and unprecedented avenue to unravel the contribution of complex traits to common diseases, and it is clear that the richness of the data generated from these studies is far greater than could be explored by a single investigator or group of investigators. To ensure that the greatest possible public benefit accrues from our investment in GWAS, under terms and conditions

consistent with the informed consent provided by research participants, the NIH has established a GWAS data-sharing policy for NIH-supported investigators (<http://grants.nih.gov/grants/gwas/>). I was pleased to lead my NIH colleagues in this effort and, now, I am honored to serve as co-chair of the NIH Senior Oversight Committee for GWAS studies. I believe that robust NIH leadership in all aspects of GWAS will enable a superior yield from this exciting approach and bring us closer to realizing the dream of personalized medicine.

#### PHARMACOGENOMICS MOVES CLOSER TO THE BEDSIDE

The long-term vision of creating a broad selection of custom-made therapies for individualized treatment is tantalizing, but a great deal of work needs to be done before it can be achieved. Much closer to near-term application is the use of pharmacogenomics—an understanding of how genetics explains individual differences in response to drugs—to guide prescribing decisions for agents currently on the market. A case in point is the use of the anticoagulant warfarin, a tricky drug to prescribe because too little or too much can produce serious problems and the dose requirement varies widely from one patient to another. Research has identified two specific genetic variations that appear to account for much of the inter-individual variation in sensitivity to warfarin, and we are now moving forward with a clinical trial to evaluate the clinical efficacy of a genotype-guided prescribing strategy for warfarin therapy and to determine whether the increment in efficacy and safety warrants the cost of genetic testing. We fully expect that genetic stratification of patients will become the norm for trials to evaluate new drugs, and that genetic information will prove invaluable for the design of novel alternatives to existing drugs that are likely to be ineffective or harmful in genetically susceptible individuals.

#### BRIDGING RESEARCH AND PRACTICE

In the upcoming years, these and other research efforts will yield an extraordinary amount of new information that will fundamentally transform medical practice and call for innovative approaches to translation and dissemination. We must be prepared to make the most of it. In line with its strategic plan, the NHLBI has developed a new knowledge network approach to bridge the gap between discovery and delivery, identify areas that should be addressed by future research, and develop more effective approaches for synthesizing and organizing scientific evidence and moving it into practice. The first network, addressing cardiovascular diseases, will be implemented globally and make innovative use of new media technologies.

The NHLBI has also begun a new effort to develop comprehensive, evidence-based, integrated guidelines to assist primary care physicians in helping adult patients reduce their risk of cardiovascular diseases. The integrated approach will focus on all cardiovascular risk factors to reflect the complicated clinical scenarios that patients and physicians typically face. Expert panels are being convened to review available scientific evidence and update existing guidelines for the prevention, detection, evaluation, and treatment of high cholesterol, hypertension, and overweightness/obesity. An important goal of both the integrative guidelines and the updates is to improve implementation, especially among high-risk and minority communities. Ensuring that the public benefits from its investment in biomedical research is, and has always been, our highest priority.

#### PREPARED STATEMENT OF DR. JOHN E. NIEDERHUBER

Mr. Chairman and Members of the Committee: Thank you for the opportunity to offer testimony on behalf of the National Cancer Institute (NCI) and the National Cancer Program. The fiscal year 2009 budget of \$4,809,819,000 includes an increase of \$4,731,000 over the fiscal year 2008 appropriated level of \$4,805,088,000.

#### A UNIQUE NATIONAL RESOURCE

At his hometown hospital, the patient remembers, “there were lots of debates and lots of questions about what I really had. They really didn’t know.” His condition was rare, and its identity remained elusive. Ultimately, one doctor made a simple promise: “I’m going to find somebody in this country that knows a lot more about this.” And so he did. Ten years ago, the patient headed to the National Institutes of Health Clinical Center in Bethesda, Maryland and a research study lead by Dr. Wyndham Wilson at the National Cancer Institute. The condition turned out to be Lymphomatoid Granulomatosis, a rare, progressive disorder of the lymph nodes and blood vessels that can, over time, involve the lungs, skin, kidneys, and central nerv-

ous system. “If you look at the published literature on my disease,” the patient says, “it’s a very high mortality rate. What the NCI’s treatment regimen has done is completely turn that around. They’re doing things that other people just aren’t doing, and then sharing it and disseminating it throughout the world.” The patient remained in remission for 9 years. Last fall, when his disease returned, the patient returned to Dr. Wilson’s care with his optimism intact. “These people at the NIH are so talented, so kind—and they’re doing this just to help people and advance learning so that other people can benefit from their work around the country. They’re an amazing group of people.”

Our patient’s cancer story is not finished. Neither is the work of the National Cancer Institute. The NCI is striving for a time when the life stories of millions of patients will no longer end with cancer. For several years now, scientists who devote their careers to the study of cancer have spoken, with increasing frequency and enthusiasm, about their hopes for an era of “personalized medicine,” when cancer will be treated as a chronic condition—not the killer it is today. Spurred by the completion of the landmark Human Genome Project, we have begun to realize a vision of cancer prevention, early diagnosis, and targeted treatment based on each patient’s tumor and unique genetic make-up. In time, this knowledge will be linked to cancer risk and the earliest cellular changes that lead to development of a malignancy—years before tumor formation or symptom onset.

Today, cancer researchers are using new molecular technologies, such as whole genome scans and actual sequencing of patients’ tumors, searching for abnormal proteins in individual patient’s body fluids that are the result of these genetic changes. As a result, scientists are studying an ever-growing group of targeted therapies, which attack cancer cells but leave healthy tissue untouched.

Scientists have also learned the critical importance of the microenvironment of tissue surrounding the tumor, and they have elucidated the essential ways in which these cells—connective tissue cells, new blood vessel cells, and cells of the immune system—support the growth and metastasis of the cancer. Scientists have increasingly identified ways in which these non-cancer cells can also be targeted, to block tumor progression. Recognizing the complexity of a cancer and of its progression to a fatal disease, researchers have come to the understanding that our treatments will not be simple; complex therapies will help fight a complex disease. Without a doubt, science and the technology that supports research are making progress against cancer at a pace never before seen.

America’s Federal investment powers—and empowers—the engine of cancer research. The National Cancer Institute, as the leader of our National Cancer Program, funds thousands of researchers (5,713 in 2007) at hundreds of our great research universities and Cancer Centers from coast to coast—along with a cadre of Government scientists based at the clinical center on the campus of the National Institutes of Health who, like Wyndham Wilson, conduct the kind of high-risk science unlikely to be found elsewhere.

Clearly, the Nation’s investment is paying dividends. There are now almost 12 million cancer survivors in America. Today’s cancer research shows great promise to reduce the personal and financial costs associated with cancer, which, according to the American Cancer Society, totaled \$206.3 billion in the United States in 2006. However of great worry, cancer is a disease of aging, the result of a lifetime of genetic alterations, additions, and subtractions that accumulate in our genes and impact their function. With a rapidly aging population, NCI estimates that the total economic burden of cancer in the United States will increase to \$1.82 trillion by 2017.<sup>1</sup> This clearly underscores the urgency of increasing our investment in cancer research.

NCI’s progress against cancer is evident across its vast research portfolio:

- Genome-wide association studies are revealing increasing numbers of genes that may contribute to cancer risk. These high-tech studies compare large groups of people: one group with a disease and one without, searching for abnormal genes, which, once validated and further studied, will lead to strategies for prevention, enhanced early cancer detection, and novel highly targeted treatments.
- The NCI Community Cancer Centers Program, now in a 3-year pilot phase at 16 sites across the country, is studying how best to bring state-of-the-art, multi-specialty cancer care, electronic medical records, and early-phase clinical testing of new therapies to patients in their own communities, because access to scientific advances is an essential factor in decreasing cancer mortality and healthcare costs.

<sup>1</sup>National Cancer Institute, Estimates of the National Economic Burden of Cancer for 2007 and 2017, April 17, 2007.

- The cancer Biomedical Informatics Grid (caBIG™) is a 21st century information initiative connecting cancer research and clinical trials—both public and academic—from coast to coast. caBIG is an essential program to address the new era of highly personalized medicine and the rapid translation of discovery to practice.
- Expanding deployment of Electronic Health Records linked to clinical research can provide security and portability for patient health and medical information.
- Pioneering a new kind of early clinical trial, which looks at small numbers of patients and uses extremely small quantities of investigational medications and high-technology imaging, to see if the drug reaches its molecular target. Phase 0 trials have the potential to shorten drug development and reduce costs by millions of dollars.
- NCI's expanding platform of new drug development actively links university scientists with the complex enterprise of novel agent chemistry, validation, and the final steps of private sector translation.

#### CANCER AS A MODEL OF DISEASE

Cancer has long been a model for the study of disease in the laboratory and a model of healthcare in the community. For example, knowledge about how tumors form new blood vessels (angiogenesis research), has contributed to our understanding of macular degeneration, diabetes, wound healing, and ischemic heart disease. In fact, the Nation's investment in cancer research has affected the diagnosis and treatment of most major diseases. Cancer is the only disease for which tissue is routinely collected for study in the laboratory. Having malignant, pre-malignant, and normal tissue from the same patient allows researchers in many fields to understand the biology of pathologic disease processes, at the cellular level. The ability to perform tissue analysis also makes cancer patients the most highly characterized population of patients with chronic disease. Physicians are now using these data to inform prevention and treatment schemes tailored to the individual. The NCI recognizes that characterizing the patient and delivering state-of-the-art care in the community setting is the model for future healthcare delivery. We are continually studying ways to optimize this approach.

#### SUPPORTING RESEARCH

The backbone of America's cancer research enterprise is the individual investigator working at a laboratory bench, conducting hypothesis-driven science. These scientists are also the academic faculty who train and guide the next generation of researchers. Understanding those dual values, NCI is working to reassign resources to provide a stable level of financial support for Principal Investigators.

NCI is also pushing to reinvigorate its intramural program, comprised of the Government scientists who study types of cancer unlikely to be addressed by the private sector and whose research encompasses high-risk science that has the potential to greatly advance our knowledge of cancer and its processes.

One of the greatest services NCI can offer the Nation is to help foster a dedicated cancer research workforce for the future. We have placed more emphasis on carefully reviewing and more-aggressively funding new applications from young scientists. We are working to bring more young scientists to Bethesda for day-long meetings and interactions with NCI staff. Moreover, because a grant from NIH is often a pre-requisite for obtaining and keeping academic tenure, NCI is developing plans to mandate a mentoring committee at each new investigator's home university.

#### WORKING FOR PATIENTS

When she arrived at the NIH Clinical Center, our patient couldn't even make a fist. Her hands, wrists, elbows, hands, and knees could scarcely bend. A once-vibrant woman in her late 20s, she was now severely anemic, wheelchair bound, and wrapped in blankets to preserve the body heat her skin could no longer retain. Over 2 years, as she suffered the disabling manifestations of cutaneous T-cell lymphoma, she spent more nights in the hospital than at home. She was in hospice care and lacked the strength to be with her two small children. She came to the Clinical Center virtually out of treatment options—and once there, an initial short list of experimental treatments had all failed. Having apparently run out of all hope, our patient came into the care of Dr. Martin E. Gutierrez, a staff clinician with the NCI's Medical Oncology Branch. Dr. Gutierrez, who has spent his career working on new therapies for T-cell lymphoma patients, tried a new drug being developed through NCI's Rapid Access to Intervention Development (RAID) program. RAID exists to speed the translation of novel anticancer therapies from laboratories to patients.

And in this case, the new drug paid off dramatically. Within the first few doses, Dr. Gutierrez began to see improvement. Within 7 months, the patient's symptoms were gone. Today, more than a year after her arrival at the Clinical Center, the patient's tests show no evidence of disease.

NCI will not rest until such stories are commonplace. Our Nation's investment in cancer research is paying dividends—in lives saved, in greater quality of life for cancer patients, and in cancers prevented. The National Cancer Institute is dedicated to a future in which cancer is no longer the killer we know today, but a condition most often prevented, or else treated effectively, with minimal side-effects. The future of medicine is personal. Our country's investment in that future is vital. Everything we do at NCI begins and ends with real people: those with cancer, those at risk for the disease, and those who care for them.

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#### PREPARED STATEMENT OF DR. FRANCIS S. COLLINS

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2009 President's budget request for the National Human Genome Research Institute (NHGRI). The fiscal year 2009 budget includes \$487,878,000; an increase of \$1,099,000 from the fiscal year 2008 enacted level of \$486,779,000.

NIH's investment in the Human Genome Project (HGP) and the International HapMap Project have moved us closer to a future that uses genomic information to diagnose, treat, and prevent disease.

#### DISEASE-GENE ASSOCIATIONS

The HapMap has introduced a new paradigm to genomic research, primarily in the form of genome-wide association studies (GWAS), enabling cost-efficient assessment of much of the common genomic variation within an individual. The GWAS approach is novel in that it surveys the genome comprehensively and without preconception as to the relationships between genetics and disease, whereas earlier research efforts were largely focused on candidate genes thought to be associated with specific diseases. The innovative GWAS approach allows for the identification of genes involved in common diseases, contributing to a better understanding of the development and progression of common diseases, and pointing to follow-up research that may lead to improved diagnostic, therapeutic, and preventive approaches.

With unprecedented speed, researchers have applied GWAS to identify a stunning number—over 70 in 2007 alone—of genetic factors associated with the most common causes of morbidity and mortality in the United States, such as diabetes, cardiovascular disease, obesity, cancer, and multiple sclerosis. Identification of gene variants associated with disease raises the possibility of using genetic testing, in combination with family history information, to identify susceptible, pre-symptomatic subjects for screening and preventive therapies. The pace of disease-gene discovery is likely to accelerate even further over the next 2 or 3 years due to the completion in 2007 of the second-generation map of human genetic variation (Phase II HapMap). This updated and powerful tool allows researchers to identify variations associated with disease even more quickly and accurately.

#### APPLYING NEW KNOWLEDGE ABOUT THE GENOME TO HEALTH

The NHGRI has increasingly directed the power of its large-scale sequencing program, which fueled the completion of the Human Genome Project, toward the long-range objective of making human DNA sequencing a tool for both research and medical practice. New directions include obtaining genomic sequence data from many individuals with various physical traits and disease states—data that will prove critical for addressing a wide range of questions important for advancing biomedicine. To move these advances more rapidly into clinical care, in 2007 the NHGRI established the Genomic Health Care Branch within its Office of Policy, Communication, and Education. The new branch's mission is to help facilitate the translation of genomic research into advances in clinical medicine, especially in the primary care setting.

#### THE CANCER GENOME ATLAS

The Cancer Genome Atlas (TCGA) is a joint NCI-NHGRI effort to accelerate understanding of the molecular basis of cancer through application of genome analysis technologies. TCGA began in 2005 with a 3-year, \$100 million pilot project to determine the feasibility of a full-scale effort to explore the universe of genomic changes involved in all human cancers.

## THE HUMAN MICROBIOME

There are more bacteria in the human gut than cells in the entire human body. Furthermore, microbes in the gut, skin, oropharynx, and vagina have a profound effect on many human physiological processes, such as digestion and drug metabolism, and play a vital role in disease susceptibility and even obesity. The Human Microbiome Project, conducted under the auspices of the NIH Roadmap Project and co-led by the NIAID, NIDCR, and NIDDK, represents an exciting new research area for the NHGRI.

## TECHNOLOGY ADVANCES, ON THE WAY TO THE \$1,000 GENOME

In August 2007, the NHGRI awarded grants to advance the development of innovative sequencing technologies intended to reduce even further the cost of DNA sequencing and expand the use of genomics in biomedical research and health care. With NHGRI support, excellent progress has been made toward both the near-term goal to lower the cost of sequencing a mammalian-sized genome to \$100,000, and the longer-term goal of \$1,000 or less. Further grant awards in this area will be announced in late summer 2008.

## CHEMICAL GENOMICS AND MOLECULAR LIBRARIES

The chemical genomics initiative, part of the NIH Roadmap, offers public sector researchers access to high-throughput screens to test small organic molecules for potential uses as research tools. This initiative will even help expedite the development of innovative drugs for rare diseases, by demonstrating how early stage compounds interact with novel molecular targets. This program provides direct translation of genomic medicine by identifying small molecule drug-like compounds that can be used as starting points for new treatments, or as new applications of that agent. A dramatic example is the recent identification of a compound that shows great promise for the treatment of schistosomiasis, a parasite disease affecting more than 200 million people in Africa, Asia, and the Middle East.

## KNOCKOUT MOUSE PROJECT

The technology to “knock out,” or inactivate, genes in mouse embryonic stem cells has led to many insights into human biological processes and human disease. However, information about knockout mice has only been published and made available to the research community for about 20 percent of the estimated 20,000 mouse genes. Recognizing the wealth of information that mouse knockouts can provide, the NHGRI launched a trans-NIH, coordinated, 5-year cooperative research plan that, in cooperation with European and Canadian programs, will produce knockout mice for every mouse gene and make these mice available as a resource to the entire community.

## 1000 GENOMES

The 1000 Genomes Project is an international research project that will sequence the genomes of at least a thousand people from around the world to create the most detailed and medically useful picture to date of human genetic variation. The 1000 Genomes Project seeks to produce a publicly available catalog of variants that are present at 1 percent or greater frequency in the human population across most of the genome.

## CLINSEQ

The purpose of ClinSeq, an intramural NHGRI research initiative, is to pilot large-scale medical sequencing (LSMS) in a clinical research setting and to investigate some of the technical and medical issues that accompany the implementation of LSMS in clinical settings. Currently, ClinSeq is recruiting 1,000 participants across the spectrum of risk for coronary heart disease (CHD). Relationships between patients’ genetic makeups and observed phenotypes will be explored to better understand how variations in genes relate to cardiac health status.

## MULTIPLEX

The NHGRI and the NCI have teamed up with Group Health Cooperative in Seattle and Henry Ford Health System in Detroit to launch the Multiplex Initiative, a prospective study that is enrolling young, healthy adults to learn how they react to the offer of genetic testing for a panel of 15 genes linked to 8 common conditions. The study will follow individuals who decide to have the testing to see how they interpret and use the results in making future health care decisions. This study

should provide insights that will be important to advancing the realization of personalized medicine.

#### ENCODE (SCALE UP AND MODENCODE)

We are continuing to expand the ENCyclopedia Of DNA Elements (ENCODE) project, a research consortium that, in its pilot phase, yielded provocative new insights into the organization and function of the human genome. The NHGRI is moving forward with a full-scale initiative which should provide a more comprehensive picture of the biological roots of human health and disease. We are also engaged in a new effort, called the model organism ENCODE (modENCODE), to apply many of the ENCODE methods and technologies to the genomes of the roundworm and fruit fly model organisms, to inform our efforts to understand how the human genome functions.

#### MINORITY OUTREACH ACTIVITIES AND HEALTH DISPARITIES

The NHGRI remains at the forefront of ensuring that minority scientists and students are equipped to meet the challenges of genome research in the 21st century. With support from the NIH Director and several Institutes and Centers, the NIH has created the NIH Intramural Center for Genomics and Health Disparities (NICGHD) within the NHGRI Division of Intramural Research, with a mission of advancing research into the role of culture, lifestyle, genetics, and genomics in health disparities.

#### GENETIC DISCRIMINATION

The NHGRI has long been concerned about the impact of potential genetic discrimination on research and clinical practice, as a wealth of research has demonstrated that many Americans are concerned about the possible misuse of their genetic information by health insurers or employers. This concern has been a constant during my tenure as director of NHGRI, so it gives me great satisfaction that after a 13-year legislative effort, the Genetic Information Nondiscrimination Act (GINA) has finally become law. When GINA takes effect in 2009, it will provide all Americans with solid protection against discrimination based on their genetic information in health insurance or employment circumstances. We hope that these protections will address the concerns that have thus far threatened the public's willingness to utilize genetic testing.

#### MEDICINE IN THE FUTURE

Broad investment in innovative, large-scale, and adaptable models of research such as GWAS may accelerate the timeline for the development of advances in clinical options and thereby contribute to a decrease in the public health burden of many common diseases. With protections against discriminatory uses of genetic information in place, we anticipate that individual genome sequencing will become both commonplace and affordable, and that primary care physicians will routinely consult their patients' genome analyses for prediction of risk, diagnosis, and drug and dosage selections. If the public and the medical community are appropriately educated about both the significance and the limitations of genomic information, it may be possible to lessen the burden of disease through better screening and prevention programs, to minimize or avoid toxicities from drugs, and to select the right drug for the right patient, at the right time.

Finally, as many of you know, next month I will step down as Director of the National Human Genome Research Institute, a position that has been my joy and privilege to hold for the past 15 years. Many historic opportunities lie ahead as genomics increasingly becomes a leading force in medicine, and I leave my position supremely confident that NHGRI and NIH will continue to achieve notable success in advancing the health of the American people. In closing, I would be remiss if I did not take this final opportunity to thank Senator Harkin and Senator Specter for their superb leadership on this committee and long-time dedication to the mission of the NIH. Your efforts, and that of your excellent staff, have been essential to the progress recently made in genomics research, and are very much appreciated.

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#### PREPARED STATEMENT OF DR. ANTHONY S. FAUCI

Mr. Chairman and members of the committee: I am pleased to present the President's budget request for the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The fiscal year 2009 budget of

\$4,568,778,000 includes an increase of \$8,123,000 over the fiscal year 2008 appropriated level of \$4,560,655,000.

The mission of NIAID is to conduct and support research to understand, treat, and prevent infectious and immune-mediated diseases. The biomedical research that NIAID supports to combat diseases of worldwide concern, such as HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, emerging and re-emerging infectious diseases, has taken on added importance in today's globalized society. As we address these problems in a global context, we naturally contribute to our country's preparedness against the threat of bioterrorism as well as naturally occurring disease outbreaks. In addition, we are advancing efforts to address other domestic health problems, such as HIV/AIDS, influenza, and asthma, allergy, and other immune-mediated diseases. Using a multidisciplinary approach that engages industrial, academic, governmental, and non-governmental partners, NIAID remains committed both to basic infectious and immune-mediated disease research and the application of this knowledge to the development of strategies to detect, prevent, and treat these diseases. This approach is emphasized in the recently updated NIAID strategic plan, NIAID: Planning for the 21st Century—2008 Update.

Looking forward, it is clear that the research activities of NIAID will become more important than ever, as current and as-yet unrecognized health threats will require new diagnostic, preventive, and therapeutic interventions. These new tools promise to have a great impact on public health over the next two decades.

#### EMERGING INFECTIOUS DISEASES AND GLOBAL HEALTH

Threats posed by infectious microbes do not remain static, but change over time as new microbes emerge and familiar ones re-emerge with new properties, such as drug resistance, or in new settings. Since 2006, we have witnessed numerous examples of newly emerging and reemerging infectious diseases outbreaks, including extensively drug resistant tuberculosis (XDR-TB), methicillin-resistant *Staphylococcus aureus* (MRSA), H5N1 avian influenza, Chikungunya fever, and dengue. We must anticipate that we will see more and more of these outbreaks in the coming decades. As economies and societies around the world have become increasingly interdependent, responding to emerging infectious diseases, as well as to long-established global health challenges such as neglected tropical diseases, has taken on a new urgency.

Tuberculosis is an example of a re-emerging threat. The World Health Organization (WHO) estimates that in 2006, new cases of active tuberculosis (TB) worldwide exceeded 9 million and 1.7 million people died from TB. Antiquated and insensitive techniques for accurately diagnosing TB, complex and lengthy drug regimens and an increase in the prevalence of multi-drug resistant (MDR-) and XDR-TB continue to present major challenges to effective TB control. In 2007, the Institute released the NIAID Research Agenda: Multidrug-Resistant and Extensively Drug-Resistant Tuberculosis, which identifies research needs and priorities in several critical TB-related areas. The agenda also highlights the importance of fostering partnerships with public and private organizations to fuel the pipeline of available drugs, diagnostics, and preventive measures for TB.

Malaria is an established infectious disease that continues to pose a significant global health burden. Malaria is becoming even more problematic with the emergence of drug-resistant malaria parasites and insecticide-resistant mosquito vectors. NIAID collaborations with public and private partners, including the Bill & Melinda Gates Foundation, build on the foundation of NIAID's robust malaria basic research program to foster the development of promising drug and vaccine candidates. Over the next two decades, we hope to have a major impact on the global TB and malaria burden through the development of vaccines that protect against these infectious killers. Our aim is excellent control of both TB and malaria through the use of vaccines and other interventions with the ultimate goal of eliminating malaria as a global disease threat.

TB and malaria are not the only diseases emerging in drug-resistant forms. The Centers for Disease Control and Prevention estimated that in 2005, more than 90,000 individuals in the United States developed invasive infections with methicillin-resistant *Staphylococcus aureus* (MRSA) and nearly 19,000 of these patients died. NIAID supports an extensive basic research portfolio on antimicrobial resistance, including studies of how bacteria develop and share resistance genes and the identification of new therapeutic targets. The Institute is partnering with industry, other Federal agencies, academia, and other organizations such as the Infectious Diseases Society of America, to identify research priorities, including clinical trials, to address this growing problem, and recently published a detailed research agenda on antimicrobial resistance in *The Journal of Infectious Diseases*.



Seasonal influenza, which changes slightly every year, is the classic example of a re-emerging infectious disease. Influenza viruses also can undergo more drastic genetic changes that periodically enable them to evade pre-existing immunity and cause a pandemic, such as the deadly influenza pandemic in 1918 that killed more than 50 million people worldwide. NIAID supports a broad portfolio of research on influenza, including basic and applied research on the development of vaccines, diagnostics, and therapeutics against both seasonal and pandemic influenza. This foundation of research has underpinned the significant progress made in the development of new influenza interventions. For example, in 2007, based on clinical data from NIAID-supported research, the FDA approved the first vaccine for humans against the H5N1 avian influenza virus. Further, NIAID-supported studies performed in collaboration with various industrial partners have demonstrated the extraordinary potential for a variety of other vaccine formulations and adjuvants to not only expand the number of doses of vaccine but also to broaden the vaccine's reactivity against various strains of influenza.

As we look to how we might respond to unknown emerging and re-emerging infectious disease threats in the future, it is apparent that the most practical approach may not always be the development of interventions such as diagnostics, vaccines, and therapeutics against just one microbe. Rather, the future of diagnostics will be rapid, accurate tools that can be used at the bedside or in the field in "real time" to detect a wide variety of pathogens. We are working to develop vaccine platforms that can be easily adapted to different microbes by shuttling the genes for different antigens in and out and that can provide protection against a broader group of pathogens. Similarly, we are developing antimicrobial therapeutics that truly are "broad spectrum" in their activity, both within and between classes of pathogens. Such antimicrobials could prove effective against drug-resistant bacteria, including MRSA.

#### HIV/AIDS RESEARCH

HIV/AIDS continues to exact a staggering toll. Although the Joint United Nations Programme on HIV/AIDS (UNAIDS) recently revised estimates to indicate a stabilization or decline in HIV infections and deaths in some parts of the world, the HIV/AIDS pandemic remains an enormous global health challenge. An estimated 33.2 million people worldwide are infected with HIV. In 2007, approximately 2.5 million people were newly infected with HIV, and 2.1 million died of AIDS.

Despite the grim numbers, the Federal investment in HIV research has generated promising new results in the prevention and treatment of HIV/AIDS and in advancing our understanding of the virus and disease. An important example is the demonstration by NIAID-supported researchers that medically supervised adult male circumcision reduced by more than 50 percent the risk of heterosexual African men becoming infected with HIV. Our hope is that this and other advances in HIV prevention research will become part of a comprehensive HIV prevention "toolkit" that will markedly decrease new infections over the next two decades.

Perhaps the greatest success story in NIAID-funded AIDS research is that of therapeutics. NIAID-supported research helped make possible antiretroviral therapies that have transformed HIV from an almost uniformly fatal infection into a manageable chronic condition. Still, existing drugs are no longer sufficient for some HIV-infected patients because of the ability of the virus to develop resistance or because of the toxicities that can be associated with the therapies. Among the fruits of NIAID fundamental HIV research is the recent approval of three new potent and highly effective antiretroviral drugs: etravirine, maraviroc, and raltegravir. NIAID will continue to support the fundamental research that will be the foundation for future therapeutics that will be even more user-friendly and inexpensive, making universal access to therapy more feasible over the next two decades.

Prevention efforts continue to be a major component of the HIV research program of NIAID, and the most powerful prevention tool would be a safe and effective HIV vaccine. The development of an HIV vaccine remains one of our greatest scientific priorities, but also one of our greatest scientific challenges. The pathway to a vaccine is being elucidated through the fundamental basic research that remains the foundation of NIAID. For example, researchers at the NIAID Vaccine Research Center and their collaborators determined the atomic structures of a neutralizing antibody and the conserved area of the HIV surface protein (gp120) to which the neutralizing antibody binds. This binding site is the same site that the virus uses to bind to cells of the immune system. Such studies are helping us to identify components of HIV that may serve as targets for future vaccine candidates and may bring us closer to a safe and effective HIV vaccine.

## BIODEFENSE RESEARCH

Since the beginning of the acceleration of our biodefense research program in fiscal year 2003, NIAID has achieved a number of successes in the development of countermeasures against significant bioterrorism threats; these countermeasures are either in the Strategic National Stockpile or available for use in an emergency. Promising candidate countermeasures in development include ST-246, a smallpox drug candidate that has protected both rodents and nonhuman primates from an otherwise lethal exposure to live poxviruses. The FDA has granted orphan drug status to ST-246 and awarded the compound fast-track status which will expedite its regulatory review. The vaccine platforms, rapid diagnostics, and broad spectrum antimicrobial therapeutics that we aim to develop for emerging infectious diseases over the next two decades will also be directly applicable to our biodefense research program.

In addition, and as important, NIAID has developed a physical and intellectual research infrastructure that has been critical to our ability to respond to new and re-emerging infectious diseases. Without this expanded infrastructure, the biomedical research response to the emergence of infectious disease threats such as H5N1 avian influenza, MRSA, and XDR-TB would not have been as rapid.

## RESEARCH ON IMMUNE-MEDIATED DISEASES

Autoimmune diseases, allergic diseases, asthma, rejection of transplanted organs, and other immune-mediated disorders are significant causes of chronic disease and disability in the United States and throughout the world. NIAID-supported research in immune-mediated diseases has led to significant advances in our understanding of the mechanisms underlying these diseases and in the development of strategies to detect, prevent, and treat them.

Food allergies continue to be a growing concern and an emerging focus of public attention. NIAID remains committed to basic research to advance the understanding of food allergy and food allergy-associated anaphylaxis. To bring new investigators and novel ideas into food allergy research, NIAID is supporting a new initiative, Exploratory Investigations in Food Allergy, in collaboration with public and private partners. NIAID also is expanding support for clinical trials in food allergy, with ongoing trials to prevent the development of allergies to particular foods, such as peanut, and to reverse established allergy to milk, eggs, and peanut.

The Institute also supports research to improve outcomes for transplant recipients, with establishment of immune tolerance as a major priority in this area. The NIAID Immune Tolerance Network is making steady progress toward the long-term goal of reducing the need for costly and potentially risky immunosuppressive drugs that are the current standard treatment to prevent transplant rejection. A total of 11 kidney and liver transplant recipients are no longer on immunosuppressive drugs, some for as long as 4 years. We hope that eventually a substantial proportion of organ transplant recipients will not require immunosuppressive drugs.

The establishment of immune tolerance is a goal not only for transplantation, but also for other immune-mediated disorders, such as allergies. We look forward to the use of tolerance to have a major impact on allergies, including food allergies, and other immune-mediated disorders in the coming decades.

## CONCLUSION

For more than six decades, NIAID has conducted and supported basic research on infectious and immune-mediated diseases that has underpinned the development of vaccines, therapeutics, and diagnostics. These, in turn, have improved health and saved millions of lives in the United States and around the world. Through partnerships with industrial, academic, governmental, and non-governmental partners, the Institute will continue to leverage these fundamental discoveries into the tools needed to achieve a healthy world.

Senator HARKIN. Dr. Zerhouni, thank you very much, that was really eloquent and elegant, and I appreciate that very much. I just wondered if—Senator Cochran has joined us, did you have a statement you'd want to make, Senator Cochran?

Senator COCHRAN. Mr. Chairman, thank you very much, I do have a statement that I would ask be included in the appropriate place in the record.

Senator HARKIN. Sure, without objection.

Senator COCHRAN. Thank you.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Dr. Zerhouni, thank you for joining us today to discuss the fiscal year 2009 budget for the National Institutes of Health. We appreciate your efforts to improve the health of Americans through medical research aimed at the prevention and treatment of diseases. I am pleased that the Committee has provided an increase of over \$1 billion above last year's level and I look forward to your comments on the agency's vision and plan for these additional resources. I would also like to welcome our distinguished panel of scientists. The insight you will share today of your experience with the NIH and its research will be helpful to the work of this committee.

The research at NIH addresses the pressing health concerns in our country and it is important not only to complete this research, but to translate it into new therapies and better outcomes for patients. This Committee will continue to encourage you all to do this.

I appreciate the challenges you are facing and your hard work. I am interested in helping the NIH succeed in these very important efforts.

NIH FUNDING

Senator HARKIN. For the record, accompanying Dr. Zerhouni today is, of course, Dr. Francis Collins whom I spoke about in my opening statement, the Director of the National Human Genome Research Institute and Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, who's been at NIH since—is that right, since 1968, Tony? Wow.

Dr. Elizabeth G. Nabel is the Director of the National Heart, Lung, and Blood Institute, appointed to that position in 2005, I think, from Dr. Lenfant, if I'm not mistaken, who was there for many years.

Dr. John Niederhuber is the Director of the National Cancer Institute.

We thank you all for being here today.

Well, Dr. Zerhouni, just picking up on that, as I said, that very elegant presentation, we think about where we've been, and we're on the cusp of some of these new things, we have to follow these leads. Tell us what that would mean in terms of budgetary implications. In other words, we've got a lot of things we've got to be looking at—I assume this spreads across every Institute, in terms of following these leads. But, what should we be thinking about in terms of the growth in NIH funding? As I said, Senator Specter and I are going to try to introduce a bill to try and get that money back up again, we're facing some pretty tough budget times right now—what should we be thinking about in terms of the funding for NIH next year? The year after, the year after, perhaps, in order to adequately follow these leads?

Dr. ZERHOUNI. There are many ways to answer this question, but I'll give you some parameters I've learned are critical.

You can not sustain an enterprise where you have to have people commit their lives, their careers—it takes 15 years, sometimes, to just make an impact when you're following the lead, this is not automatic. So, these individuals need to have some certainty that the budgets will be there to sustain them in their effort, so predictability in the budget is very important.

## SUCCESS RATE

The second is that, you have to have a reasonable success rate. When you tell a young individual, “You will come in, you will come in at age 30, 32, having spent 20 years of your life training yourself, and then you’re going to make \$40,000 for the next 10 years, and maybe at the end, if you’re very, very good, you might get a grant from the NIH with a 17 percent success rate. How does that sound to you?”

Without a 30 percent success rate, on average, we’ve notice that, fundamentally, our ability to maintain the competitive nature of science, and the ability to explore the avenues—not knowing, really, where the next breakthrough is going to come from. People forget that science is not an engineering task, we don’t know all of the answers, we have to seek them. We’ve done this for 50 years. People forget that the history of true modern research in medicine is only 50 years old. So, we are early in that stage. Losing momentum is very critical.

So, a reasonable success rate, a predictable funding, and funding that does not decrease in real terms—which is what we have had to deal with, which forces you to make priority choices, not knowing, really, where the breakthrough will come from. Because, in science, as we’ve noted, sometimes somebody is doing something completely unrelated, and all of a sudden, that something becomes a cure in cancer, or that thing in cancer becomes a cure in AIDS. We’ve seen that over and over again.

So, what is key is to maintain your capacity over time, make sure that new, young investigators are encouraged to enter the career, and make sure that we are not dealing with a very erratic process. Medical research is a long-term process, it’s not something you can manage every 12 months. You have to commit.

But we have a plan, we have a strategy. This strategy is known the world over. If we’re not following these leads, I can assure you, somebody will. That won’t be us.

## NEW INVESTIGATORS

Senator HARKIN. Dr. Zerhouni, you have the NIH Director’s New Innovator Awards that you have in your office that we provided some money last year for that, \$56 million, that goes to new investigators. We included \$108 million for the program in our next bill—will that be enough to support the New Investigators Award System? Is this part of bringing, getting these new people in, and getting them started?

Dr. ZERHOUNI. Right, so this is a stop-gap that we have to use, because what my main concern is—and my colleagues know that—is that if you do the projections, and if you don’t fund enough scientists today, you won’t have them 10, 15 years from now.

So, what we’ve done—with a lot of hardship—is to shift money into young investigators, new investigators. This needs to continue.

New Innovators was addressing two goals: one is that, once success rates go down, people become very conservative. They don’t take chances, they don’t take risk into new areas of research, they want to be sure. So, we wanted to encourage risk-taking, and en-

courage new entrants to come in—that's what the New Innovators Awards do.

Our data shows that we really need to fund something around 3,000 new scientists a year to enter NIH. Right now we're below that number, and ideally that would be the goal that we have to have—no matter what the budget does—we need to encourage risk-taking, new ideas, innovation, and new investigators.

#### FUTURE OF HUMAN GENOME RESEARCH

Senator HARKIN. Thank you, Dr. Zerhouni.

I have questions for all of the panelists, I just have one more question and then I will yield to my colleagues that are here.

Dr. Collins, obviously the presentation this morning that Dr. Zerhouni made is right up your alley. I guess what I'd like to ask you about is again, talk about the future. We've mapped and sequenced the genome, we've now made all these discoveries in terms of the clues—where we do go from here with the Human Genome Project or with the Human Genome Institute? Where do we go from here with that? Tell me about the 1000 Genomes Project, and what that might mean? Are you supportive of that, is that something that we should be looking at, and trying to support, the 1,000 people that they want to do that on?

Dr. COLLINS. Thank you, Senator. It is my last appearance, officially, as a Government employee in front of this committee, and I would like to express my sincere thanks to you, and to Senator Specter, and to the whole subcommittee for their consistent support and interest in what NIH is doing.

I certainly remember when I first came here 15 years ago, there was a lot of skepticism about whether the Human Genome Project had any chance of succeeding, and it was your support, and that of others Members of the Congress, that saw us through some challenging times, where the technology had to be invented, and people had to be recruited, and a lot of milestones had to be achieved, and the celebration of the accomplishment of those goals in April 2003 is very much a testimony to this Congress and to their vision for supporting this.

Personally, I want to say thank you to you, for all the wonderful conversations we've had through the years about this.

It is a glorious time in genome research, as Dr. Zerhouni's testimony indicated. I've just counted up the number of projects that my Institute is currently managing, going—building on the foundation of having the human genome sequence—there are 19 of them. These are all focused on specific ways in which we can learn from that instruction book, how it operates, and how glitches in the instruction book, our genome, can lead to health or disease.

We are learning a prodigious amount every day. I can tell you, however, that none of those 19 projects are going as rapidly as they could—we are constrained, and not by talent, not by ideas, not by opportunities, but very much by the budgetary abilities that we have to expand on these projects. That is, of course, for me a source of some frustration.

The 1000 Genomes Project is one of those—this is an international effort, just as many of the genome projects have been. It's rather amazing to be able to say that the people were skeptical

about whether we'd ever sequence one genome, we're now proposing to sequence 1,000 of those, derived from DNA samples from individuals in Europe, and Asia, and Africa, and to have that done in the next 2½ years.

We're doing this in collaboration with England and China, and we're already deep into a pilot project which in its first 3 months of effort generated more DNA sequence data than has ever been generated in the history of the planet, so we're really producing a vast amount of interesting information that's laying out this catalog of human variation at a level of detail not previously imagined possible.

It's going to teach us a lot about how it is that DNA variation plays a role, and who's at risk for what, and that's just one of these 19 projects.

There more that we could be doing, if you'll give me just a moment, I'd like to mention two.

#### GENES AND ENVIRONMENT

One of the things we really need to understand more about, of course, is how the genetic risk factors interact with the environment.

All of those banners on the diagram that Dr. Zerhouni showed—which are enormously exciting advances, figuring out risk factors for diabetes and heart disease and cancer and asthma—those are, of course, inherited risk factors that you're not going to be able to change in the people who have them. But it is an interaction between those genetic risks and environmental exposures, such as diet, and lifestyle and medical surveillance and whatever's in the air and the water, that determines whether somebody is going to get sick, or not. We could modify those things, if we understood exactly who's at risk, and we could focus on that, in an individualized way. That's what personalized medicine is all about.

But, collecting that data is not trivial. A dream that I've had for the last 4 years, but haven't been able to get off the ground in the current budget climate, is to have a national study of health and disease, collecting information on, perhaps, half a million volunteers from across the country, who would basically agree to have their environmental exposures studied, as well as their medical conditions, and their DNA. If we put that all together, in an organized effort with access to qualified investigators, we would finally, really have a rigorous way of understanding this.

You could call this the American Genes and Environment Study, or AGES, some of us have done that. We've organized a group of more than 60 scientists to think about how to put this together. I have yet to meet somebody who doesn't think this would be an enormously exciting project to undertake, but it's expensive. It's genome project-like in its budget, and at the present time it's been hard to get it off the ground.

#### RARE AND NEGLECTED DISEASES

That's one. Another one, which I'm enormously excited and optimistic about, is to take the discoveries that we are making about the causes of where neglected diseases, where we are making great

progress and really, in a very intentional way, translate those into treatments.

The NIH has made major investments, particularly through the Roadmap that Dr. Zerhouni has so effectively championed, to put us in the position to do that, and we have many other pieces in place, to take a discovery about a rare disease, and lead it all the way to a clinical trial. In a circumstance where the private sector, understandably, is not going to be very interested in investing, because the market size is going to be quite small. We are only missing on, sort of, major piece here, and an initiative to fill in what's called the Valley of Death, between when you have a promising lead compound, and when you have something you could actually contemplate putting into a patient is something I would be enormously excited about.

We couldn't have really done that 4 or 5 years ago, but we could now. With an infusion of just the right amount of support, I think this is something that we've underlined what we're really about at NIH, which is trying to find cures. Yes, we do great basic science, and we're proud of that, but our goal—as yours—is to take that to the clinic, and do something for patients.

#### BUDGETARY CHALLENGES

So, I'm excited about all of those things, but again, being my final hearing, I guess I could speak about as bluntly as anybody at the table—I am very concerned about whether we will achieve those kinds of optimistic outcomes, if we can't turn the corner on what has been a very difficult 5 years.

It's been my most difficult 5 years, having to turn away young investigators—some of whom have gone away and won't come back—they've given up. Having seen the way which science that could have gone forward, has been blunted by the inopportunities to jump in and provide those kinds of supports. Having seen a delay in the health benefits that we are all dedicated to achieving, being slowed down by the inability to push forward agendas which, scientifically, are very exciting, but we just can't do it with the current support.

Frankly—as we're also worried about our economic circumstances, seeing how an investment by NIH which various studies have indicated, pays back somewhere between two and sevenfold—isn't happening, either out there in our country, which is where most of our money goes.

Frankly also, as somebody who's worked in the international community, as I've had the pleasure of doing, I'm seeing our leadership on many of these projects eroded by the fact that NIH is not keeping up with what's happening in other countries, including England, and China, and India and that can't be a good thing for our country.

So, I appreciate what you and Senator Specter are doing in this hearing, to highlight the importance of maintaining that kind of support, and perhaps, catching up from what has been a pretty difficult half a decade. If we could turn that corner, keep our investigators who are just on the edge of giving up, inspired that they could actually make a contribution, then I think we could recover a lot of what we're in danger of losing.

Thank you for the extra minutes you gave me to answer that question.

Senator HARKIN. Dr. Collins, thank you very much. Again, for the benefit of members of the subcommittee and perhaps some of the public who may not know these figures, when Dr. Collins took over the Human Genome Project in 1993, I can remember the hearings at that time when I was Chair at that time, and the estimate was that it would take us 15 years, and over \$3 billion to map and sequence the human genome. But we did it in 10 years, basically—there's a few little holes that were left over—but basically 10 years, and less than about \$2.6, \$2.7 billion.

Now, that's important, but there's one other thing that's very important, that I think members ought to know. That it was about that time, about right around 1993, 1994, when there were moves made to take this from the public sector and put it in the private sector. That the Human Genome Project would better be done in the private sector, rather than the public sector. There was quite a battle about that at that time, and I can remember, people said, "Why should we be investing, why should we be investing public money in this when the private sector can do it?"

Dr. Collins was very eloquent at that time, and very forceful, in telling us that, no, this belongs in the public sector. This basic research ought to be available to everyone, and if it's in the private sector, of course, there would be patents and holds and all kinds of things on some of the basic research, and that's not where it should be held.

So, again, Dr. Collins, we owe you a great debt in being so forceful at that time and convincing us that this should remain in the public sector, because right now, because of this—a researcher anywhere in the world can get data from the Human Genome Project and further that research on.

To me, this again is a legacy that is almost incomparable in some ways. I think that the fact that we kept this in the public sector, again, is going to serve us well, not today but also in the future just making sure that everyone has access to it, and no one has to pay a single dime to get that information.

So, with that, again, Dr. Collins, thank you for your great service in that regard. I would yield now, to Senator Specter, of course, who just came back.

#### COST TO CURE CANCER

Senator SPECTER. Well, thank you, Mr. Chairman.

I've been dealing with you, Dr. Niederhuber on the cancer issue. President Nixon made his famous declaration in 1970 on a war against cancer, and I do believe that had that war been pursued with the same intensity as other wars, many of us wouldn't have contracted cancer.

We've asked for a projection as to what it would cost to "cure" cancer, and I put cure in quotation marks, because absolutes are understandably impossible, but were we to make a major frontal assault, and you come back with a figure of \$335 billion over the next 15 years.

What are the realities as to how far we can go on attaining the goal of a cure? We know that there are many, many strains.



There's been an enormous amount of research, there's been an enormous amount of progress. Talking to Senator Lindsay Graham about his mother who had Hodgkin's years ago—very, very different world from the really complex regimen that I had—am having, really—on chemotherapy. So, what is the reality? How close could he have come to a “cure”?

Dr. NIEDERHUBER. Senator, you always ask the tough question.

First of all, I'd like to say a word of congratulations to you for finishing your 12th cycle of chemotherapy. I suspect no one in the room knows, perhaps, better than I do, how difficult it is to go through these cycles of chemotherapy.

So, you're to be congratulated.

Senator SPECTER. Thank you.

Dr. NIEDERHUBER. I talked to a friend of ours at the University of Pennsylvania just a couple of days ago, and he also lauds how you've been able to do this, and do it without missing a minute of work. So, you're to be congratulated.

Cancer is, as you mentioned, is many, many diseases. Maybe more than 1,000 diseases. As we get to understand the genetic differences—the genetic differences in breast cancer, the genetic differences in colon cancer—and how those genetic differences, as Dr. Zerhouni so eloquently pointed out, affect a network within the cell. How those cells interact—not just within the cancer, but how those cells interact with the so-called normal cells in which that cancer lives. It's a very complex, and very dynamic process.

I can't tell you how many years it will take to cure, or to make this disease much more of a chronic set of diseases that we can live with, that we can prevent—that's obviously our goal—that we can understand who's at risk from the genetic kinds of analysis that we can do on individuals, and can take measures.

Senator SPECTER. Well, how far will \$335 billion take us over 15 years?

Dr. NIEDERHUBER. I think it will take us a long way.

Senator SPECTER. Because if you can quantify it, in some way, I think this subcommittee can take the lead in finding you the money, somehow.

Dr. NIEDERHUBER. What I did when I understood your asking that question and seeking advice from some of the communities, the cancer communities, the different organizations in the country, who also then came to me and asked for my opinion on this was to put together a team at NCI to think strategically about the various investments we're currently making, and what the opportunities for expanding those investments would be in the future.

We've, I think, prepared—or are in the process of preparing—what might be considered, I believe, a realistic, but well-thought out, and I would say, forward-looking business plan for the future. I'd be happy to—

Senator SPECTER. You've given us a timetable of 15 years, and you've given us a figure, \$335 billion. I've only got 8 seconds left, although once the light goes on, you can still talk.

Senator HARKIN. Take more time.

Senator SPECTER. I haven't gotten to the question yet—where are we, how close to a cure?

Dr. NIEDERHUBER. I know it's a very difficult question and I'm not sure that I can give you a figure. We've felt that if we could add to the NCI budget \$2 billion a year, each year for the next 5 years, that that would go a long way toward helping us build capacity within our country, in terms of attracting young people, attracting disciplines that haven't previously worked on cancer, to work on cancer.

I just attended a meeting that I sponsored, Monday and Tuesday, at which we brought together physicists, mathematicians, individuals who work on evolutionary biology—individuals who haven't worked in the field of cancer before. We had a 2-day meeting to brainstorm how these individuals might bring a different set of eyes, if you will, and a different set of thinking toward the magnitude of the problem that we face in cancer.

It was a very exciting meeting. I learned a lot from listening to those individuals, I think, that will greatly shape the future.

But, I think one of the things that came out of that meeting, Senator, was again what Dr. Collins said—that we, as a country, need to significantly invest in bringing bright, young people into the biological sciences, especially into cancer, and to create a capacity for us to be able to invest the resources of our country in this science. If we don't build that infrastructure and build that capacity, then it doesn't make any difference how much money we have. We have to have bright young people, we have to have people to work on the problem.

So, the first challenge, I think, for us at NCI is to increase our investment in attracting people to work on this particular problem.

I also think that we have a very real need to invest in retooling or re-engineering our clinical trial infrastructure. If we're going to take the steps forward that Dr. Collins has so eloquently talked about, and do drug discovery, and highly personalized characterization of each patient and their cancer, and match that with solutions of treatment, that's going to require different clinical trial structure than we currently have.

We worked, on July 1 and 2, with the National Institute of Medicine, at a 2-day symposium to talk about these issues about re-engineering the clinical trial structure. Again, that will take a significant amount of investment, financial investment, in order to retool that, re-engineer that, so that we can work effectively in the new era.

Senator SPECTER. Well, I won't ask another question, because others are waiting to question. But, when you talk about attracting the scientists, working with \$335 billion, you can attract scientists. You talk about retooling clinical science, clinical tests, \$335 billion will allow you to retool.

I know the questions are difficult, perhaps impossible, but we need to have, you know, the best professional judgment, because to sell that kind of money to the Congress is going to require something that we can put our hands around. When you get into the appropriations room, you have to have something more specific to pull out those big dollars.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter.

Senator Durbin.

## NIH FUNDING AND SETTING PRIORITIES

Senator DURBIN. Thank you very much.

I want to just show a chart here, if I can, which is probably familiar to you, it may have been produced by some of you, and it shows the actual appropriations on the yellow bars, since fiscal year 2003 through fiscal year 2009 and the purchasing power at NIH that came from those appropriations.

It shows two things—first, that the amount that has been appropriated by Congress has not kept up with the inflation that you face, and so the actual amount available for medical research and all of your other endeavors has actually declined during these years.

The second point it makes is the administration and Congress made conscious decisions during this period of time to initiate a war that costs \$15 billion a month, and to give tax cuts to the wealthiest people in America, so there were fewer dollars available for domestic discretionary spending, as a result of those two major policy decisions.

In that backdrop, I'd like to ask you to address one general question. I have a chart here—you're undoubtedly familiar with it, which shows the funding at each Institute at the National Institute of Health during this same period of time, and in fact, it goes back a little further in time, to 1998.

Until 2003, the amount of money to each one of the Institutes that you're in charge of was growing, and this was because of the commitment to double the medical research, and then comes that year—as evidenced on the other chart, it started to flatten out, and decline, and that shows the way that that's headed.

My question is fairly general—I started by saying that it's not uncommon for Members of the Senate to be visited by people from our States who have members of their family who are suffering from a disease—a wide spectrum of diseases. Without fail, they all ask us for more funding for medical research for the disease that affects someone they love.

They all argue that not enough money is going to that research, that field of research. I kind of took the position long ago—rightly or wrongly—I couldn't decide, I'm a liberal arts lawyer, what do I know about where the money ought to go? I said, I'm just going to give the NIH as much money as I can in the aggregate, and I hope they'll make the right decision.

It turns out that was a probably incorrect, if not simplistic answer. We do fund the Institutes. We really, kind of, decide at the congressional level, how much money will go to each Institute. There are winners and losers in that process.

So, when the family with a child—an autistic child—comes to see me, and says, "You're not spending enough money on autism. Don't you know, Senator, that 1 out of every 150 kids in America has this disorder?"

In my State, in the last 10 years, there's been a 353 percent increase in the diagnosis of autism, and of course, the costs are unimaginable for these children, and their care throughout their entire lives.

So, my first question—fairly simple question—but maybe not easy to answer. If we gave you \$30 billion, and didn't have any strings attached, what would be the difference in this chart? Do we make choices—political choices—on Institutes, which you as researchers and doctors, step back from and say, "That isn't where I'd spend the money."

Dr. ZERHOUNI. This is a great question, this is a question I face all the time, personally. I know, over the past 5 years, I can tell you, there's no tears left in my lachrymal glands about how you make those decisions.

That's the important question, but it's not true that all of the money, when it doubled, went into the same things without any change or any decisions. Actually, if you look at the topics that NIH has, over a period of 10 years, for example, 50 percent of the efforts that we make in any one area, turn over in about 8 years.

#### GENOMICS

So, although NIH, you have a \$30 billion budget, and you see these budgets, what's underneath these curves, is very different. For example, if you look at the efforts that are done in genomics, those didn't exist 10 years ago across all of the Institutes. Every single Institute here, I will tell you, spent 5, 10 percent of its dollars on these genomic studies, which were not done 10 years ago. Bio-computing—if you look at their basis—are available for bio-computing, for doing research on every disease—autism included, or any other diseases, these were not there 10 years ago.

We just developed, for example, through Roadmap, a Chemical Genomics Center. That center, that Dr. Francis Collins reflected about, can perform, in 2 days, 1.5 million tests. This is the equivalent of what it would have taken a scientific group to do in 15 years.

So, there are things that you change, the process that you have to really engage into is an open, transparent, portfolio analysis process, which we do.

Senator DURBIN. I'm running out of time. Maybe it will take you a moment, maybe you can't answer this. But, if we gave you \$30 billion, with no strings attached, would this look the same?

Dr. ZERHOUNI. No, absolutely not. It never looks the same, from year to year—even between 2003 and today.

#### NIH FUNDING

Senator DURBIN. My point is, are we pushing allocating, politically, on our end of it, research into areas that you think are not the best expenditure of limited tax dollars?

Dr. ZERHOUNI. I would say that this is not an issue, in the aggregate. Frankly, Congress expresses priorities, we have an independent peer-review process which we absolutely cherish, because it is the process by which we go into scientific opportunity.

So, I think what is important, however, is that without the dollars, you tend to have to make choices that sustain what you have, and do not allow you to be as risk-taking as you would, otherwise.

## DISEASE FUNDING

Senator DURBIN. Mr. Chairman, can I ask one last question?

Senator HARKIN. Sure.

Senator DURBIN. Would you address this issue of autism? I know there have been so many theories——

Dr. ZERHOUNI. Right.

Senator DURBIN. The parents that come see us share compelling stories about what they're dealing with, and arguing that we're not putting in the adequate money into research into this disease.

Dr. ZERHOUNI. Autism is one of the most important and greatest concerns that I have, as well as my colleagues, in particular, National Institute of Mental Health, Dr. Insel.

As you know, we have put an Inter-agency Committee on Autism, that is coming up with a strategic plan—that is how we're going to drive, essentially, the investments in autism, we're funding more centers; you just heard about a study that came out last week about the first really important discoveries in terms of the genetics of autism. I think it's advancing, it's progressing.

Could I use twice the money? Absolutely, I could. But I have other competing priorities, too.

Senator DURBIN. Thanks, Mr. Chairman.

Senator HARKIN. Thank you.

Senator Murray.

## TRAUMATIC BRAIN INJURY

Senator MURRAY. Well, thank you very much, Mr. Chairman, and thank you for an excellent presentation. I really appreciate the tremendous work that all of you do.

You focused a lot on diseases—one of the, kind of the other side of the picture that I've been looking at as a member of the Veterans' Committee and working with returning soldiers on traumatic brain injuries and post-traumatic stress syndrome, and the growing number of men and women that are dealing with that, and the broader picture across America of neurological disease and disorders, and injuries and was surprised to learn that nearly 100 million Americans are affected by that, and the huge impact on people's health and our economy—I think it's \$1 trillion that's being spent on neurological illnesses, the long-term impacts of that. Can you talk to me a little bit about what NIH is doing in a coordinated neurotechnology research, and what we can expect?

Dr. ZERHOUNI. In terms of traumatic brain injuries, we have really increased our investment—it's about \$87 million a year now, as compared to a few million just a few years ago, primarily because of the issues—fundamental issues, related to our understanding of traumatic brain injury in the context of conflict, and the Iraq war, in particular.

In terms of injuries, generally, when you look at all sorts of injuries, we spend about \$17 million, understanding musculo-scalpal injury, and all types of injuries. However, at this moment, this is not the only focus we have.

In collaboration with the Department of Defense, we have mounted an initiative in trying to understand both traumatic injury at the fundamental level, and post-traumatic stress disorder.

Now, when you really look at the impact of post-traumatic stress disorder and our understanding of it, you realize that this is going to require a response that is not just affecting the individual that is affected by PTSD, but the family around the individual, the community around the individual, and we do have to have a proactive response, because there are 1.7 million service members that have served in Iraq, and about 15 percent of those suffer from PTSD, a major public health issue, that will require full spectrum.

We do the research; we're collaborating with the Armed Services today on a \$70 million joint project to create, in fact, the ability to diagnose PTSD very reliably. Then, with the Department of Defense, we're working on a project that will create community centers, so that we can, in fact, detect and manage that on the ground.

Senator MURRAY. So, we can expect to see a coordinated, solid look at this?

Dr. ZERHOUNI. Actually, you know, it's interesting—we have never been more coordinated than on this issue, across agencies, including DOD, VA, NIH, CDC, all of us.

#### PANCREATIC CANCER RESEARCH

Senator MURRAY. Fantastic. Thank you, I appreciate that.

On another question, Senator Durbin mentioned we have constituents who come to us—one of the groups that I'm hearing a lot from is the pancreatic cancer groups, they are very concerned. They know that NCI developed, I think it was 39 recommendations for pancreatic research back in 2001, and only 5 of those are being implemented. Can someone give me an update on where we are with pancreatic research? There's a growing trend of that.

Dr. NIEDERHUBER. Well, we're continuing to increase our incentives to the research community but trying to write specific RFA grant applications or opportunities. We continue to support, through the SPORE program, our Specialized Program of Research Excellence, which is focused on translational research.

So, I think we can continue to put resources on the table and ask for applications due to increased interest.

The second, and probably more stimulatory work is our whole genome scanning. We are actually looking at pancreas, in large cohorts, and one of the organ sites to try to determine, if we can, what regions in the genome might predict risk for developing pancreatic cancer.

Senator MURRAY. So, there's a lot of potential at that point?

Dr. NIEDERHUBER. So, there's a lot of potential to inform that. We hope, too, that the TCGA pilot project will eventually get expanded to other tumors—pancreas would certainly one of those that we'd be very, very interested in doing, as that pilot project is proving very successful.

#### HIV/AIDS VACCINE TRIALS NETWORK LIABILITY ISSUES

Senator MURRAY. Thank you very much, I appreciate that.

Dr. Fauci, while you're in front of me, as you well know, Fred Hutchinson Cancer Research Center in my home State is working with the NIH to administer the HIV/AIDS vaccine trials network, and it's inherently a Government function, they are doing the research on it, and they're very concerned about being sued for dam-

ages, and the issue of liability is really threatening them. Can you tell me, is there any update on that?

Dr. FAUCI. We've been working very closely with the officials, at the Institute, at the University of Washington, particularly at the Fred Hutchinson Cancer Research Center (the Hutch), because as you know—and for those who are not aware of it—the data center for our vast vaccine trials network is centered at the Hutch, with Dr. Lawrence Corey being the principal investigator.

The issue is the concern that of, in fact, there is a suit against an adverse event that might occur somewhere far distant to the Hutch, what would that mean with regard to the liability and the vulnerability of the Institution for being funded? So, we're working very closely with the officials from the Hutch, together with members of the Department of Health and Human Services to figure out if we can evoke some of the existing authorities to help cover.

The idea of insurance itself—they have plenty of insurance there, but they're afraid that if it's a massive suit, that they would not be able to cover that. So, we really—literally—on a weekly and monthly basis, are trying to work something. I know officials have met with me, with people from Dr. Zerhouni's office, and himself, as well as with people at the Department of Health and Human Services, Secretary Levitt's staff—so we're actively on that. I do hope, and feel optimistic that we'll come to some sort of resolution, so that we can continue without the anxiety of liability.

Senator MURRAY. I really—this is really incredibly important research that they're doing, I would hate to see it halted or slowed down as a result of the liability issues.

Dr. FAUCI. We agree with you completely, Senator.

Senator MURRAY. Okay, thank you very much. I appreciate it.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Murray.

Senator Cochran.

#### OBESITY CHALLENGES

Senator COCHRAN. Mr. Chairman, thank you very much.

Dr. Nabel, I'm advised that since the early 1990s, the obesity rate has increased by 33 percent, resulting in serious health consequences for over 60 million people.

Ten years ago, there were guidelines that NIH issues, regarding overweight and obese challenges, and physicians have been relying on those guidelines for 10 years. Is it time that we updated the guidelines? Or does your Institute, or others, have specific plans to deal with the challenges that this problem presents?

Dr. NABEL. Senator Cochran, that's an excellent question and you importantly highlight the grave importance of overweight and obesity in our country, particularly among young people, and we're very, very concerned.

The answer is yes—we're in the process right now, the National Heart, Lung, and Blood Institute—is in the process right now, in collaboration with our partners, the American Heart Association, and the American College of Cardiology, to update our obesity guidelines. We will have those available soon for adults, and importantly, for children, as well. A very important task is to get those guidelines implemented into clinical practice.

## CARDIOVASCULAR GUIDELINES

Another task that we are—have embarked on, Senator Cochran—is to develop a set of integrated cardiovascular guidelines. In the past, we’ve had guidelines for blood pressure, for cholesterol, for obesity, and it’s really time we begin to integrate those.

So, we started down that road, we’re using a web-based tool, because we know most people, now, get their information through the Internet—we want this to be a consumer-driven project, again, in partnership with the Heart Association, the College of Cardiology.

We’re hoping that this is a tool by which people can understand their composite risk for heart disease and obesity, given all of these individual risk factors.

So, the answer is yes, sir, we’re working very hard at it.

Senator COCHRAN. I know one other area that you’re familiar with is the Jackson Heart Study, based in Jackson, Mississippi, named for the city, to try to improve our screening and knowledge of heart disease and things that can be done—societal changes, diet, exercise, the like—to more successfully deal with that problem. What is the status of that project, and is there a continuing need for funding for this review that’s being undertaken?

Dr. NABEL. Well, thank you very much, Senator. I want to personally thank you for the time and attention that you have brought to the Jackson Heart Study. You know that it’s a very, very important project to us at the National Heart, Lung, and Blood Institute, and we have worked collaboratively with you, and your office, as well as individuals at the University of Mississippi, Jackson State, and other institutions in Mississippi to bring this to fruition.

We have a lifetime commitment to this project. We believe that this project is so important, in terms of understanding the origins and the development and the treatment of heart disease in African-Americans in this country—it’s critically important to us, as a Nation, and we will stay steadfastly committed to it.

## ADDITIONAL FUNDING FOR NIH

Senator COCHRAN. Dr. Zerhouni, we’re really pleased that the committee is moving to increase the appropriations for NIH, and I’m not going to make any predictions before we get through our work, but I think there is a consensus in this committee to do just that. What would an additional \$1 billion increase do in terms of practical consequences at NIH in what you’re able to accomplish?

Dr. ZERHOUNI. You said \$1 billion?

Senator COCHRAN. Yes.

Dr. ZERHOUNI. Okay. If I had my choice, the first thing I would do, is I would really fund and protect the next generation of scientists. I would create a lock box within the budget, and say, we need to absolutely fund the next generation, and it has to be that number, and come hell or high water, we will fund them. So, the first thing is protect that future of protectors, who are going to follow these clues—if you don’t have them, you don’t have a research enterprise. That’s number one.

The second is to address what I think are important resources across the entire Nation that are absolutely needed to conduct clinical trials, they are like what Dr. Niederhuber was talking about—



to do, and you want to conduct research—we have to have the physical resources to do that, and to allow laboratory tests, to allow screening, for example, of millions of compounds, when we have a lead, or a target.

Dr. Collins was talking about the investment we made through the Roadmap through chemical genomics. With the robotics technology that we've implemented at NIH, we can do 1.5 million tests in a day and a half. Well, you couldn't do that 5 years ago. That's what I would like to expand, so that more people have that availability.

The third investment that I would make is engage the community of scientists in more integrative science. Work across disciplines, fund them so that at the end of the day, they can coordinate their work to address problems that, as I said in my opening statement, tend to be very complex, and they require the collaboration of physicists, mathematicians, biologists, doctors and nurses, endopediologists—all of these need to be able to work together. It's not so easy to do when you don't have the dollars to sustain that infrastructure.

So, the third point—\$1 billion won't be enough, actually, to do all this—is absolutely continue to encourage innovation—break-through innovation. Encourage people like the Pioneer Award, the New Innovator Awards, and we are launching a new program called Transformative R01s—we are doing it, but it's just not enough. We absolutely need to tell people, "It is the best place to do research, America is the best place to do research, and we will actually give you the freedom to explore ideas that have been knocked out through, by all of us here today."

Those three things—young investigators, infrastructure to conduct better research with better resources at a faster pace, and give the leeway, the freedom for people to explore new avenues that we may not be exploring today.

Senator COCHRAN. Thank you very much, thank you for your leadership, all of you.

Dr. Collins, best wishes to you, as you move onto other interests and pursuits, thank you for your service.

#### PANDEMIC INFLUENZA VACCINE DEVELOPMENT

Senator HARKIN. Thank you, Dr. Zerhouni, for that last answer to that question, I thought that really laid it out, where we ought to be headed.

Dr. Fauci, let me pick up with you, here, on pandemic flu. It's sort of, you know, we've had hearings with you in the past on this, and talked about the threats of pandemic flu. It's sort of, somehow faded to the background, although things that I read about and keep up on indicate that the threat is still there, as real as it ever has been.

We've been trying to develop vaccines, and to—develop, I should say, develop systems for developing vaccines—that can respond to whatever the strain is that might be the outbreak.

Most of it's been egg-based in the past, we know that takes a long time, and then we went into cell-based, but that still takes a few months, several months, to develop the amount of vaccines that we need. I keep hearing about other kinds of ways of developing

vaccines in a more rapid manner, I'm not—I can't speak about them, I don't know much about them, and so my question is, what's happening with—in your shop—in systems developments so, to respond to a pandemic flu outbreak? To get the vaccines made as rapidly as possible?

Dr. FAUCI. Well, thank you for that question. Just because Mr. Chairman, as you well know better than anybody—just because something is not on the front pages anymore, that doesn't mean that it's not an important issue.

So, there are two parts to your question that I can answer very briefly and succinctly. First, where do we stand with regard to a potential pandemic flu? That's not gotten a lot of press lately.

Number two, what about the investments that we spoke about at several committee hearings that you had, that I discussed with you at an official hearing and in private, about some of the systems involved, and some of our previous lack of ability to scale up manufacturing of vaccines, and surge, if, in fact, we have the unfortunate event of a transition from an endemic virus that still currently is in chickens. H5NI is still killing a lot of chickens, in Southeast Asia, and occasionally we see a burst of a transmission in a particular region, with culling of the chickens, and then it dies down.

The numbers now, we have about 385 human cases, 243 deaths as of yesterday, which gives you a sense of how the threat of the pandemic is emerging. That means it's smoldering, it has not gone away.

What have we done from a scientific standpoint? There have been major advances that I welcome the opportunity and thank you for asking the question about, with regard to some of the things that we set into play a year, 2, or 3 years ago. There's been a significant amount of movement now by several companies to varying proportions, away from egg-based, more toward cell-based, vaccine manufacturing which gives a considerable degree of flexibility, number one.

Number three, and I think to myself as a scientist, this is perhaps the most exciting—as I mentioned to you previously, about a year or so ago, there is great potential for the use of adjuvants. As you know, an adjuvant is a compound that you give together with the main component of a vaccine, that we call the immunogen, and it has the capability of doing two things.

It allows you to get an amplification of effect with a lesser dose; this is critical to stockpiling.

Number four, and we didn't know this for sure, but we've seen it in a number of other studies, is that it broadens the breadth of the response, which means, critically, that if we're looking at a vaccine that's circulating in Southeast Asia now, and we make a vaccine from that virus, there's always the possibility, if not the likelihood, that if it evolves to now become very efficient in going from human to human, if we stockpile that particular virus vaccine, we're going to have to change it—perhaps significantly—to keep up with the evolving strain.

What we have found out in three or four separate studies, conducted either by ourselves or together with pharmaceutical companies, or by pharmaceutical companies alone, is that the use of adjuvants has now dramatically increased our capability of scaling up.

So, what was formerly the famous 90 micrograms times two that I told you about several times, we can get down, now, to 7.5 micrograms, or 3.75 micrograms, times two.

And then, the final part of that is that much to our—I wouldn't say surprise, because I would like to have predicted—but much to our gratification, the response to a strain that's an Indonesian strain, when you vaccinate you get cross reactivity now, to some of the evolving strains. So, this really is very good news for the ability to scale up, and in fact, have a stockpile that would be more than just a stop-gap, but would actually, might afford this broader cross-protection.

So, again, though it hasn't been highly publicized, I think the news is all gradually heading in the right direction.

#### MOLECULAR ADVANCES IN VACCINE DEVELOPMENT

Senator HARKIN. Is there something besides cell-based developments that's going on?

Dr. FAUCI. There's the whole issue of the molecular-biological approach, because the standard vaccinology is, you get the virus itself, whether you grow it in eggs, or you grow it in cells, it's still the virus itself, and then you purify it, spin it down, get the right components of it. That's standard, classical vaccinology.

We're moving to what we call the 21st century vaccinology, which means you can, for example, take DNA, and insert into that the coding elements for a particular, specific protein, in this case with influenza, it would be the hemagglutinin, or the neuraminidase, or the M-Protein, and if successful, you can make an unlimited amount by the production using what we know from decades of experience with molecular biology, and recombinant DNA technology. We're starting to see that, right now, evolve and replace the standard vaccinology.

Dr. Zerhouni reminded me of a question that you didn't ask, but you've asked me in the past, is where we are with the universal vaccine, namely are we making headway in that? Some of the animal studies, again, are looking promising. This is one of those real tough nuts to crack, but I hope that at a future hearing, we'll be able to come to you with some real hard data that we've actually made progress in getting a product that could actually handle the drifting strains as they evolve from one year to another.

#### AIDS VACCINE RESEARCH

Senator HARKIN. To go from that kind of good news, and hopeful outlook, I now go to the AIDS vaccine.

Dr. FAUCI. Yes.

Senator HARKIN. All of the years and the money that's been spent on that, and the depressing news that we received recently, that not only is the AIDS vaccine not working, it may actually increase the susceptibility to AIDS. So, where are we? Where are we heading?

Dr. FAUCI. Well, where we're heading is a bit more back to the fundamental basics of asking and answering some of the questions that I mentioned to you and this committee years ago, related to the fact that HIV is really very different. In vaccinology, in general, when we make a vaccine, the standard paradigm is to make a vac-

cine that mimics natural infection. Because when all is said and done, when you're dealing with smallpox, when you're dealing with influenza, when you're dealing with polio, the body ultimately induces successfully an immune response, and although people get sick, and some die, at the end of the day, that virus, that microbe induces a response that completely eradicates the particular microbe from the body.

So, nature is smarter than we are, so when we want to make a vaccine, we want to mimic natural infection.

Senator HARKIN. Yeah, I understand.

Dr. FAUCI. The problem with HIV is that the body, to our great dismay, does not make an adequate immune response against the virus, such that there are essentially no examples of a person who gets infected, has an established infection, and then eliminate the virus from the body.

The reason is the way the virus presents itself: the body doesn't recognize it in the way that it induces a protective response. So, the failures that you've been hearing about, were that we were hoping that with the balance between empiricism, and fundamental scientific concept questions, we would be fortunate enough to have a situation where it would work.

It's becoming very, very clear now, that we need to go back and try and make ourselves smarter than the body, namely by developing whatever it is that—we call it an epitope, which is a component of the virus—and present it to the body in a way that would have it induce neutralizing antibodies that would ultimately protect.

So, you heard about the disappointing Merck study, it was called the STEP study, we were partners in that. And right now, we're going to very carefully go ahead and raise the bar a bit higher, before we go ahead into a big clinical trial, and turn the knob more toward asking and answering some of those fundamental questions.

We actually had a very successful summit in March of this past year, and we gathered all of the players, and even some people not involved in HIV vaccines, to plot the way over the next several years, and that's what we're trying to do.

#### CANCER AND THE IMMUNE SYSTEM

Senator HARKIN. Thank you very much.

Well, thank you very much, Dr. Fauci, for bringing us up on that.

I have a couple of things I wanted to bring up with Dr. Niederhuber on cancer research.

I wanted to get your thoughts on a researcher, you may not be familiar with, but I hope you will look into this. There's a researcher at Wake Forest that I met a few weeks ago and then have had some correspondence with—he recently presented a paper at UCLA that I heard about, his name is Jiang Cui, C-U-I, Dr. Jiang Cui.

He came to my attention because it was told to me that he'd been bringing mice with certain immune cells that were resistant to cancer. That no matter how much cancer cells were injected into the mice, the mice never got cancer.

Then he was taking some of these immune cells from these mice and putting them into other mice, and when he did that, those

mice didn't get cancer. Well, this kind of intrigued me, so I met with him, he had quite an interesting laptop display that he showed me on this. These immune cells—he called them granulocytes, which I've never even heard of before.

Now, again, this is in mice—I understand mice are different than humans—but as someone once said, we're about 90 percent rat ourselves, close to that, anyway. It doesn't matter to just politicians, I mean all of us.

So it's very close. So, again, it raises the possibility that you can use the immune system cells to boost a cancer patient's resistance, an ability to fight the disease. Are you aware of his research at all? I asked him if he'd had an NIH grant, he said he did, once, some time ago, but he doesn't now. I just wondered if you were at all familiar with his research, at all, at Wake Forest. If not, that's fine. I just encourage you to take a look at it.

Dr. NIEDERHUBER. I'm a little bit familiar with it, Senator, he has had grants—two grants, I believe, in the past—an R01, and then an R55 that was converted to an R01. Both of those lapsed and he did not come back in for additional funding. Both of those were in areas that weren't quite related to what you're describing. He does have an IND which allows him to do research in this area, neither using these granulocytes that he harvests from patients nor in mouse models.

I would only say that I think that, as you're very much aware, we have probably at the NCI, and also with our colleagues at the NIAID, some of the best immunologists in the world, that are working not only on infectious disease and inflammation, but also on the relationship of cancer to the immune system.

I know that you are very familiar with the similar work in what we call cell-based therapy, of Steve Rosenberg. I think this is probably the most exciting work in the country, or maybe even in the world, right now, in terms of using cells from our immune system, tricking them or arming them in a way that they can specifically attack cancer.

So, we've very excited about the progress that Dr. Rosenberg has made. I think he is out in front as one of the real leaders in this—what I would call—cell-based therapy. There are certainly other workers across the country, some funded, some not funded, that are doing some similar things, but I don't think any of them at quite the sophistication of Dr. Rosenberg.

#### CONFLICT OF INTEREST IN EXTRAMURAL RESEARCH

Senator HARKIN. I'm obviously familiar with Dr. Rosenberg's history and what he's been doing, but it seems to me that that's the area that he's sort of been involved in for a long time, that is, the immune system and how that relates to our ability to fight off cancer cells. I thought of that when I met Dr. Cui, I thought of Dr. Rosenberg and all the work that he'd done in the past on this.

But, I would appreciate it if you'd take a look at that and see if there's anything different there, that what Dr. Cui is doing at Wake Forest.

[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
NATIONAL INSTITUTES OF HEALTH, NATIONAL CANCER INSTITUTE,  
*Bethesda, Maryland, August 11, 2008.*

The Honorable TOM HARKIN,  
*United States Senate, Washington, DC.*

DEAR SENATOR HARKIN: At the, July 16 hearing to consider Appropriations for the National Institutes of Health (NIH), you asked me to look into research done by Dr. Zheng Cui at Wake Forest University. Several scientists at the National Cancer Institute (NCI) have had the opportunity to examine Dr. Cui's work which is indeed very interesting. In the course of routine experimentation, Dr. Cui discovered a single male mouse that did not develop cancer despite repeated infusions with increasing numbers of cancer cells known to cause cancer in other mice. When he bred this mouse, he found that 40 percent of its progeny also proved resistant to cancer suggesting that there was an inherited genetic element to the observed resistance. Further experimentation has demonstrated that the immunity displayed in these mice is mediated by cellular elements of the immune system, called, as indicated at the hearing, granulocytes. The cellular immunity has proven to be effective against multiple types of cancer and has proved transferable. Injection of previously susceptible mice with granulocytes from resistant mice has conferred cancer resistance to the recipients. If the recipients already had cancer, the tumors regressed. Dr. Cui has not however been able to isolate the genes in the resistant mice responsible for this characteristic, postulating that this may be due to the fact that they are mobile genetic elements, genes that do not have a fixed location on a chromosome.

It is unclear what experiments were done with human granulocytes to determine that they too displayed the cancer resistance found in the mice. Perhaps an in vitro assay of the ability of these immune cells to kill a variety cancer cells would be informative. While in vitro experiments might be encouraging, there is not yet reason to believe that granulocyte infusion from a donor would have in vivo anti-tumor activity and no evidence to suggest that the infused granulocytes will traffic to tumor sites. An additional concern is the potential risk of graft versus host disease which is not a concern in the experimental mice, but would certainly be in humans. Dr. Cui's planned trial will attempt to determine the risk of this complication in which donor cells (lymphocytes) attack healthy cells in the recipient, leading to serious health problems. While the trial design only calls for the infusion of granulocytes, there is no guarantee that all lymphocyte contamination would be removed.

This approach differs somewhat from that of Dr. Steve Rosenberg. In Dr. Rosenberg's case, the transferred cells are lymphocytes which have been proven to have anti-tumor activity in vivo. In addition, Dr. Rosenberg's research now involves the use of the patient's own cells in the treatment of cancer rather than donor cells. The patient's cells are genetically modified outside of the body in order to increase their anti-tumor activity and are then infused back into the patient.

Dr. Cui's approach, while interesting does make certain leaps of faith with regard to the similarities between the mouse and the human. The upcoming clinical trial will determine whether these leaps were warranted. I appreciate your interest in cancer research and am pleased to have the opportunity to provide this information to you.

Sincerely,

JOHN E. NIEDERHUBER, M.D.,  
*Director, National Cancer Institute.*

Senator HARKIN. I just have one other area that I really wanted to cover here, Dr. Zerhouni, conflict of interest. You led the way on changing the rules for NIH employees. I know you share my concerns about conflicts of interest among extramural investigators, as well. We have to maintain the public's trust in NIH, and eliminating conflict of interest is an important part of that.

I know you supported the amendment I offered in last month's Appropriations Committee markup to require HHS to issue "an advanced notice of proposed rulemaking," which will start the formal process of revising the current HHS guidelines.

Clearly, NIH and academic institutions will have to work together to end the problems that we've been reading about. There's obviously been some correspondence from other Senators in this regard and some of this has made its way into the press.

The HHS Inspector General recently found several problems with the way NIH is currently overseeing grantee institutions. For example, NIH couldn't provide an accurate count of the number of conflict of interest reports it had received. More importantly, the AIG found many Institutes basically take grantee institutions at their word, that they're following the regulations, rather than doing any oversight of their own.

Again, in your opinion, what should NIH be doing to improve its oversight of the extramural research that's being done, and any problems of conflict of interest in that extramural activity?

Dr. ZERHOUNI. As you know, the issue of conflict of interest has sort of grown in importance over the past 15 years, much more so than ever in our history, simply because of the intertwining of industry and academia, in terms of marketing and understanding the proper use of drugs.

We also need to state that there is good value to good interactions that are well-managed, between industry, academia, and Government that create public good. Many of the discoveries and the products that we make, come from that interaction.

So, the real challenge, Senator, is how do you balance, the good—the public good—that comes in from proper, fully disclosed, fully understood interactions that do not—do not—present a risk to either individuals, human subjects, or the risk to the objectivity of the science?

So, we need to work together, NIH, the institutions, Congress, to find exactly how this needs to be put in place. Given the fact that the world has changed, and given the fact that I think our number one priority is to make sure that the American public who funds this research is ensured that we have systems in place, common standards in place, that are transparent that allow us to also stratify the risk.

I don't believe there is the same degree of risk in terms of conflict of interest when you're talking about very early discovery or genetic research that doesn't have a human application, as opposed to a clinical trial. As opposed to teaching, giving opinions that are not evidence-based, or using scientific prestige to promote private interests.

That gradient, if you will, that stratification, needs to occur. So, what I'm hoping for is that, and something I've said all along, is that we need to come up with a consensus about common standards that all institutions need to use. If you really look at the Inspector General report, our own analysis, you'll find that institutions have not yet converged toward one common, coherent set that we can all implement, that's number one.

Number two, I think it's important to stratify the risk. I think it's different when you're talking about risking the life of someone, or imposing treatments that are not evidence-based on thousands of individuals, as opposed to doing good research that may discover the next cure for a disease.

I think we need to understand that better, and I think the advanced notice of rulemaking will establish that debate, so that we understand that.

Third, I believe that there is a cultural responsibility that is absolutely necessary for that. The first thing that has to happen is

sunshine. So, I think I support the concept of sunshine in disclosing these relationships, first and foremost.

The second step after sunshine, is to understand how you manage those things to, guarantee the integrity of the process. You can't do that, really, in my opinion, without some third party that will be the arbiter of this between institutions and the NIH.

So, we need to think about some independent way of really being proactive, if you will, a sort of quality control over the process. It's really hard for NIH to, essentially, check 300,000 scientists out there. We don't have to rely on some degree of self-regulation, self-reporting, and I think that is the challenge that we all face.

We all want the same thing, which is let's not discourage innovation, but not at the expense of either individuals, or the integrity of the scientific process.

#### AAMC AND AAU RECOMMENDATIONS

Senator HARKIN. I'm assuming, Dr. Zerhouni, you would support the AAMC and the AAU recommendation that investigators should have to report all of their financial interests? Regardless of the amount, regardless of whether it might appear to be affected by their research? That's the idea of just sunshine, are you supporting that?

Dr. ZERHOUNI. I think so. I think we need to do that and actually when we looked at the issue at the NIH, one of the problems was lack of disclosure. I mean, you can't manage something you don't know about, right? I mean, how do you start managing something when there is no disclosure requirement? I think that's the number one step.

I think we also need to be very careful not to go too far and damage innovation by having very strict rules that are one-size-fits-all. I'd be willing to be very, very strict when it comes to risk to patients, risk to populations, and risk to the integrity of science. That's different than someone who has a patent, a discovery, a new device or a brilliant idea—I don't think we want to stomp that, so reaching the balance is the key concept here, while preserving public trust.

#### FOOD ALLERGY RESEARCH

Senator HARKIN. I keep shifting back and forth, but I forgot to ask Dr. Fauci another question.

In my other capacity as chairman of the Agriculture Committee, which has to do with a lot of food programs, and feeding programs, next year we have the reauthorization of the child nutrition bill, which provides funds for school lunch programs, school breakfast programs. Through all of this, I think maybe we've talked about this in the past, and I'm sure I've asking you about this at other hearings—the seemingly explosion of food allergies among kids.

Dr. FAUCI. Right.

Senator HARKIN. I'm hearing back from school that are having problems, because of all of the food allergies that kids have. So, what's happening out there, and what's your Institute doing to look at this, seemingly, explosion of food allergies?

Dr. FAUCI. Yes, that's a very, very important issue, in fact, you recall we had a hearing just on this particular subject. A lot is hap-



pening now, I think that there really is a full realization that this is a serious problem. As you know, 6 to 8 percent of children less than 4 years old have a food allergy, and 4 percent of adults have a food allergy. There are 30,000 anaphylactic reactions a year, and about 150 to 250 deaths.

So, we really need to, actually—and this is what I believe we're on the way to being more successful than we were in the past—of rejuvenating the field along the lines that Dr. Zerhouni and Dr. Collins and everyone was talking about about getting people in the field who are interested, who are motivated to get involved, bring some of the more sophisticated science to try and understand what is the pathophysiological mechanism of why this is occurring, asking whether some of the old assumptions that we have about food allergies, including things like peanut allergy should we be exposing early or avoiding? Things like that.

Senator HARKIN. Which I asked you about at that hearing, remember? I mentioned to you—

Dr. FAUCI. Exactly, exactly.

Senator HARKIN. That, why China—they eat all those peanuts in China, and they don't have allergies?

Dr. FAUCI. Exactly—they boil them, we roast them.

Senator HARKIN. There's something going on.

Dr. FAUCI. In Israel, they give infants and children peanuts as a little snack, we don't.

So, there are so many fundamental questions and I'm so pleased, we had a hearing with Senator Dodd a few months ago, about what's going on in food allergy, and we're very pleased that we have a program of a new investigators. We are trying to ask some fundamental concept questions, hoping to bring new people into the field. We have committed about \$5 million over 2 years and we're just now in the process of awarding those grants. To my great satisfaction, I think 11 out of 12, or maybe even 12 out of 12 of the investigators are actually people new to the field. That's very important when you think in terms of the things that Dr. Zerhouni said, about getting new, fresh, young ideas.

So, we have—in a very limited budget, I have to say—we've increased our food allergy allocations from a pittance of just less than \$2 million to close to \$13 million, but we really need to do much more, but in an arena of fiscal constraint, it's very difficult to do. So, we're really trying to jumpstart that system. But, I'm very pleased that you, and Senator Dodd, have brought that up, because it is now really focusing on the importance of the problem.

Dr. ZERHOUNI. If I may, Senator, also as part of the National Children's Study, there is a component of the Children's Study that is going to look carefully at this from the moment of conception, all the way to 21 years of age, trying to capture, in fact, the food exposures, if you will, that we have and the emergence of allergy, trying to understand a little bit better what happens in early life. Dr. Dwayne Alexander is not here, but I'm sure he would have mentioned that and I think we've updated your office on that.

## HEART ATTACK PREVENTION

Senator HARKIN. I'm going to reassure you that we are going to continue to fund the Children's Study. We're not going to let that one drop, either. We're going to continue to fund that.

I was, Dr. Nabel, I haven't asked you a question and I wanted to get to one thing. Since Tim Russert's death, we get a lot of people asking about, what are we doing to really prevent heart attacks? It seems like kind of random, and they happen, I'm just getting a lot of input into my office about that, they're going to their doctors, are they a risk for heart attack—what kind of research is being done in preventing heart attacks?

Dr. NABEL. Well, that's a very important and delicate question. Mr. Russert's death was a great tragic loss for our country and many of us have mourned his death.

We have now referred to this as the Russert Effect, you've probably seen stories in the newspaper, on television, of middle-aged men—a story in the Times a week ago, a middle-aged man, age 50, on a bike ride on a Saturday morning, didn't feel well, a little fatigued, a little short of breath, his partners had to leave him behind. He called his wife, "I'm not well," he went home, laid down, and thought, "Tim Russert." He drove himself to the hospital and he was having a heart attack.

It is true that we know a lot about the risk factors for heart disease and we're doing all we can to help individuals identify their risks very early in life and modify those risks.

Yet, at the end of the day, despite all of our best abilities to modify those risks, we know that at some time, a little bit of the blockage in the heart artery can break off, and that blockage might only be a 5 or a 10 percent blockage, might break off, leading to a blood clot and a heart attack.

That doesn't stop us from doing everything we can to help individuals understand their risk, and to help them to do all they can to modify their risk. As you know, we've had a very active program over the past 5 years for women and heart disease to have women identify the risk.

I think, quite honestly in all of our efforts to focus on women, we've left the men behind. Now we need to catch up, and help men remember that they're at great risk, as well.

It's really a public education, it's a campaign that we work on arduously, every day, with our partners, the American Heart Association, to help people understand their risk, and to take action.

## STATINS AND MORTALITY

Senator HARKIN. Is there any evidence, at all, any medical evidence at all that the use of statins has reduced mortality—

Dr. NABEL. We know that the use of statins lowers your risk for having a heart event—by that I mean, a heart attack, or dying of a heart attack.

Senator HARKIN. Because I've been informed that there really is no medical evidence that statins has reduced either morbidity or mortality from heart attacks.

Dr. NABEL. For people who have known heart disease, the answer is yes, statins clearly reduce the risk for having a second heart attack, or for dying from heart disease.

Senator HARKIN. Which raises the question, should so many people be taking statins, who have never had any incidents of heart disease at all?

Dr. NABEL. That's exactly the question that needs to be asked, and that's the study that we would love to do. If we had incremental money in our budget.

Senator HARKIN. But we're spending billions of dollars a year taking statins—

Dr. NABEL. We are.

Senator HARKIN. There's a lot of counter-evidence that they really—unless you've had an incident—

Dr. NABEL. Yes.

Senator HARKIN. That it really doesn't prevent.

Dr. NABEL. You're right, Senator. What we're really doing, is we're hedging our bet. Because what we don't know, is that for individuals who are at low, or even moderate, risk for heart disease, does starting taking a statin—age 20, age 30, age 40, age 50, or even in childhood—make a difference? We don't know the answer to that question.

We know that if you're at a very high risk for heart disease, then you've got very high LDL cholesterol, and you've got two, three, four other risk factors, then yes, in that group, taking a statin does help.

But, the majority of people really taking statins in our country today are people who are hedging their bets. A little bit of an increase in blood pressure, a little bit of an increase in cholesterol, figure lowering your statin may be helpful. It's common judgment, it may be helpful, but we don't know the answer.

The study that we would like to do, is a longitudinal study of primary prevention. Does taking a statin when you start, say, in your 30s or 40s, when you might have one or two risk factors for heart disease, does that lower your risk, or prevent you from getting a heart attack in your 50s, 60s or 70s, or dying from heart disease? We would love to do that study, if we had the money.

Senator HARKIN. Why don't you do that study?

Dr. NABEL. We would love to, it's an expensive study.

Senator HARKIN. Well, tell me how much.

Dr. NABEL. We're estimating that—

Senator HARKIN. I mean, if not today, I mean, at least—

Dr. NABEL. Yes, it's in the estimate of hundreds of millions of dollars. Because you would need to enroll people very early in life, you would need to follow them carefully over decades—we could certainly do that study. We've done an equivalent in the Framingham Heart Study, we're doing it in the Jackson Heart Study.

But, at this point, to dedicate that size of sum of money from our budget, which is limited, it's just tough to do.

#### CARDIOVASCULAR DISEASE

Dr. ZERHOUNI. If I may, from the overall standpoint, not looking specifically at this—if you look at the total mortality and morbidity for cardiovascular disease and stroke, it has dropped by 60, 70 per-

cent. The real question is how do you and what do you attribute that drop to? Is it cessation of smoking? Is it taking aspirin? Is it taking, having good diets? There's controlling blood pressure, taking statins.

So, when you look at the policy aspect of this, how do you really start demonstrating whether or not something works or doesn't work? Well, you have to take the high-risk group. In this case, in statins, it's clear that if you take patients who have had a heart attack, therefore, absolute proof-positive that they have an underlying cardiovascular disease, the evidence is clear that statins do help reduce the number of second events, and so on.

The same thing is true when you're looking at the issue of secondary prevention, versus primary prevention, which is the topic that Dr. Nabel talks about. As a country, we're going to have to make that decision, why? Because there are many things we do, for example, in diabetes. Diabetes, we have oral drugs that reduce glycemia. We have, also, studies that NIDDK has done that show that if you use them as a pre-diabetic patient, when you're not diabetic, you will reduce the risk of the disease emerging.

What is the key to all of this? The key, Senator, is can we predict in the millions of people who take statins, those who have a real risk, as opposed to those who do not have a real risk? That's where the predictive nature of the genomic research and the personalized medicine research that Dr. Francis Collins has been talking about comes in. As long as we don't have that knowledge, you know we will have to do very long trials where we follow people over many years, which are very costly.

#### BIOLOGY OF AGING AND THE AGING PROCESS

Senator HARKIN. Speaking of long years, Dr. Zerhouni, I want to talk about the biology of aging. Diseases like Alzheimer's, you mentioned diabetes, heart failure, stroke—operate in different ways, but the one thing that they all have in common, they tend to strike older people.

Traditionally, our research in these diseases has approached them separately, one at a time, we look at these diseases, and we investigate them. Now, we're learning more about the basic biology of aging, that suggests there may be ways to postpone all of these diseases, by slowing down the human aging process.

If we could add 5 to 7 years of healthy, vital life to millions of people, it would have an enormous impact on healthcare spending. Plus, the fact that we know that most of the spending on medical care in this country goes in the last couple of years of life.

Someone once said to me, a long time ago, that one of the primary goals of biomedical research was to enable to die young, as late in life as possible. I've always remembered that. So, what are you doing, what are you looking at in terms of this whole biology of aging and the aging process, as it might impact all of these different—heart diseases, strokes, diabetes, and everything else?

Dr. ZERHOUNI. Right.

Senator HARKIN. I imagine that must spill over into Dr. Collins' area, too, big-time.

Dr. ZERHOUNI. I will start and then he'll tell you what the future is like.

Clearly, when you look at the aging process, and you started by saying, there are multiple conditions that affect people at the same time.

Senator HARKIN. Yes.

Dr. ZERHOUNI. So, there are really two questions, there are—do we age the same way? Does our population age in the same way, or do we have clusters? People age one way and then others age another way?

So, the first thing is, is there a heterogeneity in aging, do we all age in the same fashion? We know, today, that the aging process over the past 30, 40 years—people are living longer and healthier, so the disability rates for seniors have dropped. So, we know that there are things you can do that seem to improve your aging process.

Second, we also know, as Dr. Nabel was just mentioning, and she's saying something very important—we've done one disease at a time, now we need to integrate the factors, and it's very clear that if you look at the aging process, some of us age faster, and seem to present a collated set of diseases—diabetes, high blood pressure, the metabolic sort of—low exercise levels, obesity, Alzheimer's disease that relates, now, as we know, to diabetes in some ways, and cardiovascular disease. You look at the genetic spectrum of these diseases, one subgroup seems to be affected more than other subgroups, and we are honing down on those discoveries.

So, that's one aspect of the aging process. Are we accelerating unhealthy aging in certain members of our population, what is the evidence that that's the case, and what can we do about it? So, that's one way to approach the problem, Senator.

The second problem is we also have evidence that you can, in fact, slow down the aging process. So, we have found a molecule—there's a famous molecule now, retro, which comes from red wine, which seems to be, in fact, having this effect.

The other remarkable finding is that if you have caloric restrictions—if you just reduce the number of calories in an experiment in animals, you can lengthen life expectancy by 30, 40 percent.

Our researchers at the NIA are doing another experiment where they're saying, what if you have one day of fasting and another day where you don't fast? So, intermittent fasting? They see the same results, even without loss of weight.

So, there's fundamental research on one end that shows that there are mechanisms that complex network of molecules that say, there is a way of good, graceful, healthy aging. There's also this body of research that shows that, in fact, chronic diseases seem to start in a combinatorial way where you seem to have everything at once and then you have to take 12 drugs to live your life and those are not the exact same processes.

Well, now I'll turn it over to Francis, who's done a lot of work with NIA about how do we, then, see the future in these two directions?

#### GENETICS OF AGING

Dr. COLLINS. So, despite all of the exciting research that's going on, I think you're right, Senator, that the goal ought to be to try to give each of us the chance to die young, but at a very old age.

The death rate will probably continue to be one per person, at least that's my prediction in the current climate.

But I'd like to see that death rate extended out, to a full four score and ten or more for all of us.

So, how are we going to get there? Obviously a great area of interest is what is the program that's basically built into our system that is supposed to be responsible for the fact that we don't live forever? In evolutionary terms, there needs to be such a program, otherwise, nothing could ever really progress, so lifespan has to be limited so future generations can have the resources, and let the older generations fade away.

But, obviously, we've learned a lot about the way in which different individuals seem to age at different rates, simply by observing them—what's going on there?

There are studies now underway looking specifically at individuals who have reached the age of 100 or more, to ask the question, do they have some genetic susceptibility to very long lives? This is not a susceptibility to disease, this is the opposite side of that, the flip side of the coin.

In fact, there are, in the last couple of months, discoveries of exactly those kinds of genetic factors—based on the same strategy that Dr. Zerhouni talked about in his opening statement, that led to all of those banners on the chromosomes for various diseases—there are also genes that are good for you, apparently, and that are capable of giving you this kind of opportunity to live a long and healthy life.

If we understood how those worked a little bit better, then perhaps by modifying diet, lifestyle, we would contribute those same opportunities to people who don't have the inheritance—the genetic endowment—that they wish they did.

Another area that's of great interest, is studying nature's surprise experiments of individuals who have a very rapid aging process. Dr. Nabel and I, in our own research laboratories, are working on a disease called progeria, which is the most dramatic form of premature aging. These kids appear normal at birth, but by about a year of age, they stop growing, and then their hair falls out and their skin gets old and leathery, and they die, generally, at age 12 or 13, of a heart attack or a stroke. So, they're aging at about seven times the normal rate.

My laboratory identified the genetic glitch in progeria 5 years ago, and it turns out to be in a gene that codes for a protein that had some fair amount of cell biology work already done on it. In just 5 years, we have gone from a complete enigma of what this rare disease was all about, to a clinical trial of a drug which appears to work quite well in an animal model. This trial being conducted in Boston, and now already a year along, with about 30 kids with this rare disease being treated.

That is breathtakingly quick, and it, again, is a testimonial to the richness of the research environment that's being created by NIH investments.

Is that disease anything like normal aging? Well, obviously it's dramatically accelerated, but we have now very strong evidence that that same pathway is just a little bit tweaked as we get older,

and maybe part of the time clock that we're all living with, hearing that ticking in the background, coming from this same pathway.

Therefore, studying the rare disease may teach us something about the common, universal feature of aging, which is a very exciting series of observations we can expect to make in the next few years.

Senator HARKIN. Well, that's very provocative.

Dr. COLLINS. Indeed.

Senator HARKIN. In a good way.

Dr. COLLINS. Yes.

#### PROMISE OF PERSONALIZED MEDICINE

Senator HARKIN. Is there anything anybody else wanted to bring up here, that wasn't probed, or asked or anything? Any of you want to make any other—Dr. Collins?

Dr. COLLINS. If I could, again, because it's my last chance, I think it has been mentioned by Dr. Zerhouni and others about personalized medicine, and I just wanted to say a word about that, in terms of the promise that this provides for where we may be able to go, in terms of clinical care.

We are learning, as you saw in the course of the last couple of hours, a remarkable amount about hereditary risk factors for disease. We've known they were there, we largely guessed at them by family history, everybody has a family history of something, and generally that gives us a clue about our own risks, and it's been the best clue we've had.

#### HEREDITARY RISK FACTORS

But, we're unraveling—especially in the last 2 years—the molecular basis of those hereditary factors, at a prodigious pace. It's no accident that Science magazine called this the breakthrough of the year in 2007, in all of science was this understanding of human heredity and how it plays a role in common disease.

That really does position us, relatively soon, to be able to offer to anybody who wants the information, a chance to find out, in a much more precise way, what their risk factors are—while they're still healthy—and then to design a plan of prevention that is the one-size-fits-all approach, not anymore it's focused on what that person most needs to pay attention to. That's pre-emptive, that's personalized, it's all of the things that Dr. Zerhouni is talking about in terms of where we need to go. It focuses on prevention, and spending our healthcare dollars keeping people well, instead of waiting until they're in the ICU for something that we might have been able to prevent.

#### PHARMACOGENOMICS

On top of that, we're learning a prodigious amount about the way in which drug responses also vary from person to person, allowing us—in the not too distant future—to do a more evidence-based assessment of which drug should that person get, and at what dose.

Senator Specter, who courageously is going through this experience with Hodgkin's disease—if we had just a bit more information, and we desperately need to get that—to pick exactly the right kind

of combination of chemotherapies for his particular situation, as opposed to a larger group of people, we could have an even better shot at reducing the likelihood of side effects, and improving the outcome, and we need to really push on that. But we're getting there at a pretty fast rate.

#### THERAPEUTIC TARGETS

Then, the therapeutics that we have to offer which, in many ways, we have been sticking with drugs that work pretty well, for decades, but we've really needed this breakthrough in an idea about new targets—that's what the genome has given us. For most of the pharmaceutical industry's history, they've been limited, pretty much, to working with 500 or 600 targets—the things that we knew something about. The human genome breaks that wide open, and all of these discoveries about genes for common disease are pointing us much more precisely toward targets that are not secondary in the problem, they're the primary place that you would want to go to apply your therapeutics.

We can see that happening for common diseases, and the drug industry is jumping on that appropriately, and for rare diseases, NIH has the chance to step in, and for neglected diseases of the developing world, as well, as we've recently seen done for some of those diseases like schistosomiasis.

So, I think, when we put that all together, we have a pretty exciting shift in the paradigm from waiting until illness strikes and hoping you have something to do for it, to focusing on prevention in an individualized way—which I think will motivate people a lot more to actually act on the prevention opportunities, because it's about them—it's not some sort of generic prescription—and the opportunity to change our therapeutic agenda in a direction that's much more rational and evidence based.

But we can't get there without the support of this wonderful Congress, and this subcommittee that you've so ably led. I think we all come here today in hopes that the difficult times of the last few years may be about to turn a corner, and that we can bring back into the fold, investigators who are on the edge of departing, and not returning. That's our hope. We don't want to see all of this done in Singapore. It would be great if a lot of it got done right here in the United States of America.

Senator HARKIN. Your remarks remind me, number one, that's why it is so important to pass the Genetic Information Non-discrimination Act.

Dr. COLLINS. Absolutely.

#### INDIVIDUAL GENOME MAPPING

Senator HARKIN. Second, are we going to be able to afford—where do we get the price of mapping each of our own genes, like Dr. Watson did, and others, I mean, now what is it—\$100,000 or something, and they wanted to get it down to just a few hundred dollars per person, is that really going to happen?

Dr. COLLINS. Oh, absolutely. We are on that pathway at a remarkable rate. In the last 2 years, two very new strategies for doing DNA sequencing have found their way, really, into the mainstream of this research arena, and one can now sequence a ge-



nome—which originally cost us, as you reported, somewhere in the neighborhood of \$300 million for that first one. It can now be done for about \$100,000, and the trajectory we’re on, I would predict, will get us to the \$1,000 genome in the next 6 or 7 years.

Already, now, one can—if you don’t want the whole sequence, if you want to focus on, say, 1 million places in your genome where we know there are variations that might play a role in disease—you can do that, now, for about \$1,000, in fact, there are companies out there that are marketing that directly to the public, which is an exciting thing, although some of us are a little worried about whether we’re jumping the gun, here, in terms of knowing exactly what people should do with that information, but it’s coming very fast.

The technology, the cost, are not going to be rate-limiting, what’s going to be rate-limiting is to do the research to know what to do with that information so that people, once they have it, can be given good recommendations about how to reduce that risk and stay healthy, and that’s a huge agenda for NIH right now, but those are—as you’ve heard—expensive, longer-term clinical studies—we should be doing them now, and not putting that off.

Senator HARKIN. I’m hopeful that sometime in the near future that we’re going to find some—a dedicated source of revenue for NIH. I’ve got some thoughts on that, in fact, Senator Mark Hatfield and I had proposed that back in 1994.

Dr. COLLINS. I just remembered that, Senator.

Senator HARKIN. 1994 we proposed that, of course everything came crashing down, but maybe we’ll revive that again, to get a dedicated source of revenue.

Well, it was very simple. It was everyone’s health insurance policy would take a certain—and it was only just a few pennies, it wasn’t very much—that would go for basic medial research to enhance prevention.

Well, I have never given up on that.

But, Dr. Zerhouni?

#### DR. ZERHOUNI’S FAREWELL REMARKS

Dr. ZERHOUNI. I’d like to just say two things—one is, 1,000 years from now, when people look back at 2007–2008, one of the things they’ll remember is the impact of the human genome on the history of mankind. When \$1,000 genome, or \$100 genome—whatever it is—people will remember that as a defining event of the first decade of the 21st century.

The second is that, as they look back and they wonder about where were the Seven Wonders of the World then? As we do today with the pyramids and Taj Mahal, and I would say that they will remember that of the seven most wonderful institutions of that time, NIH was part of it.

As part that, I have a great privilege to have been, to be the Director of NIH, and to have been working with great colleagues.

So, I’d like to add my voice to both the appreciation we have for you, and for the members of the subcommittee and for your continuous understanding and support, and I’d like to take this opportunity to also add my voice and those of my colleagues at NIH to really wish Dr. Collins the greatest possible future. He’s been an

enormous asset to our country, and to NIH, and I don't know if protocol allows, but I think we owe him a round of applause.

Senator HARKIN. Well, I join with you, Dr. Zerhouni.

Dr. Collins, you know the high esteem that I personally have for you, and I know that all of the members of the subcommittee—I know I can speak for my great friend Arlen Specter, too—we have the highest esteem for you. We thank you for all of your dedication to health, to research, and to the goals of research, which is to help us live healthier lives.

So, we wish you the best in whatever endeavors you're going to pursue and don't get too far away, we're going to need to call on you every once in a while, you know, to tell me things which I might understand 5 percent of, okay?

Dr. COLLINS. Call me anytime.

Senator HARKIN. I appreciate that.

Well, thank you all, very much.

Dr. Zerhouni, thank you for your great leadership, Dr. Fauci, Dr. Nabel, Dr. Niederhuber, all of you. Through you, to all of the other Institutes. Like I said, only because of time, and I had a farm bill that I had to get through this year that just kept going on and on and on and on, and other things, and we just weren't able to have the kind of hearings that I like to have with NIH.

But, I can assure you that—even if I'm not chairman next year Senator Specter will allow me to do that next year. We're going to have more at-length hearings with all of the Institutes next year.

But, again, thank you all very much for being here, thank you all for your great leadership in so many areas. We appreciate it.

#### ADDITIONAL COMMITTEE QUESTIONS

There will be additional questions that will be submitted for your response in the record.

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

#### QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

##### K30 AWARDS

*Question.* Dr. Zerhouni, thank you for your continued leadership in supporting the transformation of clinical research and clinical research training through the establishment of the Clinical and Translational Science Awards (CTSA) initiative. As the NIH transitions to the CTSA program, there is the potential for an institution which has not yet been awarded a CTSA grant to also have its K30 Clinical Research Curriculum Award phased out. Because not every K30 award recipient institution will receive a CTSA grant, it seems to make sense to continue the K30 mechanism for those institutions which have not received a CTSA grant. Does the NIH and the NCI have a plan for the continuation of K30 awards to those institutions not receiving a CTSA grant?

*Answer.* The K30 program supports curriculum development and has proven to be an extremely effective career development activity. The program was initiated in fiscal year 1999 following recommendations from an NIH panel on clinical research and expanded to 43 awards in fiscal year 2000. The program was re-competed in fiscal year 2005, when the average grant cost was increased from \$200,000 to \$300,000, and 51 K30 grants were awarded. The last year of funding for these grants is fiscal year 2009. Curriculum development is a core feature of the CTSA program, so 31 of the K30 awards have already merged into the currently funded CTSA sites. For the remaining 20 institutions with K30 awards, most are well positioned to succeed with CTSA applications.

## VACCINE SAFETY

*Question.* Dr. Fauci, given the increased rates of refusal for immunization, the hesitancy of parents who do allow their children to be immunized, and the increased, but fortunately small, outbreaks of vaccine preventable diseases such as measles, please tell us: What resources of the NIH have been allocated to address increasing public concerns about the safety of the U.S. childhood immunization program?

*Answer.* The NIH has three broad goals in vaccine research: (1) to identify new vaccine candidates to prevent diseases for which no vaccines currently exist; (2) to improve the safety and efficacy of existing vaccines; and (3) to design novel generic vaccine approaches, such as new vectors and adjuvants. To carry out these goals, the NIH supports basic and applied research at 18 Institutes in fields such as immunology, microbiology and disease pathology. Scientific knowledge gained through this basic research provides the foundation to develop new or improved vaccines, treatments, or diagnostics.

NIH does not categorize vaccine safety research funding separately from vaccine research and development funding. Rather, NIH considers vaccine safety to be an integral component of all vaccine research and development. NIH spent just over \$1.3 billion on vaccine related research in fiscal year 2007 and estimates \$1.3 billion for spending in subsequent years. Federal regulations require that vaccines undergo extensive testing before they can be licensed and distributed. At the NIH, the evaluation of vaccine safety is an essential part of every vaccine clinical trial that we sponsor. Study participants are closely monitored for any adverse effects of the vaccinations they receive. In addition to research on new vaccines, the NIH devotes substantial resources to developing improved vaccines that are more effective and have fewer side effects than currently licensed vaccines. The NIH also pursues research to address specific vaccine safety research hypotheses as they arise. For example, several years ago the NIH supported several studies to find out more about the effects of thimerosal (ethyl mercury) exposure and how it compares with published data on methyl mercury exposure.

*Question.* Please provide information on resource levels for the past 3 years and for 2009 as proposed, and separate out those funds for smallpox and bioterrorism-related vaccines?

*Answer.* The NIH has provided the total funding levels for bioterrorism vaccines for fiscal years 2006–2009 in the table below. The NIH does not have funding available for small pox vaccines; however, the NIAID conducts Category A Pathogen Vaccine research which includes the microbes that cause smallpox, anthrax, plague and others. The funding levels for Category A Pathogen Vaccine research for fiscal years 2006–2009 for NIAID only are provided in the table below.

[In millions of dollars]

Disease	Fiscal year			
	2006	2007	2008 (est.)	2009 (est.)
Bioterrorism Vaccines, NIH .....	481.1	417.2	408.7	415.9
NIAID Category A Pathogen Vaccine Research ....	258	200	196	200

*Question.* Also, is there an entity within NIH that looks across Institutes to assure that research is directed at the safety of vaccines? If so, who is responsible for determining priorities in this effort?

*Answer.* NIH considers vaccine safety to be an integral component of all vaccine research and development, there is no specific entity within NIH that looks across Institutes to assure that research is directed at the safety of vaccines. There are coordinating groups that collaborate on a regular basis to discuss vaccine safety and other related issues in the context of specific diseases or disorders. For example, the NIH Autism Coordinating Committee considers potential underlying mechanisms or triggers for autism-spectrum disorders (ASD), including vaccines. Recently, several NIH institutes developed a Program Announcement (PA) which was released August 2008 to broadly address important scientific questions relating to vaccine safety.

Once in use, vaccines are monitored for safety and efficacy by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC). The Federal Government has numerous checks and balances in place to monitor the safety and efficacy of vaccines and to ensure that recommendations about immunization practices and procedures reflect the best available science. It is also important to note the key role of the National Vaccine Program Office (NVPO) within the Department of Health and Human Services, which has responsibility for coordi-

nating and ensuring collaboration among the many Federal agencies involved in vaccine and immunization activities, including NIH, CDC, FDA, and the Department of Defense, among others. Vaccine safety is and will remain a top priority for the NIH.

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QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUE

WEICKER BUILDING

*Question.* Dr. Zerhouni, at my request the Congress named the NIH building 36 after the former Senator Lowell P. Weicker. Driving by NIH almost daily, I am reminded that the Lowell P. Weicker building was torn down. I am aware that the building was demolished to facilitate the Master Plan for the Bethesda campus. As the Master Plan is developed, is there a plan to name another NIH building after Senator Weicker?

*Answer.* Building 36, which bore Senator Weicker's name, has been demolished to make way for a new research building. NIH is currently reviewing the status of existing facilities on our campus, including the naming of buildings. In light of your interest, I will keep you informed as we proceed with our review.

BEHAVIORAL RESEARCH

*Question.* Dr. Zerhouni, last fiscal year, the committee included report language on the subject of basic behavioral research that stated: "It is therefore requested that the Director submit a report to the committee by December 1, 2007, indicating the scientific leadership structure for this field within the appropriate grant-making Institute." NIH responded in April 2008 with a report titled "Scientific Leadership Structure for Basic Behavioral Research" which reported that 12 of the Institutes fund basic behavioral research totaling approximately \$1 billion annually. While many in the field dispute the accuracy of these numbers, the NIH report seems to further strengthen the rationale of the committee's repeated recommendations to NIH that scientific leadership be provided for this important area of research at a grant-making Institute.

While the NIH report of April 2008 provided the committee with a description of the status quo, it failed to address the central question of the need for scientific leadership in the field at the appropriate grant-making Institute. At minimum and as a first step, would NIH agree to create a senior advisory position within NIGMS, which would be filled by a person with appropriate scientific credentials and who would provide leadership and coordination for this important field?

*Answer.* The NIH created the Office of Behavioral and Social Sciences Research (OBSSR) within the NIH Office of the Director to provide senior advisory leadership and coordination of NIH efforts in these fields. Having a senior advisory position in the Office of the Director allows NIH to fully utilize and coordinate resources across all the Institutes rather than limiting it to one IC. NIGMS is actively supporting basic behavioral research and training. For example, NIGMS has recently hired an individual with a Ph.D. in sociology to help oversee behavioral research and training within NIGMS and coordinate this research with the OBSSR. NIGMS has developed a new predoctoral training program directed toward the interface between basic behavioral and biomedical research and has funded a number of new training grants in this area. Furthermore, NIGMS has taken the lead in supporting social science research on the impact of interventions in developing research careers; specifically, NIGMS has spearheaded two initiatives—one directed to understanding interventions that help underrepresented group participate in research careers and the second (just released) regarding women. See <http://grants1.nih.gov/grants/guide/rfa-files/RFA-GM-09-011.html>, <http://www.nigms.nih.gov/Minority/Interventions.htm> and <http://www.nih.gov/news/health/jul2008/od-14.htm>. Several NIGMS staff members are involved in these programs including the recently hired individual with a Ph.D. in sociology.

*Question.* The Institute's statutory mandate includes basic behavioral research and training, and the committee has repeatedly stated its belief that NIGMS has a scientific mandate in this area because of the clear relevance of fundamental behavioral factors to a variety of diseases and health conditions. Will the NIH work with the committee to address the need for scientific leadership of this field at NIGMS?

*Answer.* NIH will work with the committee as these basic behavioral research and training activities continue to develop within NIGMS and across NIH. NIGMS is playing an increasingly important leadership role in supporting basic behavioral research. For example, they have initiated a new predoctoral training program di-

rected toward the basic behavioral-biomedical research interface and are taking the lead in stimulating and supporting research to include key aspects of human behavior in computer models of how infectious diseases spread through populations. They have also taken the lead in supporting social science research directed toward understanding the efficacy of interventions in promoting research careers. They are also continuing their support of behavioral genetics in model organisms.

#### TRANSLATION OF RESEARCH FINDINGS

*Question.* Dr. Nabel, you emphasize the importance of the translation of research findings to the clinic and the community. What is NHLBI doing to help communities and physicians adopt interventions that have been shown to be effective, such as the Diabetes Prevention Program, which demonstrated the effectiveness of moderate diet and exercise interventions on preventing development of diabetes?

*Answer.* The NHLBI translates and disseminates research findings to health professionals, patients, and the public in a number of ways. To ensure that clinicians and patients can avail themselves of the latest scientific knowledge in making health-care decisions, we convene expert panels, which include representatives from other relevant departments and HHS agencies including the CDC, to develop evidence-based clinical guidelines. Updated guidelines for asthma management and control and new guidelines for the diagnosis, evaluation, and management of von Willebrand disease, an inherited bleeding disorder, were released in fiscal year 2007, and the Institute is currently developing the first-ever integrated cardiovascular risk-reduction guidelines for adults and children as well as updating its specific guidelines on adult hypertension, high blood cholesterol, and overweight/obesity.

We also communicate research findings through community education programs. For example, We Can!™ promotes maintenance of a healthy weight in children through partnerships and media outreach operating in more than 500 community sites in 46 States, the District of Columbia, and 7 foreign countries. The sites include hospitals, schools, clinics, faith-based organizations, parks and recreation departments, extension services, YMCAs, and State health departments. The Institute also mounts public awareness campaigns such as The Heart Truth for women and heart disease, the leading cause of death among American women, and Learn More, Breathe Better for chronic obstructive pulmonary disease, the fourth most common cause of death in the United States.

The NHLBI supports effectiveness studies to test interventions designed for easy and effective adoption in real-world settings. For instance, in 2006 we funded three clinical trials of strategies to reduce cardiovascular disease risk in obese patients who also have hypertension or metabolic syndrome. Although the primary emphasis is on developing and evaluating weight-loss programs that are effective in routine clinical practice, an important secondary focus is on improving application of evidence-based guidelines to reduce other CVD risk factors.

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#### QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

##### NEUROLOGICAL DISEASES

*Question.* Dr. Zerhouni, neurological diseases, disorders, and injuries affect as many as 100 million Americans—1 out of 3. In addition to the pain that they cause, not just to those suffering but to their families as well, the annual economic burden of neurological illness is over \$1 trillion. I will look forward to working with you and your staff to ensure that NIH has the resources it needs to fully explore these important avenues of research. Would you agree that comprehensive, coordinated neurotechnology research should be a top priority for NIH?

*Answer.* Finding treatments and cures for neurological diseases, disorders, and injuries are high priority for NIH. The NIH budget strongly supports neuroscience research, and programs already underway at NIH ensure a comprehensive, coordinated approach to developing tools and technologies to combat problems that affect the nervous system.

The neuroprosthesis program, which began more than 35 years ago at NINDS, led to the development of cochlear implants, the first practical neuroprosthetic devices, which the FDA first approved in the 1980s and is now used by more than 100,000 people worldwide. Among its many other contributions, this program also made significant contributions to the development of deep brain stimulation (DBS), which the FDA approved for essential tremor and Parkinson's disease in the 1990s, and is continuing to improve DBS technology and expand its application to other diseases. More recently, advanced neuroprosthetics, including those directly controlled

by signals from the brain, are emerging from this research. The NIH neuroprosthesis program, like other NIH neurotechnology programs, coordinates research across several NIH Institutes, including the newest, the National Institute of Biomedical Imaging and Bioengineering.

The Neuroscience Blueprint, begun in 2004, is a cooperative framework among the 16 NIH Institutes, Centers and Offices that support neuroscience research. By pooling resources and expertise, the Blueprint develops tools, training opportunities, and resources to assist neuroscientists in both basic and clinical research. For example, the Blueprint currently supports the development of genetically manipulated mouse models and their use to map gene expression in the brain and to better understand brain development and functioning; neuroimaging studies of normal brain development and neuroinformatics tools to improve brain imaging techniques; and resources and repositories for genetic material as well as neural cell and tissue samples.

Another trans-NIH mechanism, the NIH Common Fund, also supports the development of tools and technologies to benefit all biomedical research, including neuroscience. For example, NIH Roadmap initiatives on bioinformatics and computational biology, on interdisciplinary research, and on “molecular libraries” each support extensive research related to neurological problems.

Finally, I would also like to emphasize that NIH coordinates neurotechnology-related activities with other Federal agencies. The development of neural prosthetics and better treatments for traumatic brain injury are two examples that are particularly important now, because of the injuries to people serving our country in Iraq and Afghanistan. In both these examples, we coordinate extensively not just within NIH but also with the Department of Defense, the Department of Veterans Affairs and other agencies through formal and informal contacts, interagency conferences, review panels, planning meetings, and support of extramural investigators for related projects.

#### PANCREATIC CANCER

*Question.* Dr. John Niederhuber, given the fact that pancreatic cancer deaths are increasing, what concrete steps will you take to make this field of study a higher priority?

*Answer.* NCI continues to fund research to understand the molecular pathways and genomic changes associated with many cancers. Similar genetic changes are seen in several tumor types. For example, Ras is a protein that under normal conditions regulates cell growth. When mutated it can cause uncontrollable cell growth or cancer to occur. Ras is associated with prostate, breast, colon, and pancreatic cancer among others. Further understanding Ras will help identify targets for new drugs and therapies for pancreatic cancer.

In addition, NCI will continue to invest specifically in pancreatic cancer research. For example, NCI's major new initiatives—including the NCI Alliance for Nanotechnology in Cancer and the Cancer Biomedical Informatics Grid (caBIG)—hold a great deal of promise for improving and extending the lives of pancreatic cancer patients.

These efforts have resulted in a strong infrastructure and cutting-edge scientific research program to study all aspects of pancreatic cancer including prevention, early diagnosis, and therapy. It is expected that NCI's support of pancreatic cancer research and resulting science advances will continue to increase.

*Question.* We've seen how important early detection tests have been in reducing mortality for other cancers. How far away are we from finding an early detection test for pancreatic cancer?

*Answer.* While it is very difficult to estimate how far we are from a new diagnostic test, the peer-reviewed NCI-supported projects listed below are part of multiple NCI activities that are relevant to reaching that goal.

—Commonly used imaging methods, such as endoscopic ultrasound, abdominal CT scan, or MRI, are inadequate for the detection of early stage pancreatic cancer.

This has led to NCI's investment in a portfolio that includes multiple relevant early biomarker detection research projects. Sixteen early detection biomarkers for pancreatic cancer are in pre-validation studies with others rapidly being added to the validation pipeline.

—CA 19-9 is presently the most widely used serum marker for pancreatic cancer, but as a screening test in an asymptomatic population, its positive predictive value is below 1 percent. Early Detection Research Network (EDRN) investigators are actively exploring both genomic and proteomic markers to improve the ability to detect early stage pancreatic cancers.

—Scientists at the University of Texas M.D. Anderson Cancer Center are also taking a targeted approach to identify biomarkers for early detection of pancreatic

cancer by focusing on abnormal genetic pathways. They have identified a number of genes that are consistently differentially expressed in pancreatic cancer and are examining these genes as candidate biomarkers.

*Question.* How much funding would you need to find a pancreatic cancer early detection test?

*Answer.* NCI will continue to make progress in the understanding pancreatic cancer and finding ways to diagnosis the disease early. The development of advanced technologies, new research projects, and a cadre of expert scientists working on the problem are critical to this effort. As noted above, NCI is supporting a number of early detection research initiatives and promising results have been realized. While it is impossible to say how much funding is needed to develop an early detection test for pancreatic cancer, investment in cancer research has never been more critical or more needed.

*Question.* How is the NCI prioritizing this effort given that pancreatic cancer is one of the deadliest forms of cancer and is currently the fourth leading cancer killer?

*Answer.* NCI recognizes the importance of pancreatic cancer research efforts. For example, a pancreas state-of-the-science meeting was held at NCI in December of 2007 to bring together investigators and other stakeholders to develop a research agenda for adenocarcinoma of the pancreas over the next 3–5 years. Based on input from the meeting, the Gastrointestinal Scientific Steering Committee of the NCI Clinical Trials Working Group (CTWG), working with cooperative groups and other groups that are active in pancreatic cancer clinical research, are developing strategic priorities for future clinical trials. Their recommendations will be disseminated to the relevant oncology, imaging and translational research communities.

In addition, the Pancreatic Cancer Research Map (<http://www.cancermap.org/pancreatic/index.jsp>) was recently developed as a tool for tracking pancreatic cancer research, clinical trials, and investigators. The map is a collaborative project between NCI, the Pancreatic Cancer Action Network (PanCAN), and the Lustgarten Foundation for Pancreatic Cancer Research. The map is designed to facilitate and expedite collaborations among researchers in the pancreatic cancer research community by helping them find related projects in pancreatic cancer research and network with other researchers, and also to identify funding opportunities specific to pancreatic cancer research.

As mentioned above, NCI is also supporting major new initiatives—including the NCI Alliance for Nanotechnology in Cancer, PanScan, and the Cancer Biomedical Informatics Grid (caBIG)—which have great potential for advancing pancreatic research.

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#### QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

##### NIH FUNDING

*Question.* Dr. Zerhouni, on May 23, 2008, I wrote to you asking “how much would it cost to cure cancer or at least make a major frontal attack on the many strains of cancer?” You responded with an estimate of \$5.2 billion (\$1.2 billion for NCI and \$4 billion for the rest of NIH). Could you please elaborate on the need for this funding with respect to finding cures for cancer and other diseases?

*Answer.* Despite the extraordinary progress made across all fields of biomedical sciences funded by the NIH in the past 50 years, we still do not know much of the basic biology that is needed to cure the more than 200 types and subtypes of cancers our patients battle daily. Much more work is needed to speed progress.

As the NIH Director, I have witnessed a great acceleration in the pace of discoveries, many derived from the completion of the Human Genome Project in 2003. These discoveries provide unprecedented research opportunities across all disease areas. The National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI) are currently collaborating in a Cancer Genome initiative. In July 2008, a pilot study by NCI and NHGRI produced new clues of genetic factors that play an important role in one of the most aggressive forms of brain cancer. Similarly, a landmark study identified new genes, and therefore, new leads in understanding autism, a disease of growing and grave concern to all of us. These are examples of the almost weekly reports I received of the discovery of novel factors in many diseases, as opposed to a few reports per year at the beginning of my tenure in 2002.

Given the nature of scientific discovery, any estimates about exact costs and timing of breakthroughs in any disease are uncertain. Moreover, we have seen progress in one disease often comes from unrelated areas of investigation, thus, we must support a wide range of approaches across all fields of science.

*Question.* Why do you feel that the success rate for grant proposals should be 30 percent instead of the 18 percent currently projected?

*Answer.* The success rate of 30 percent for grant proposals would contribute to scientific progress. We estimate the success rate of research applications could be 18 percent in fiscal year 2009. Young investigators too often become discouraged and opt for other careers, depleting the ranks of the next general of scientists and depriving the Nation of important new talent and ideas that could exploit the unprecedented opportunities NIH research has made possible and help keep our Nation competitive in this strategic area.

*Question.* For all witnesses: Senator Harkin and I have introduced legislation providing an additional \$5.2 billion to the NIH. What activities would you emphasize with additional funds?

*Answer.* Efforts to prevent, detect, and treat disease require better understanding of the dynamic complexity of the many biological systems of the human body and their interactions with our environment at several scales—from atoms, molecules, cells and organs, to body and mind. As the questions become more complex, and even as knowledge grows, research itself becomes more multi-faceted. With additional resources above the \$29.5 billion requested in the President's budget for NIH as proposed in your legislation, much work could be done to speed progress.

These funds would allow NIH to leverage scientific opportunities in areas like:

—*Research Pipeline.*—Additional funds will provide NIH with the ability to increase its focus on the troubling trends in training and research career support, which will affect the pipeline of researchers for many years in the future. Examples include: Training programs for pediatric diabetes researchers; increased career development awards; increased trainees; opportunities to train new clinical researchers; more support for Malaria research training programs; increased training in informatics; and expanded women's health training programs.

—*Repositories.*—Additional funds would allow NIH the ability to expand critical data and tissue repositories. Examples include: expand tissue repositories for breast and prostate cancer; expanded Human Genetics Repository; expanded support for in-depth analysis of data collected from whole genome association studies; support for research related to the Genome-wide Association Studies (GWAS) findings; and increased applications/utilization of GWAS data.

—*Clinical Trials.*—Additional funds would provide NIH the ability to expand in the area of clinical trials research. Examples include: expand the special program of translational research in Acute Stroke centers; launch a study to treat children with critical asthma; fund more studies in certain minority populations, including Asian Americans and Native Americans; support an initiative in Noise-Induced Hearing Loss; increased support for the Bipolar Trials Network; and increased support for Phase III trials in medications development.

—*Technologies.*—Additional funds would provide NIH the ability to pursue next-generation technologies that will facilitate research progress. Examples include: work to increase non-invasive functional monitoring to improve clinical studies in kidney diseases; increase investment in projects related to the Brain-Computer Interface; ensure steady program in research to develop the \$1,000 genome; and increase NIH's ability to pursue opportunities in advanced imaging and delivery technologies.

In addition to the examples provided above, NIH could support nearly 1-in-3 of every application received, for a success rate of 30 percent.

*Question.* Have the flat funding levels provided to the NIH over the past 5 years seriously harmed the United States research enterprise?

*Answer.* Within resources available, currently \$29.5 billion in fiscal year 2008, NIH has supported the highest priority research. Recent budgets have reduced overall purchasing power for the biomedical research community and have required NIH to make tough decisions on how resources are allocated. The success rate for applicants receiving awards has declined from 30 percent in fiscal 2003 to 21 percent in fiscal year 2007 and an estimated 18 percent in fiscal year 2009, though the rapid rise in the number of applications submitted has also been a major factor.

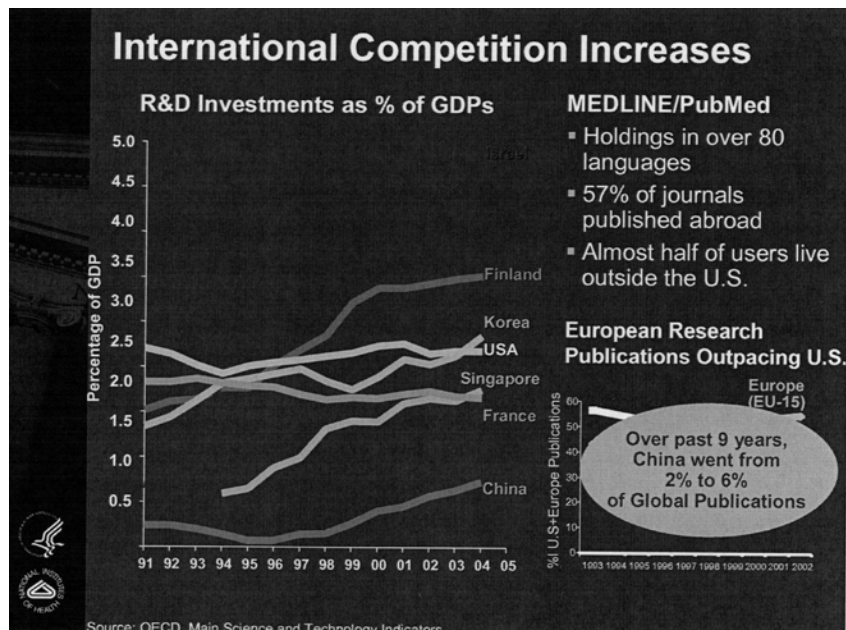
Some of the ways in which NIH has managed current resources across the Institutes and Centers include: reducing/delaying support for clinical trials; scaling back certain research training programs; data and tissue repositories have not been expanded as initially planned or have been deferred; and slowing or deferring the planning for developing specific computer interface, non-invasive monitoring, and advanced imaging and delivery technologies.

The fiscal year 2009 request will, however, continue to move science forward. We will continue to invest in the best science and work with the community to use the resources provided to develop and translate scientific advances into therapies, cures, and diagnostics.



*Question.* Is our international scientific pre-eminence in jeopardy due to these flat budgets?

*Answer.* The United States is now the pre-eminent force in biomedical research. Our Nation continues to lead the highly competitive biotechnology and pharmaceutical sectors. Yet, we are also the focus of increasing competition from growing research in Europe and Asia. We must continually sustain the momentum of U.S. biomedical research. The table below reflects the increased rate of global competition.



#### STEM CELLS

*Question.* Dr. Zerhouni, you have publicly stated that it is time for scientists to have access to more embryonic stem cell lines. Under your leadership, NIH funding for stem cell research has slowly but steadily grown and the work of the NIH stem cell unit to characterize the available stem cell lines has been excellent. When the ban on funding for additional lines is rescinded, how would you suggest the NIH work to realize the full potential of embryonic stem cells as quickly and efficiently as possible?

*Answer.* NIH keeps abreast of the current policies that guide Federal funding of human embryonic stem cell (hESC) research. We will modify these policies and the eligibility criteria for Federal funding, including the rapid development of Guidelines, as necessary, taking into consideration all the information currently available. In addition, NIH continues to rapidly assess research needs and opportunities in stem cell biology and develop initiatives that meet those needs to capitalize on these opportunities, consistent with existing policies.

*Question.* Dr. Nabel, a recent report in the journal *Nature* described how a laboratory was able to turn human embryonic stem cells into heart progenitor cells and sort them from the non-heart cells. Please explain why this advance is important and how stem cells may one day be used to treat heart disease or test prospective heart drugs.

*Answer.* The investigators reporting in the journal *Nature* successfully used human embryonic stem cells to produce cardiovascular progenitor cells that, in turn, were able to differentiate into the three cell types needed to form the human heart—cardiomyocytes (to make the heart muscle), smooth muscle cells, and endothelial cells (to make blood vessels). This is an important step toward development of new strategies to regenerate damaged hearts.

Heart progenitor cells have great potential for the repair of heart muscle injured by myocardial infarction or other cardiac diseases. Researchers hope that injection

of the cells into patients early after a heart attack, either through the coronary arteries or directly into the muscle, could help to restore heart function and prevent the development of heart failure. In patients with chronic heart disease who have already developed heart failure, the cardiac progenitor cells may be able to restore the heart's ability to pump effectively.

LP(A)

*Question.* Dr. Nabel, is there anything new that you can tell me about the status of research toward a medication that lowers Lp(a)?

*Answer.* There is little evidence that lowering Lipoprotein (a) (Lp(a)) with specific drugs reduces cardiovascular risk. In fact, based on the current scientific evidence, Lp(a) measurement is not recommended as a screening tool for cardiovascular disease (CVD) risk in the general population, but only for individuals with a personal or family history of early-onset heart disease. At present, if an individual is found to have elevated levels of Lp(a), the recommended treatment strategy, which is supported by clinical trial evidence, is to aggressively lower the individual's LDL cholesterol with statins to decrease overall CVD risk.

The Institute will continue to review the scientific evidence related to emerging CVD risk factors such as Lp(a). We are currently in the process of updating the Adult Treatment Panel (ATP) guidelines of the National Cholesterol Education Program, an evidence-based set of guidelines on cholesterol management published in 2001. As part of that effort, the expert panel developing ATP IV will evaluate the evidence that Lp(a) confers risk for CVD and will consider the evidence regarding whether Lp(a) lowering is warranted.

HIV/AIDS VACCINE

*Question.* Dr. Fauci, you recently called for a re-evaluation of our efforts toward finding an HIV/AIDS vaccine. Why have we had so many false starts toward HIV/AIDS vaccines and how should we approach the problem in the future?

*Answer.* There is rarely a clear pathway to developing a vaccine, and it is not unusual for investigational vaccines to fail. It took decades to develop currently licensed vaccines to combat typhoid, pertussis, polio, and measles. Science is iterative, and from each product that fails in clinical trials, we learn something that informs the next clinical trial.

HIV vaccine development has been challenging for a number of reasons, including the fact that the virus mutates rapidly, hides from the immune system, and targets and destroys the immune system cells that are successful in fighting and clearing most other viruses from the body. With HIV we will have to do better than nature if we are to develop a vaccine, unlike the situation with other viral diseases such as measles and influenza, where we have succeeded in inducing protective responses with vaccines by mimicking the response to natural infection. And because of safety concerns, vaccine approaches commonly used to fight other infectious diseases, such as the live attenuated (weakened) or killed viruses used in other vaccines, are not tenable in HIV vaccine development.

The failure of the Merck HIV vaccine candidate used in the STEP clinical trial prompted NIAID to re-evaluate our HIV vaccine research efforts. We initiated numerous consultative meetings with scientific experts and various stakeholders on how best to reinvigorate and advance HIV vaccine research in the wake of the STEP trial, culminating in an HIV vaccine summit on March 25, 2008. Those discussions revealed widespread consensus that the development of a safe and effective HIV vaccine will require significant advances in our understanding of the virus and an increased emphasis on basic vaccine discovery research to learn more about immune responses and better identify potential vaccine candidates while simultaneously advancing the most promising vaccine candidates into human clinical trials when appropriate.

NIAID has already taken a number of steps designed to achieve a more appropriate balance between vaccine discovery and clinical development. In May 2008, we supported a new program to study the response of B-cells to HIV infection—a departure from previous efforts, which had focused on T-cell response. NIAID also began two new major initiatives designed to support investigator-initiated grants for discovery research on HIV vaccines and tactics to interrupt HIV transmission. We are also expanding non-human primate research to support HIV vaccine discovery, and improved animal models are being developed for use in the pre-clinical evaluation of vaccine candidates and to identify correlates of immunity. Lastly, NIAID created a Vaccine Discovery Branch in the Vaccine Research Program within the Division of AIDS to help build bridges between basic researchers and HIV vaccine designers,

identify gaps in knowledge needed to develop an HIV vaccine, and promote research to fill those gaps.

#### GENETICS RESEARCH

*Question.* Dr. Collins, the Human Genome Project was completed in 2003. What is left to do in the area of genetics research?

*Answer.* After leading the Human Genome Project to the successful completion of its extraordinary goal of sequencing the entire human genome in 2003, NHGRI expanded its mission to encompass a broad range of studies aimed at understanding the structure and function of the human genome and its role in health and disease. To that end, NHGRI supports the development of resources and technology that will accelerate genomic research and its application to human health, thus enabling truly pre-emptive, predictive, personalized, and participatory health care.

*Question.* What practical medical benefits have been achieved and what will soon be available?

*Answer.* The Human Genome Project has led to important discoveries related to genetic predisposition to some of the most common causes of morbidity and mortality in the United States today. These discoveries can lead to improved diagnostic, therapeutic, and pre-emptive approaches. Examples are listed below.

—*Type 2 Diabetes.*—Nearly 20 new genetic markers have been discovered to be associated with type 2 diabetes. For example, homozygosity—that is, having two identical forms of a gene—or TCF7L2 gene mutations has been shown to convey a 140 percent increased risk of type 2 diabetes.

—*Heart Disease.*—Multiple new markers associated with coronary heart disease have been discovered. For example, homozygosity for a variant on chromosome 9p21—as occurs in approximately 25 percent of people of European ancestry—increases risk for coronary artery disease by an estimated 60 percent.

—*Breast Cancer.*—A number of genetic markers are now known to affect risk for developing breast cancer. Recently-discovered variations in the FGFR2 and CASP8 genes are associated with a 13–26 percent increase in risk of developing breast cancer.

—*Prostate Cancer.*—Variations in several genes on chromosome 8 have been shown to be associated with 30–50 percent increase in the risk of prostate cancer.

—*Age-Related Macular Degeneration (AMD).*—Five genes have been found to account for over 70 percent of the incidence of age-related macular degeneration, which is the leading cause of severe vision loss in older Americans. Each of these genes is associated with a 30–160 percent increased risk of AMD.

The Human Genome Project has led to improved diagnostic testing, with diagnostics now available for more than 1,300 genetic disorders, and also to improved prognostic testing, such as microarray-based assays like MammaPrint and Oncotype DX that predict breast cancer recurrence and guide treatment options.

The HGP has also led to the rapid development of pharmacogenomics, giving physicians the ability to prescribe a wide range of medications more safely. For example, a recent study has shown that HLA-B\*5701 testing effectively predicts potentially severe adverse reactions to the HIV medicine abacavir.

Susceptibility to disease is only part of the picture. The HGP has also enabled development of many new drugs targeted at diseases such as age-related macular degeneration, myocardial infarction, and melanoma. In addition, the NIH Roadmap project on Molecular Libraries enables direct translation from gene discovery to treatment by finding new uses for pre-existing drugs and identifying small molecule, drug-like compounds that can serve as starting points for new treatments. For example, this approach was recently used by the NIH Chemical Genomics Center (NCGC) to identify a potential new treatment against the parasitic disease, schistosomiasis, which affects upwards of 200 million people in the developing world, causing an estimated 280,000 deaths annually.

#### CANCER

*Question.* Dr. Niederhuber, what is your projection on when cancer—or many cancers—will be treatable or curable? Also, in a response to a question from me, the cancer community has indicated that \$335 billion over the next 15 years is necessary to make real progress toward cancer cures. What do you think is necessary in terms of time, funding, and research breakthroughs to make a real difference in curing cancer?

*Answer.* Cancer, as you know, is not just one disease. It is perhaps as many as 1,000 different diseases, and as such it is a very complex and dynamic process. Unfortunately, I can't give you a timeframe for how long it will take to cure cancer

or make it much more than a chronic set of diseases that we can prevent or live with. However, we're learning and understanding more and more every day, and we are gaining vital new knowledge that will get us closer to our goal.

As the leader of the National Cancer Program, NCI is, today, building on its history of research success and wisely spending every dollar it receives, in a continual effort to foster the best research and to connect the public, private, and academic sectors for effective translation of these discoveries. If NCI were to receive the increase of \$1.2 billion identified in the fiscal year 2009 by-pass budget, then NCI could better lead these collaborations and connectivity—to shorten the path from an innovative discovery in the laboratory to making an effective difference with a patient in the clinic. Listed below are some potential investments:

- Increase the number of new investigators;
- Expand research training opportunities;
- Rebuild scientific infrastructure;
- Expand caBIG;
- Raise RPG success rate and average cost per grant;
- Expand Cancer Centers program;
- Invest in intramural program;
- Expand The Cancer Genome Atlas;
- Increase Drug Development;
- Re-engineer Clinical Trials;
- Fund early phase pharmacodynamic studies;
- Create a U.S. oncology tissue bank;
- Establish certified centralized tumor characterization labs;
- Enhance technological efforts around nanoparticles and proteins;
- Enhance technology development in clinical proteomics;
- Invest in systems biology;
- Increase biomedical computing capabilities; and
- Develop imaging tools.

To effectively operationalize this plan would require that we build scientific capacity. We must maximize our efforts to recruit and sustain the very best and brightest to work on cancer. As in the past, an investment in understanding the complex systems involved in cancer initiation and growth will continue to impact our understanding and treatment of all diseases—acute and chronic.

#### CONCLUSION OF HEARINGS

Senator HARKIN. So, thank you all very much, that concludes our hearings.

[Whereupon, at 11:56 a.m., Wednesday, July 16, 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 2009**

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

**NONDEPARTMENTAL WITNESSES**

[CLERK'S NOTE.—The subcommittee was unable to hold hearings on nondepartmental witnesses. The statements and letters of those submitting written testimony are as follows:]

**PREPARED STATEMENT OF ABBEY CURRAN, MISS IOWA USA**

Mr. Chairman and members of the committee: I am proud and honored to be here today, representing the hundreds of thousands of Americans who deal each day with the special needs and challenges of cerebral palsy. I am testifying on behalf of "Reaching For The Stars. A Foundation of Hope for Children with Cerebral Palsy" (CP)—a national nonprofit pediatric cerebral palsy foundation I have become proud to be affiliated with over the last several months in the pursuit of advocating for national cerebral palsy research funding.

I am humbled to address you today as this Committee has been witness to so much of our country's history. I am only a small part of that history, but, like all of you, I am here to make a difference. Today, I would like to ask you to support \$10 million in funding for national Cerebral Palsy surveillance and epidemiological research by the Centers for Disease Control and Prevention (CDC).

I am a daughter, a child, a friend, a successful student, but most importantly, a woman who has sought to overcome the struggles that cerebral palsy has presented to me in my own life, and as a woman who has worked hard to achieve her dreams, no matter what obstacles may have occurred because of my cerebral palsy. I am only one person, but I have been given a great responsibility and opportunity through my CP to speak up for the important research that can change the lives and the future of the hundreds of thousands of children with cerebral palsy right now—those who will be diagnosed with CP right now as we speak and the increasing number of those children who will be diagnosed tomorrow based on recent CDC reports pointing to an increasing CP prevalence rate.

I am the current reigning Miss Iowa USA 2008. To some, this achievement may be no more special than any other achievement, but to me, this title affirms the fact that cerebral palsy does not define me. I am Abbey Curran, Miss Iowa USA, a successful and happy person, not Abbey Curran, disabled woman.

When I was born, my parents were unaware of the fact that I had CP until I was two- years old since diagnostic tests nor medical specialists in CP were not widely available. I was not born prematurely or with any other complications at birth that would have led my parents to suspect CP right away. Why do I have cerebral palsy? No one knows. Unfortunately that is still the case today since the cause of CP is unknown in over 80 percent of the cases.

I believe that anyone with CP can achieve their dreams, which is why I feel so strongly about the need for national CP research and why I am supporting "Reaching For The Stars" in their advocacy efforts for CDC funding. As I have continued to learn more about cerebral palsy and talk to more and more medical professionals, I realize that with more research, the cause, new treatments and a cure for CP

might be discovered and that is extremely exciting for the future of all Americans with CP.

My friends and family are always there to lend an arm to lean on when I need assistance, and today, Mr. Chairman and members of the committee, I would like to ask you to be the “arm” that we, the people affected with CP can depend on. With only \$10 million of funding for national CP research and surveillance through the CDC you could permanently change the lives and destiny of children with CP and their families forever for the better.

I strive to be not only a model citizen for the great state of Iowa, but also as a model example for those people living with cerebral palsy—especially children growing up with the disorder to help them know their dreams really can come true.

For my entire life, I have lived by the motto that I have to seize the day, take every chance and every opportunity that I can because you never know until you try. Accomplishment begins with these two simple words: I’ll try. Our life choices, not chance alone, determine our destiny. Some people, like me, are more fortunate to have mild CP and to be able to live normally for the most part, but there are thousands of others whose CP affects them even more significantly—to the extent that they are unable to care for themselves—exact a staggering toll on our medical and healthcare system. For the most part, these are bright, capable human beings trapped in bodies that don’t work like yours. The decisions this committee makes will affect the course of my life, the over 800,000 Americans living with CP and the lives of our children and our children’s children.

By funding the necessary national CP surveillance and epidemiological research by the CDC, you can give hope to children with cerebral palsy and their families. I ask you to please allocate \$10 million to the CDC for CP research on behalf of the hundreds of thousands of Americans who struggle each day with cerebral palsy. You have the power to make a difference in our lives.

Thank you.

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#### PREPARED STATEMENT OF THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

As one of the largest national medical organizations, the American Academy of Family Physicians (AAFP), representing family physicians, residents, and medical students, urges the House Appropriations Subcommittee on Labor, Health and Human Services, and Education to increase funding for programs to support better health care for more people in this country. As the subcommittee prepares the fiscal year 2009 spending bill, we strongly recommend that you restore funding for health professions training programs; continue support for rural health programs and increase our investment in the Agency for Healthcare Research and Quality.

#### HEALTH RESOURCES AND SERVICES ADMINISTRATION

The Health Resources and Services Administration (HRSA) is charged with improving access to health care services for people who are uninsured, isolated or medically vulnerable. One of the most critical aspects of this mission is ensuring a health care workforce which is sufficient to meet the needs of patients and communities.

#### HRSA—HEALTH PROFESSIONS

For 40 years, the training programs authorized by Title VII of the Public Health Services Act evolved to meet our Nation’s health care workforce needs. It is increasingly clear that our Nation has a worsening shortage of primary care physicians. Earlier this year, in testimony before the Senate HELP Committee, the Government Accountability Office cited the “growing recognition that greater use of primary care services and less reliance on specialty services can lead to better health outcomes at lower cost.”<sup>1</sup>

To improve how health care is delivered, we must modernize workforce and education policies to ensure an adequate number of primary care physicians trained to serve in a patient centered medical home. The patient centered medical home will give patients access to preventive care and coordination of the care needed to manage chronic diseases as well as appropriate care for acute illness. The patient centered medical home provides improved efficiency and better health because it serves as a principal source of access and care. As a result, duplication of tests and proce-

<sup>1</sup>Steinwald, A. Primary Care Professionals: Recent Supply Trends Projections, and Valuation of Services. Testimony Before the Committee on Health Education, Labor, and Pensions, U.S. Senate, Government Accountability Office GAO-08-472T February 2008.

dures and unnecessary emergency department visits and hospitalizations can be avoided.

Section 747 of Title VII, the Primary Care Medicine and Dentistry Cluster, is aimed at increasing the number of primary care physicians (family physicians, general internists and pediatricians). Section 747 offers competitive grants for family medicine training programs in medical schools and in residency programs. Section 747 is vital to stimulate medical education, residency programs, as well as academic and faculty development in primary care to prepare physicians to support the patient centered medical home medical practice model.

The value of Title VII grants extends far beyond the medical schools that receive them. The United States lags behind other countries in its focus on primary care. However, the evidence shows that countries with primary care-based health systems have population health outcomes that are better than those of the United States at lower costs.<sup>2</sup> Health Professions Grants are one important tool to help refocus the Nation's health system on primary care.

The Health Professions programs have been targeted for elimination in the President's budget despite of the fact that they exceeded program goals in the following categories:

- In 2007, 57 percent of graduates and program completers of Titles VII and VIII supported programs were underrepresented minorities and/or from disadvantaged backgrounds. This exceeded the target by 17 percent.
- The proportion of trainees in Titles VII and VIII supported programs training in medically underserved communities was 43 percent in 2007 which exceeded the target of 41 percent.
- The percentage of health professionals supported by the program entering practice in underserved areas was 35 percent in 2007. This exceeded the target by 14 percent.<sup>3</sup>

The across-the-board cut reduced fiscal year 2008 section 747 funding below the House-passed level to under \$48 million or \$853,000 less than the fiscal year 2007 level of \$48.9 million. It falls far short of the \$92 million provided for Primary Care Medicine and Dentistry Training in fiscal year 2003. The Nation needs significant additional support from section 747 because it is the only national federally-funded program that provides resources for important innovations necessary to increase the number of physicians who will lead the primary care teams providing care in patient centered medical homes.

AAFP recommends an increase in the fiscal year 2009 appropriation bill for the Health Professions Training Programs authorized under Title VII of the Public Health Services Act. We respectfully suggest that the Committee provide at least \$300 million for Title VII, including \$92 million for the section 747, the Primary Care Medicine and Dentistry Cluster, which will restore this vital program to its fiscal year 2003 level.

#### HRSA—NATIONAL HEALTH SERVICE CORPS

The National Health Service Corps (NHSC) offers scholarship and loan repayment awards to primary care physicians, nurse practitioners, dentists, mental and behavioral health professionals, physician assistants, certified nurse-midwives, and dental hygienists serving in underserved communities. The President has proposed a 2.4 percent decrease in NHSC to \$121 million for fiscal year 2009. The President's budget also proposes to decrease the NHSC field allocation, which provides funding for recruitment and retention administrative functions, by \$14 million (35 percent) to \$26 million. The AAFP supports the work of the NHSC toward the goal of full funding for the training of the health workforce and zero disparities in health care.

AAFP opposes the proposed cut in NHSC funding and respectfully requests that the Committee provide \$150 million for NHSC in fiscal year 2009.

#### HRSA—RURAL HEALTH

Americans in rural areas face more barriers to care than those in urban and suburban areas. Rural residents also struggle with the higher rates of illness associated with lower socioeconomic status.

<sup>2</sup>Starfield B, et al. The effects of specialist supply on populations' health: assessing the evidence. Health Affairs. 15 March 2005.

<sup>3</sup>Department of Health and Human Services. Fiscal year 2009 Health Resources and Services Administration Justification of Estimates for Appropriations Committee.

Family physicians provide the majority of care for America's underserved and rural populations.<sup>4</sup> Despite efforts to meet scarcities in rural areas, the shortage of primary care physicians continues. Studies, whether they be based on the demand to hire physicians by hospitals and physician groups or based on the number of individuals per physician in a rural area, all indicate a need for additional physicians in rural areas.

HRSA's Office of Rural Health administers a number of programs to improve health care services to the quarter of our population residing in rural communities. Rural Health Policy Development and Outreach Grants fund innovative programs to provide health care in rural areas. State rural health offices, funded through the National Health Services Corps budget, help States implement these programs so that rural residents benefit as much as urban patients. The President's budget proposes to cut the Rural Health Programs by 86 percent.

AAFP encourages the Subcommittee to oppose the President's request to terminate these important programs and provide for their continued funding the fiscal year 2009 appropriation bill. We respectfully suggest that the Committee provide at least \$175 million for HRSA Rural Health.

#### AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

The mission of the Agency for Healthcare Research and Quality (AHRQ)—to improve the quality, safety, efficiency, and effectiveness of health care for all Americans—closely mirrors AAFP's own mission. AHRQ is a small agency with a huge responsibility for research to support clinical decision-making, reduce costs, advance patient safety, decrease medical errors and improve health care quality and access.

#### AHRQ—COMPARATIVE EFFECTIVENESS RESEARCH

One of the hallmarks of the patient centered medical home is evidence-based medicine. Comparative effectiveness research, which compares the impact of different options for treating a given medical condition, is vital to quality care. Studies comparing various treatments (e.g. competing drugs) or differing approaches (e.g. surgery and drug therapy) can inform clinical decisions by analyzing not only costs but the relative medical benefits and risks for particular patient populations.

Comparative effectiveness research holds out the promise of reducing health care costs while improving medical outcomes. AHRQ's Effective Health Care Program is critical if we are to realize that promise. Although the President's budget request proposed to hold this important program at \$30 million, the same as fiscal year 2008, we hope that the Congress will increase our investment in comparative effectiveness research.

#### AHRQ—HEALTH INFORMATION TECHNOLOGY

AHRQ plays a key role in the adoption of the health information technology (HIT) which is a vital component of the patient centered medical home. HIT is important to improving patient safety by reducing medical errors and avoiding costly duplication of services. It also is a vital to managing a patient's care when numerous providers are required. AAFP recognizes that HIT, used effectively, has the potential to help physicians make continuing improvements in the quality of care. However, simply implementing current HIT tools will not bring about these results. HIT adoption must go hand in hand with the implementation of the patient centered medical home model.

It also is vital that AHRQ have the necessary resources to promote standards for portability and interoperability which ensure that health data is appropriately available and privacy protected. AAFP has called for HIT implementation which recognizes that over 80 percent of health care is delivered in doctors' offices.

Adoption of good information systems can lay the groundwork for decision support and high quality health care. However, the communities which would benefit the most from HIT face barriers to adoption. Physicians treating vulnerable populations should be our highest priority. Any payments to physicians to purchase HIT systems should go to those serving in underserved areas in small or medium-sized practices where the capital to purchase EHRs is hardest to secure. These payments should not go through third-parties such as hospitals, integrated health systems, or health plans, but directly to clinics and practices based on financial need.

AAFP recommends an increase in the fiscal year 2009 appropriation bill for the Agency for Healthcare Research and Quality (AHRQ). We respectfully suggest that

<sup>4</sup>Hing E, Burt CW. Characteristics of office-based physicians and their practices: United States, 2003–04. Series 13, No. 164. Hyattsville, MD: National Center for Health Statistics. 2007.



the Committee provide at least \$360 million for AHRQ, an increase of \$26 million above the fiscal year 2008 level.

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PREPARED STATEMENT OF THE AMERICAN ACADEMY OF OTOLARYNGOLOGY—HEAD  
AND NECK SURGERY

Chairman Harkin, ranking member specter, and members of the subcommittee, on behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), I first want to thank you for your past support of medical research and the critical efforts of the National Institutes of Health (NIH), particularly the National Institute on Deafness and Other Communications Disorders. The AAO-HNS represents more than 13,000 physicians and allied health professionals who specialize in the disorders of the ears, nose, throat, and related structures of the head and neck. Our members are deeply committed to providing the best care possible for our patients. For that reason, we strongly support the NIH, which is the leading source of new discoveries that improve the health of the American people.

The AAO-HNS is concerned, however, that the President's fiscal year 2009 budget request for NIH represents zero growth. For the past six years, the NIH budget has failed to keep pace with inflation, severely weakening NIH's ability to expand the frontier of medicine. The AAO-HNS joins other organizations in the medical and research community in urging you to support an increase of NIH's budget by \$1.9 billion in fiscal year 2009. This 6.6 percent increase would bring significant change by halting the erosion of the Nation's medical research efforts, as well as help develop cutting edge medicines, techniques, and treatments to ensure the good health of millions of Americans.

The AAO-HNS is also concerned that the President's budget did not include a funding request for the Early Hearing Detection and Intervention (EHDI) program. This program, initiated by Congress and administered within the U.S. Department of Health and Human Services, has dramatically increased the number of infants being tested for hearing loss. In 1998, prior to implementation of the program, 22 percent of babies were reported as having received a hearing screen. Now, roughly 95 percent of all newborns are screened, and each year there are thousands of infants with hearing loss and their families who benefit from early identification.

It is now time to focus upon the next goal of the program: to improve the outcomes of infants found to have hearing loss, by helping them enroll in early intervention programs. Currently, just over half of those infants diagnosed with hearing loss are enrolled in such programs by 6 months of age. Thus, continued federal funding is necessary to help ensure that all states and U.S. territories are given the opportunity to successfully implement comprehensive EHDI programs that will help improve the overall quality of life for deaf and hard-of-hearing children. The AAO-HNS strongly urges the committee to provide, at a minimum, an inflationary increase for this program above the appropriated level in fiscal year 2008.

On behalf of my fellow otolaryngologist-head and neck surgeons throughout America, I thank you for your attention to these important issues and your continued efforts to improve healthcare.

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PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH  
EXECUTIVE SUMMARY

The American Association for Cancer Research (AACR) would like to thank members for their support of National Institutes of Health (NIH) and National Cancer Institute (NCI) research on the biology, treatment and prevention of the more than 200 diseases called cancer. The AACR, with more than 26,000 members worldwide, represents and supports scientists by publishing respected, peer-reviewed scientific journals, hosting international scientific conferences, and awarding millions of dollars in research grants. Together, we have made great strides in the war on cancer, but much remains to be done. One in four deaths in America this year will be caused by cancer. Cancer-related deaths will increase dramatically as the baby boom generation ages, and we must be prepared to prevent, treat, and manage the impending wave of new cancers.

Cancer is no longer a death sentence thanks to decades of research and development made possible by strong commitments from Congress and the American people, but now that commitment is wavering. After expanding capacity during the NIH budget doubling, researchers at hospitals and universities across the country now face shrinking budgets. Promising young researchers, unable to secure grants, turn to other careers. This disruption of the research pipeline will slow the develop-

ment of new treatments and set back America's biomedical leadership for decades to come.

We are at the vanguard of a revolution in healthcare, where personalized treatment will improve health, reduce harmful side effects, and lower costs. We have the opportunity to build upon our previous investments and accelerate the research process. Now is the time to face the nation's growing healthcare needs, reaffirm our role as world leaders in science, and renew our commitment to the research and development that brings hope to millions of suffering Americans. The AACR urges the U.S. Senate to support the following appropriations funding levels for cancer research in fiscal year 2009:

- \$32.1 billion for the National Institutes of Health, a 10.24 percent increase over fiscal year 2008.
- At least \$5.3 billion for the National Cancer Institute (the NCI Professional Judgment budget required to maintain current services), a 9.5 percent increase over fiscal year 2008.

The American Association for Cancer Research (AACR) recognizes and expresses its thanks to the United States Congress for its longstanding support and commitment to funding cancer research. The completion of the five-year doubling of the budget of the National Institutes of Health (NIH) in 2003 was a stunning accomplishment that is already showing impressive returns and benefits to patients with cancer. Recently, however, budgets for cancer research have declined; this commitment appears to be wavering. Budget doubling enabled a significant expansion of infrastructure and scientific opportunities. Budget cuts prevent us from capitalizing on them.

Unquestionably, the Nation's investment in cancer research is having a remarkable impact. Cancer death rates have been declining for over a decade, and the total number of annual cancer deaths declined in 2003 and 2004. This progress occurred in spite of an aging population and the fact that more than three-quarters of all cancers are diagnosed in individuals aged 55 and older. Yet this good news will not continue without sustained and substantial Federal funding for critical cancer research priorities. Indeed, cancer deaths are again on the rise as the population ages. The American Association for Cancer Research joins the 95 Senators who voted in favor of the Specter/Harkin budget amendment in urging the United States Senate to support the following appropriations funding levels for cancer research in fiscal year 2009:

- \$32.1 billion for the National Institutes of Health, a 10.24 percent increase over fiscal year 2008.
- At least \$5.3 billion for the National Cancer Institute (the NCI Professional Judgment budget required to maintain current services), a 9.5 percent increase over fiscal year 2008.

#### AACR: FOSTERING A CENTURY OF RESEARCH PROGRESS

The American Association for Cancer Research has been moving cancer research forward since its founding 101 years ago in 1907. The AACR and its more than 26,000 members worldwide strive tirelessly to carry out its important mission to prevent and cure cancer through research, education, and communication. It does so by:

- fostering research in cancer and related biomedical science;
- accelerating the dissemination of new research findings among scientists and others dedicated to the conquest of cancer;
- promoting science education and training; and
- advancing the understanding of cancer etiology, prevention, diagnosis, and treatment throughout the world.

#### FACING AN IMPENDING CANCER "TSUNAMI"

Over the past century, enormous progress has been made toward the conquest of the nation's second most lethal disease (after heart disease). Thanks to discoveries and developments in prevention, early detection, and more effective treatments, many of the more than 200 diseases called cancer have been cured or converted into manageable chronic conditions while preserving quality of life. The 5-year survival rate for all cancers has improved over the past 30 years to more than 65 percent. The completion of the doubling of the NIH budget in 2003 is bearing fruit as many new and promising discoveries are unearthed and their potential realized. However, there is much left to be done, especially for the most lethal and rarer forms of the disease.

We recognize that the underlying causes of the disease and its incidence have not been significantly altered. The fact remains that men have a 1 in 2 lifetime risk

of developing cancer, while women have a 1 in 3 lifetime risk. The leading cancer sites in men are the prostate, lung and bronchus, and colon and rectum. For women, the leading cancer sites are breast, lung and bronchus, and colon and rectum. And cancer still accounts for 1 in 4 deaths, with more than 565,650 people expected to die from their cancer in 2006. Age is a major risk factor—this Nation faces a virtual “cancer tsunami” as the baby boomer generation reaches age 65 in 2011. A renewed commitment to progress in cancer research through leadership and resources will be essential to dodge this cancer crisis.

#### FEDERAL INVESTMENT FOR LOCAL BENEFIT

Nearly 80 percent of the NCI budget is awarded to scientists who work at local hospitals and universities throughout the country. More than 5,400 research grants are funded at more than 150 cancer centers and specialized research facilities located in 49 states. Over half the states receive more than \$15 million in grants and contracts to institutions located within their borders. Many AACR member scientists are engaged in this rewarding work. But too many of them have had their long-term research jeopardized by grant reductions caused by the flat and declining overall funding for the NCI since 2003. The AACR recommends, at a minimum, a 9.5 percent increase in funding for the National Cancer Institute to maintain its current services, supports a 10.24 percent increase to enable the National Cancer Institute to expand its work on focused research questions.

#### UNDERSTANDING THE CAUSES AND MECHANISMS OF CANCER

Basic research into the causes and mechanisms of cancer is at the heart of what the NCI and many of AACR's member scientists do. Basic research is the engine that drives scientific progress. The outcomes from this fundamental basic research—including laboratory and animal research in addition to population studies and the deployment of state-of-the-art technologies—will inform and drive the cancer research enterprise in ways and directions that will lead to unparalleled progress in the search for cures.

#### ACCELERATING PROGRESS IN CANCER PREVENTION

Preventing cancer is far more cost-effective and desirable than treating it. The NCI uses multidisciplinary teams and a systems biology approach to identify early events and how to modify them. More than half of all cancers are related to modifiable behavioral factors, including tobacco use, diet, physical inactivity, sun exposure, and failure to get cancer screenings. The NCI supports research to understand how people perceive risk, make health-related decisions, and maintain healthy behavior. Prevention is the keystone to success in the battle against cancer.

#### DEVELOPING EFFECTIVE AND EFFICIENT TREATMENTS

The future of cancer care is all about developing individualized therapies tailored to the specific characteristics of a patient's cancer. Noteworthy recent advances in this area have included the development of oral versions of medicines that were formerly only available by injection, thus improving patients' quality of life; and the discovery of intraperitoneal (IP) chemotherapy—delivering drugs directly to the abdominal cavity—that can add more than a year to survival for some women with ovarian cancer.

#### OVERCOMING CANCER HEALTH DISPARITIES

Some minority and underserved population groups suffer disproportionately from cancer. Solving this issue will contribute significantly to reducing the cancer burden. Successful achievements in this important area include the development and dissemination of the patient navigator program that assists patients and caregivers to access and chart a course through the healthcare system, and the NCI Cancer Information Services Partnership Program that provides information and education about cancer in lay language to the medically underserved through community organizations.

#### AACR'S INITIATIVES AUGMENT SUPPORT FOR THE NCI

The NCI is not working alone or in isolation in any of these key areas. NCI research scientists reach out to other organizations to further their work. The AACR is engaged in scores of initiatives that strengthen, support, and facilitate the work of the NCI, including:

- sponsoring the largest meeting of cancer researchers in the world, with more than 17,000 scientists and 6,000 abstracts featuring the latest scientific advances;
- publishing more than 3,400 original research articles each year in six prestigious peer-reviewed scientific journals, including *Cancer Research*;
- sponsoring the annual International Conference on Frontiers of Cancer Prevention Research, the largest such prevention meeting of its kind in the world;
- raising and distributing more than \$5 million in awards and research grants.

#### TRAINING AND CAREER DEVELOPMENT FOR THE NEXT GENERATION OF RESEARCHERS

Of critical importance to the viability of the long-term cancer research enterprise is supporting, fostering, and mentoring the next generation of investigators. The NCI devotes approximately four percent of its budget to multiple strategies to training and career development, including sponsored traineeships, a Medical Scientist Training Program, special set-aside grant programs and bridge grants for early career cancer investigators. Increased funding for these foundational opportunities is essential to retain the scientific workforce that is needed to continue the fight against cancer.

#### INCREASE RESEARCH FUNDING NOW

Remarkable progress is being made in cancer research, but much more remains to be done. Cancer costs the nation more than \$219 billion in direct medical costs and lost productivity due to illness and premature death. Respected University of Chicago economists Kevin Murphy and Robert Topel have estimated that even a modest one percent reduction in mortality from cancer would be worth nearly \$500 billion in social value. Investments in cancer research have huge potential returns. Thanks to successful past investments, promising research opportunities abound and must not be lost. To maintain our research momentum, the American Association for Cancer Research (AACR) urges the United States Senate to support the following appropriations funding levels for cancer research in fiscal year 2009:

- \$32.1 billion for the National Institutes of Health, a 10.24 percent increase over fiscal year 2008.
- At least \$5.3 billion for the National Cancer Institute (the NCI Professional Judgment budget required to maintain current services), a 9.5 percent increase over fiscal year 2008.

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#### PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR GERIATRIC PSYCHIATRY

The American Association for Geriatric Psychiatry (AAGP) appreciates this opportunity to present its recommendations on issues related to fiscal year 2009 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 approximately 2,000 geriatric psychiatrists as well as other health professionals who focus on the mental health problems faced by senior citizens.

AAGP appreciates the work this subcommittee has done in recent years in support of funding for research and services in the area of mental health and aging through the National Institutes of Health (NIH) and the Substance Abuse and Mental Health Services Administration (SAMHSA). 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.

#### DEMOGRAPHIC PROJECTIONS AND THE MENTAL DISORDERS OF AGING

With the baby boom generation nearing retirement, the number of older Americans with mental disorders is certain to increase in the future. By the year 2010, there will be approximately 40 million people in the United States over the age of 65. Over 20 percent of those people will experience mental health problems.

Current and projected economic costs of mental disorders alone are staggering. It is estimated that total costs associated with the care of patients with Alzheimer's disease is over \$100 billion per year in the United States. Psychiatric symptoms (including depression, agitation, and psychotic symptoms) affect 30 to 40 percent of people with Alzheimer's and are associated with increased hospitalization, nursing home placement, and family burden. These psychiatric symptoms, associated with

Alzheimer's disease, can increase the cost of treating these patients by more than 20 percent.

Depression is another example of a common problem among older persons. Of the approximately 32 million Americans who have attained age 65, about 5 million suffer from depression, resulting in increased disability, general health care utilization, and increased risk of suicide. Depression is associated with poorer health outcomes and higher health care costs. Co-morbid depression with other medical conditions affects a greater use and cost of medications as well as increased use of health services (e.g., medical outpatient visits, emergency visits, and hospitalizations). For example, individuals with depression are admitted to the emergency room for hypertension, arthritis, and ulcers at nearly twice the rate of those without depression. Those individuals with depression are more likely to be hospitalized for hypertension, arthritis, and ulcers than those without depression. Those with depression experience almost twice the number of medical visits for hypertension, arthritis and ulcers than those without depression. Finally, the cost of prescriptions and number of prescriptions for hypertension, arthritis, and ulcers were more than twice than those without depression.

Older adults have the highest rate of suicide compared to any other age group. Comprising only 13 percent of the U.S. population, individuals age 65 and older account for 19 percent of all suicides. The suicide rate for those 85 and older is twice the national average. More than half of older persons who commit suicide visited their primary care physician in the prior month—a truly stunning statistic.

THE CHALLENGE OF MEETING THE MENTAL HEALTH NEEDS OF THE AGING POPULATION—PROPOSAL FOR IOM STUDY ON MENTAL HEALTH WORKFORCE NEEDS OF OLDER AMERICANS

On April 14, 2008, the Institute of Medicine (IOM) of the National Academy of Sciences released a study of the readiness of the nation's healthcare workforce to meet the needs of its aging population. In discussions with AAGP prior to the release of the study, IOM recommended that, because the scope of this study would not provide for in-depth consideration of the mental health workforce needed to meet future needs of the elderly, a complementary study be undertaken to consider specifically this vital area of concern. This complementary study would focus on the mental health professional workforce that will be needed to meet the demands of the aging population in this country. IOM has advised AAGP that \$1 million would be needed to undertake this complementary mental health study.

In discussions with AAGP, the senior staff of IOM suggested the following language for inclusion in the LaborHHS Appropriations bill:

The Committee provides \$1,000,000 for a study by the Institute of Medicine of the National Academy of Sciences to determine the multi-disciplinary mental health workforce needed to serve older adults. The initiation of this study should be not later than 60 days after the date of enactment of this Act, whereby the Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine to conduct a thorough analysis of the forces that shape the mental health care workforce for older adults, including education, training, modes of practice, and reimbursement.

AAGP strongly urges inclusion of this proposal for funding for an IOM study on mental health workforce needs of older Americans in the fiscal year 2009 Labor HHS Appropriations bill.

NATIONAL INSTITUTE OF MENTAL HEALTH

In his fiscal year 2009 budget, the President again proposed decreased funding for the National Institutes of Health (NIH). This decline in funding would have a devastating impact on the ability of NIH to sustain the ongoing, multi-year research grants that have been initiated in recent years.

AAGP would like to call to the subcommittee's attention the fact that, even in the years in which funding was increased for NIH and NIMH, these increases did not always translate into comparable increases in funding that specifically address problems of older adults. Data supplied to AAGP by NIMH indicates that while extramural research grants by NIMH increased 59 percent during the five-year period from fiscal year 1995 through fiscal year 2000 (from \$485,140,000 in fiscal year 1995 to \$771,765,000 in fiscal year 2000), NIMH grants for aging research increased at less than half that rate: only 27.2 percent during the same period (from \$46,989,000 to \$59,771,000).

Despite the fact that over the past 7 years Congress, through Committee report language, has specifically urged NIMH to increase research grant funding devoted

to older adults, this has not occurred. In fact, this Committee's report accompanying the appropriations bill for fiscal year 2008, stated:

*Older Adults.*—The Committee urges the NIMH to place a stronger emphasis on research on adults over age 65 to reflect the growth in numbers of this population. The Committee requests that the Institute provide data in the fiscal year 2009 congressional budget justifications on the amount of NIMH funding directed toward geriatric mental health research over the past 5 years.

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.

#### CENTER FOR MENTAL HEALTH SERVICES

It is also critical that there be adequate funding for the mental health initiatives under the jurisdiction of the Center for Mental Health Services (CMHS) within SAMHSA. While research is of critical importance to a better future, the patients of today must also receive appropriate treatment for their mental health problems. SAMHSA provides funding to State and local mental health departments, which in turn provide community-based mental health services to Americans of all ages, without regard to the ability to pay. AAGP was pleased that the final budgets for the last five years have included \$5 million for evidence-based mental health outreach and treatment to the elderly. AAGP worked with members of this subcommittee and its House counterpart on this initiative, which is a very important program for addressing the mental health needs of the nation's senior citizens. However, AAGP is extremely alarmed to see that this program was eliminated in President Bush's fiscal year 2009 budget proposal. Restoring and increasing this mental health outreach and treatment program must be a top priority, as it is the only Federally funded services program dedicated specifically to the mental health care of older adults.

The greatest challenge for the future of mental health care for older Americans is to bridge the gap between scientific knowledge and clinical practice in the community, and to translate research into patient care. Adequate funding for this geriatric mental health services initiative is essential to disseminate and implement evidence-based practices in routine clinical settings across the States. Consequently, we would urge that the \$5 million for mental health outreach and treatment for the elderly included in the CMHS budget for fiscal year 2008 be increased to \$20 million for fiscal year 2009. Of that \$20 million appropriation, AAGP believes that \$10 million should be allocated to a National Evidence-Based Practices Program, which will disseminate and implement evidence-based mental health practices for older persons in usual care settings in the community. This program will provide the foundation for a longer-term national effort that will have a direct effect on the well-being and mental health of older Americans.

#### HEALTH RESOURCES AND SERVICES ADMINISTRATION

Despite growing evidence of the need for more geriatric specialists to care for the nation's elderly population, a critical shortage persists. AAGP appreciates the work of this Subcommittee in providing for the restoration of funding for the geriatric health professions programs under Title VII of the Public Health Service Act, which was eliminated for fiscal year 2006. The restoration of this program has prevented a devastating impact on physician workforce development over the next decade, with would have dangerous consequences for the growing population of older adults who will need access to appropriate specialized care. The Administration has again proposed eliminating most Title VII programs, including geriatrics. We urge the Subcommittee to fund them at the final fiscal year 2008 level. The geriatric health professions program supports three important initiatives. The Geriatric Faculty Fellowship trains faculty in geriatric medicine, dentistry, and psychiatry. The Geriatric Academic Career Award program encourages newly trained geriatric specialists to move into academic medicine. The Geriatric Education Center (GEC) program provides grants to support collaborative arrangements that provide training in the diagnosis, treatment, and prevention of disease.

## CONCLUSION

Based on AAGP's assessment of the current need and future challenges of late life mental disorders, we submit the following fiscal year 2009 funding recommendations:

1. An Institute of Medicine study on the future mental health workforce needs for older adults should be funded at \$1 million, in accordance with the recommendation of the IOM.

2. The current rate of funding for aging grants at NIMH and CMHS is inadequate and should be increased to at least three times their current funding levels. In addition, the substantial projected increase in mental disorders in our aging population should be reflected in the budget process in terms of dollar amount of grants and absolute number of new grants.

3. To help the country's elderly access necessary mental health care, previous years' funding of \$5 million for evidence-based mental health outreach and treatment for the elderly within CMHS must be increased to \$20 million.

4. Funding for the geriatric health professions program under Title VII of the Public Health Service Act should be continued at no less than fiscal year 2008 levels.

AAGP looks forward to working with the members of this subcommittee and others in Congress to establish geriatric mental health research and services as a priority at appropriate agencies within the Department of Health and Human Services.

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 PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

The American Association of Immunologists ("AAI"), a not-for-profit professional society representing more than 6,500 of the world's leading experts on the immune system, respectfully submits this testimony regarding fiscal year 2009 appropriations for the National Institutes of Health ("NIH"). The vast majority of AAI's members—research scientists and physicians who work in academia, government, and industry—depend on NIH funding to advance their own work and the broader field of immunology.<sup>1</sup> With approximately 83 percent of NIH's \$29.2 billion budget awarded to scientists throughout the United States and around the world, NIH funding advances both immunological/biomedical research and the regional and national economies.<sup>2</sup>

## WHY IMMUNOLOGY?

HIV/AIDS, Cancer, Influenza, Malaria, Diabetes, Rheumatoid arthritis, Smallpox, Organ Transplants, and Asthma.

Treatments and cures for these, and for many more infectious and chronic diseases, depend on our understanding of the immune system. And yet, the study of immunology is relatively new. Although scientists developed the first vaccine (against smallpox) in 1798, most of our basic understanding of the immune system has developed in the past 30–40 years, and new discoveries are being made every day.

What advances have been made! Vaccines protect us from childhood diseases that historically caused millions of childhood deaths and contributed to lower life expectancy.<sup>3</sup> Advances in understanding the immune system enable us to better control environmental threats. Progress in our urgent quest to understand the immune response to natural infectious organisms that can be used as agents of bioterrorism (including plague, smallpox, and anthrax) or that threaten to cause the next pandemic (including avian influenza) may soon protect us against these dangerous

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<sup>1</sup> The majority of AAI members receive grants from the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), and/or the National Institute on Aging (NIA).

<sup>2</sup> NIH funding supports more than 300,000 scientists/staff at more than 3,000 universities/medical schools/research institutions in every state and internationally. Fiscal year 2009 Director's Budget Request Statement: fiscal year 2009 Budget Request, Witness appearing before the House Subcommittee on Labor-HHS-Education Appropriations, Elias A. Zerhouni, M.D., Director, National Institutes of Health (3/5/08).

<sup>3</sup> Scientists have reported that vaccines for 7 of 12 routinely recommended childhood diseases prevent 33,000 deaths annually and 14 million cases of disease [a], resulting in a savings of \$10 billion in direct health costs and a savings of \$33 billion in disability and lost productivity costs." Roush et al. "Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases." *The Journal of the American Medical Association*, Vol. 298, No. 18, pp. 2155–2163 (2007).

pathogens. For all of these pressing needs and more, we need basic research on the immune system if we are to discover ways to prevent, treat, and cure disease.<sup>4</sup>

Recent scientific discoveries: Blockbusters and hope Vaccines are arguably the most successful immunotherapeutics that mankind has produced. Effective in preventing and all but eliminating a wide range of childhood and adult infectious diseases, their usefulness in cancer and chronic infectious disease has not been fully realized. That may all change due to the discovery of Toll-like Receptors (TLR), which recognize products (like DNA, lipids, lipoproteins, and flagella) present in pathogens (such as bacteria, viruses, and parasites) and mount an intense immune response; this could lead to the creation of a whole new generation of vaccines.

A highly effective vaccine against cervical cancer caused by Human Papillomavirus (HPV), which infects over 8 percent of women aged 15–50, was recently approved by the Food and Drug Administration. The new vaccine (“Gardasil”) is efficacious in preventing primary infection and therefore in reducing the incidence of cervical cancer. More recently, a TLR immune adjuvant called MPL is being used as an adjuvant in a newer HPV vaccine; results from early clinical trials indicate that the adjuvant induces a more robust immune response in older adults and a faster response in young adults than does Gardasil.

In 2007, B lymphocyte-depleting therapies were shown to be a revolutionary advance in the treatment of autoimmune diseases. In Rheumatoid Arthritis (RA), the anti-CD20 monoclonal antibody, rituximab, was shown to induce clinical remissions in previously unresponsive patients, to improve signs and symptoms, and to prevent structural damage. Rituximab therapy is now being used with impressive success in the treatment of many other autoimmune diseases, such as systemic lupus erythematosus (lupus) and relapsing remitting multiple sclerosis (MS) (controlling inflammation and further brain damage within one month).

Other potentially important therapeutic avenues needing further support include the development of additional therapeutic monoclonal antibodies, increasingly recognized as the most promising mode of treatment for a myriad of human diseases, and the use of pre-transplant conditioning and administration of bone marrow to eliminate the need for immunosuppression following organ transplantation.

#### NIH BUDGET CONTINUES TO ERODE

AAI greatly appreciates this subcommittee’s leadership in the successful effort to double the NIH budget. With this funding, biomedical scientists grew the research enterprise and trained new young investigators, preparing them to become tomorrow’s teachers and leaders. Although the NIH budget has grown since the doubling ended in fiscal year 2003 (from \$27.067 billion to \$29.2 billion in fiscal year 2008), sub-inflationary budget increases since fiscal year 2003 have resulted in a loss of purchasing power of more than 13 percent. Last year, AAI warned that such a loss in purchasing power was already beginning to have a devastating effect; this year, AAI can testify to the inordinate stress and life-altering consequences this has had on many researchers whose work continues to be excellent but whose grants simply cannot be funded when key NIH Institutes have already dropped their RO1 paylines to as low as 10–14 percent, significantly below the approximately 22 percent during the doubling period. In addition, success rates [the percentage of reviewed Research Project Grant (RPG) applications receiving funding computed on a fiscal year basis] have dropped to 21 percent in fiscal year 2007, the lowest since 1970, and to 19 percent in fiscal year 2008. With funding so low, many senior investigators with outstanding, innovative ideas—many of whom support (through their NIH grants) entire laboratories filled with younger faculty and post-doctoral fellows—are not being funded on their first renewal grant submission, forcing them to spend valuable time revising and resubmitting their applications.

The President’s fiscal year 2009 budget will exacerbate the above-described situation by:

1. providing no inflationary increase (for the 4th year) for direct, recurring costs in non-competing RPGs;
2. providing inadequate increases (1 percent) to already inadequate stipends for pre- and post-doctoral fellows, whose work is critical to established investigators and who will be the principal scientists of tomorrow;

<sup>4</sup>The immune system works by recognizing and attacking “foreign invaders” (e.g., 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 or partially (resulting in a less serious illness). It is also responsible for the rejection responses observed following transplantation of organs or bone marrow. The immune system can malfunction, allowing the body to attack itself instead of an invader (resulting in an “autoimmune” disease, such as Type 1 diabetes, multiple sclerosis, or rheumatoid arthritis).



3. increasing the adverse repercussions on Americans' health and the national economy: in addition to their terrible human toll, disease and disability cost society trillions of dollars annually in medical care, lost wages and benefits, and lost productivity;<sup>5</sup> and

4. jeopardizing the future of the biomedical research enterprise: our brightest young people will be deterred from pursuing biomedical research careers if their chances of receiving an NIH grant, or of sustaining a career as an NIH-funded scientist, do not improve. If we do not act soon, the United States will lose more of its scientists, as well as its preeminence in medical research and science, to nations (including India, Singapore, and China) that are already investing heavily in this essential economic sector.

#### AAI RECOMMENDS A 6.5 PERCENT BUDGET INCREASE FOR FISCAL YEAR 2009

AAI urges the subcommittee to increase the NIH budget by 6.5 percent (\$1.9 billion) in fiscal year 2009, to \$31.1 billion. This increase, which is only 3 percent above the projected rate of biomedical research inflation, would begin to restore both the loss in purchasing power that has occurred since the NIH budget doubling ended in fiscal year 2003<sup>6</sup> and the confidence of young scientists that a career in biomedical research is possible.

#### OTHER KEY ISSUES: INFLUENZA AND BIOTERRORISM

Seasonal influenza leads to more than 200,000 hospitalizations and about 36,000 deaths nationwide in an average year. Moreover, an influenza pandemic as serious as the one that occurred in 1918 could result in the illness of almost 90 million Americans and the death of more than 2 million, at a projected cost of \$683 billion.<sup>7</sup> AAI strongly believes that the best preparation for a pandemic is to focus on basic research to combat seasonal flu, including building capacity, pursuing new production methods (cell based), and seeking optimized flu vaccines and delivery methods. For bioterrorism, the focus should also be on basic research, including identifying new and potentially modified pathogens, understanding the immune response, and developing tools (including new and more potent vaccines) to protect against pathogens.

#### OTHER KEY ISSUES: THE NIH "COMMON FUND"

The NIH Reform Act of 2006 established within NIH a "Common Fund" ("CF") to support trans-NIH initiatives. The President's budget would increase the CF by \$38 million, or 7.66 percent. While there is value to interdisciplinary research, AAI believes that CF funds should not grow faster than the NIH budget, and that all CF awards and grants must be awarded through a transparent and rigorous peer review process.

#### OTHER KEY ISSUES: THE NIH PUBLIC ACCESS POLICY

AAI respectfully requests that the subcommittee require that NIH report on the cost of implementing the NIH Public Access Policy ("Policy"). To the best of AAI's knowledge, NIH has never reported the cost of the former voluntary Policy or the projected cost of the new mandatory Policy, and there is no requirement in law that NIH ever do so. AAI therefore requests that the subcommittee require NIH to publicly report by April 2009: (1) the total funds expended on implementing the voluntary Policy (May 2, 2005-January 11, 2008); (2) the cost anticipated for implementation of the mandatory Policy in fiscal year 2009; and (3) how much of the cost anticipated for fiscal year 2009 will be a one-time implementation cost, and how much will be an annual cost. AAI has submitted proposed language to the sub-

<sup>5</sup>National health expenditures cost \$3.28 trillion in 2006 and are projected to be \$4.1 trillion in 2016. See <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2006.pdf> <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/highlights.pdf>

<sup>6</sup>According to the U.S. Department of Commerce's Biomedical Research and Development Price Index ("BRDPI"), the projected rate of biomedical research inflation for fiscal year 2009 is 3.5 percent. NIH funding increases since fiscal year 2003 have all been below the BRDPI. NIH memo dated February 4, 2008: "Biomedical Research and Development Price Index: Fiscal Year 2007 Update and Projections for Fiscal year 2008-2013" [http://officeofbudget.od.nih.gov/UI/2008/BRDPI\\_Proj\\_2008\\_final.pdf](http://officeofbudget.od.nih.gov/UI/2008/BRDPI_Proj_2008_final.pdf)

<sup>7</sup>A report issued by Trust for America's Health ("Pandemic Flu and the Potential for U.S. Economic Recession") predicts that a severe pandemic flu outbreak could result in the second worst recession in the United States since World War II, resulting in a drop in the U.S. Gross Domestic Product of over 5.5 percent.

committee's Chairman and Ranking Member for consideration (letter from AAI to Chairman Harkin and Senator Specter, March 18, 2008).

AAI continues to believe that the Policy will duplicate, at great cost to NIH and to taxpayers, publication services which are already provided cost-effectively and well by the private sector. The private sector, including not-for-profit scientific societies, already publishes—and makes publicly available—thousands of scientific journals that report cutting-edge research funded by both NIH and other public and private entities. AAI urges that, rather than creating a new government bureaucracy (a particular burden in this era of severe budget constraints), NIH should partner with these publishers to develop a plan that enhances public access while also addressing publishers' key concerns, which include respecting copyright law and ensuring journals' continued ability to provide quality, independent peer review of NIH-funded research.

#### OTHER KEY ISSUES: PRESERVING HIGH QUALITY PEER REVIEW

NIH has recently conducted a "Self-Study" of its peer review system, soliciting the views of a wide range of stakeholders in an effort to improve what is already the world's best system. AAI applauds, and has participated fully in, this important effort. Nevertheless, AAI has some concerns that NIH has not adequately considered the importance of transparent evaluation and urges the subcommittee to ensure that NIH: (1) provides adequate time for stakeholder review and input on all final recommendations; and (2) conducts timely and transparent evaluation of all pilot projects and permanent changes, with ample opportunity for public comment. Even as NIH seeks to make needed improvements, it is essential that changes to our extraordinary peer review system, already the envy of the world, must first "do no harm".

#### OTHER KEY ISSUES: ENSURING THE INDEPENDENCE OF SCIENCE

Millions of lives—as well as the prudent use of taxpayer dollars—depend on the willingness of government officials to accept the best, most independent scientific advice available. AAI urges the subcommittee to ensure that funds expended protect the ability of scientists to provide independent scientific advice, whether through government advisory panels, through the peer review process, or by supporting the vitality of independent scientific journals that provide expert peer review of taxpayer funded research.

#### OTHER KEY ISSUES: ENSURING NIH OPERATIONS AND OVERSIGHT

AAI urges the subcommittee to explore whether the President's proposed sub-inflationary increase of \$20 million (1.49 percent) for Research, Management, and Services, which supports the management, monitoring, and oversight of all research activities (including peer review), is adequate to ensure NIH supervision of a portfolio of increasing size and complexity, as well as to ensure that NIH funds are properly spent.

#### CONCLUSION

AAI greatly appreciates this opportunity to submit testimony and thanks the Chairman, Ranking Member, and subcommittee for their strong support for biomedical research, the NIH, and the scientists who devote their lives to preventing, treating, and curing disease.

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#### PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF MUSEUMS

Chairman Harkin, ranking member Specter, and distinguished members of the subcommittee, the American Association of Museums appreciates the opportunity to submit testimony on the fiscal year 2009 budget for the museum program at the Institute of Museum and Library Services (IMLS).

The American Association of Museums (AAM) is the only organization representing the full scope of museums—art museums, history museums, science centers, children's museums, zoos and aquariums, public gardens and many specialty museums—along with professional staff and volunteers who work for and with museums. AAM currently represents more than 15,000 individual museum professionals and volunteers, 3,000 institutions and 300 corporate members. Our membership is as diverse as the collections contained in the museums we represent.

We respectfully request your approval of \$46.3 million for grants to museums administered through the Office of Museum Services (OMS) at the Institute of Mu-

seum and Library Services (IMLS) and the agency's overall budget request of \$500,000 for museum data collection.

Museums and libraries are the most trusted sources of online information among adults of all ages, education levels, races and ethnicities. According to a recent IMLS report, museums and libraries rank higher in trustworthiness than all other information sources, including government, commercial and private websites. This report highlighted the vital role of museums in supplementing formal education and providing informal learning opportunities.

There are more than 17,500 museums in America. As vibrant community assets and sources of civic pride, museums perform an essential function in the creation of America's social and cultural fabric.

However, unlike schools and libraries, most museums operate as private, nonprofit organizations with nominal government funding. According to AAM's most recent financial survey, nonprofit museums receive approximately 24 percent of their budget from local, state and federal funding.

#### PRESERVING OUR PAST

Museums preserve and present to the public the collections that helped make America a great nation. The care of these objects is critical to their preservation for future generations. Toward that end, IMLS funded the Heritage Health Index, the first comprehensive survey ever conducted of the condition and preservation needs of our nation's collections, in museums, libraries, archives, historical societies and scientific research organizations. The survey produced two startling facts: These collections are visited more than 2.5 billion times a year, yet 630 million artifacts, encompassing works of art, photographs, historic objects, natural science specimens, books and periodicals, are currently at risk.

One result of this survey was a multifaceted plan to manage, protect, and preserve these valuable objects. "Connecting to Collections" is an IMLS-supported initiative, through which grants fund statewide planning on preserving a state's collections.

IMLS assists museums with efforts to examine, document, treat, stabilize, and restore their collections through the consultation services of the Conservation and Museum Assessment Programs and with financial assistance through the Conservation Project Support program. But the Conservation Project Support program's resources never meet the demand. In fiscal year 2008 IMLS received 172 applications and made a total of 65 grants (for a total of \$4.9 million).

An example of a State anticipating these needs and of the effectiveness of "Connecting to Collections" grants is the effort underway in Rhode Island. A \$40,000 grant to the Rhode Island Office of Library and Information Services in 2008 enabled it to define and inventory the universe of statewide heritage collections, institute an online disaster planning program, train stakeholders in its use and share this knowledge with state and local emergency management agencies, first responders and heritage stakeholders. To date, 19 similar statewide grants have been awarded.

IMLS funds have enabled the Martin Art Gallery at Muhlenberg College in Muhlenberg, Pennsylvania, to give more serious attention to collections management. They are currently moving approximately 50 percent of the Tanner Collection (works on paper) to storage in a climate-controlled storage area. In addition, a large 1868 painting is slated for conservation, and there is an increase in awareness about the responsibilities of holding collections in trust for the public.

#### EDUCATING THE PUBLIC

As State and local public education mandates have changed, students' access to education in the arts, history and other subjects has been reduced. Museums have helped fill the void with invaluable learning experience for K-12 students. As school budgets have been cut, especially for off-site field trips, many museums have aggressively brought their institutions and collections directly to the students.

#### SUPPORTING RESEARCH

The United States needs a robust program of research in order to understand the larger impact of museums nationwide. Important areas of future research include:

- measuring the educational and social influence of museums at the national level while building the capacity of institutions to measure how they affect their communities,
- studying what skills are needed to be a successful 21st-century museum professional, and what training is needed to nurture leaders in the field,

- supporting the ongoing collection of core data about museums, such as financial benchmarks, attendance patterns and long-term social impacts, and
- examining areas of special interest to the museum field, such as collections stewardship and the relationship between museums and both formal and informal learning.

#### STRIVING FOR EXCELLENCE

Museums must consistently strive to improve if they are to retain the public trust and fulfill their mission of education and public service. IMLS has been integral to that ongoing effort, in numerous ways. One of the most critical is its support of the Museum Assessment Program (MAP), a program that brings fresh, experienced, outside eyes to a museum's operations and collections management. MAP participants come to understand their strengths and weaknesses, learning how to improve overall operations and set institutional priorities. These museum improvements directly benefit the public they serve.

#### CELEBRATING DIVERSITY

While IMLS funds a wide range of programs and efforts at a broad range of institutions, two of the newest programs help ensure that museums reflect our nation's diversity. AAM supports the continuation of the Native American/Native Hawaiian Museum Services grants and Museum Grants for African American History and Culture. These institutions are among the newest specialized type of museums and must be supported to ensure that the public has access to the broadest interpretation and representation of the history and culture of our Nation.

#### TRAINING MUSEUM LEADERS AND EDUCATORS

To further connect museums and their public to the future, IMLS has led the way in supporting the 21st Century Museum Professionals program, an initiative designed to empower future museum leaders to face a field that is rapidly changing. Today, the demands of a museum director are such that boards search for candidates who are strategic thinkers, excellent communicators and talented fundraisers, as well as having an entrepreneurial spirit and energy that will enable them to bridge the worlds of commerce and scholarly pursuits. According to a 2006 AAM survey of museum finances, the average museum has a staff of six full-time employees and four part-time employees, including curators, educators, registrars, accountants and marketing and development professionals, with many filling more than one role. Like many other nonprofits, museums have also struggled to identify diverse pools of qualified workers.

IMLS works to fill this void via the 21st Century Museum Professionals program. In its first two years of existence, the program has attracted 97 applicants for only 19 fundable spots. The agency's fiscal year 2009 request would allow IMLS to fund approximately 20 more applications in fiscal year 2009 than were funded in fiscal year 2007 or will be funded in fiscal year 2008. IMLS received far more quality applications for this program than there are funds to grant. We urge the subcommittee to consider increasing future investment in the development of a diverse, talented and qualified workforce of museum professionals.

#### BUILDING COMMUNITIES

Museums are iconic entities in their communities. Citizens take pride in their local museums. Museum-focused programs supported by IMLS strengthen these community ties while also serving a useful civic role, the benefits of which may reach well beyond local boundaries.

A compelling example comes from St. Paul, where the Minnesota Historical Society used a 2002 IMLS grant of \$125,389 to initiate a program designed to further integrate the Twin Cities' sizeable Somali population into their new host culture. This program trained 15 Somali women in the use of digital technology, resulting in a compelling film, *Two Homes, One Dream: The Somalis in Minnesota*. For the film the women did historical research; conducted oral history interviews with peers, elders, educators and community leaders; and filmed events across the Twin Cities. Some four years after its completion, *Two Homes, One Dream* is still requested and featured in public screenings throughout the region, as its themes of cultural identity and the immigrant experience continue to resonate with a diverse group of Minnesotans.

## CONCLUSION

We realize how difficult it is to prioritize how resources are allocated among all the worthy programs that are within this subcommittee's jurisdiction. Our appeal is that, in making these important choices, you consider the vital contribution museums make in communities nationwide. Investing in museums is investing in our traditions, our culture, our heritage and in the American spirit of creativity and independence. By way of evidence, we offer this story of two Philadelphians for whom museums have been both an inspiration and a lifeline (first reported in February 2008 in the Philadelphia Inquirer):

Bill McLaughlin and Dick Hughes are World War II veterans. Both are in their 80s. They attend the same church in Philadelphia, but were not really close friends. When Bill's wife was losing her battle with Alzheimer's, Dick thought it was his "Christian duty" to pull Bill out of his despondency. They spent an afternoon at the Academy of Natural Sciences in Philadelphia. They enjoyed it, for the intellectual stimulation and for the way it diverted their attention from other pressing matters. The following week, they visited the battleship New Jersey. And they continued to visit Philadelphia-area museums and historic sites for three years and a total of 203 museums. The result was a handy guide they recently published, entitled *Travels with Dick and Bill*, sales of which benefit their church. But more importantly, these travels cultivated their love for museums, an appreciation of their hometown and an enduring friendship that will undoubtedly last the rest of their lives.

This is a poignant example of how museums bring us together, and of how these public institutions served two men who had served their country so nobly. With the continued support and leadership of an increased investment of federal funding in museums, and by working with our partners in the private sector, museums can continue to strive for the highest standards in fulfilling their mission of educating the public and preserving our heritage—and perhaps even more importantly, in continuing to touch American lives like those of Bill McLaughlin and Dick Hughes.

## PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF NURSE ANESTHETISTS

## FISCAL YEAR 2009 APPROPRIATIONS REQUEST SUMMARY

	Fiscal year 2008 actual	Fiscal year 2009 budget	AANA fiscal year 2009 request
HHS/HRSA/BHPr Title VIII Advanced Education Nursing, Nurse Anesthetist Education Reserve.	Awaiting grant allocations—in fiscal year 2007 awards amounted to approx. \$3,500,000	Grant allocations not specified.	\$4,000,000 for nurse anesthesia education.
Total for Advanced Education Nursing, from Title VIII	\$61,800,000 for Advanced Education Nursing	\$0 for Advanced Education Nursing.	\$67,000,000 for advanced education nursing.
Title VIII HRSA BHPr Nursing Education Programs.	\$156,046,000	\$109,853,000	\$200,000,000

The AANA is the professional association for more than 37,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists, representing over 90 percent of the nurse anesthetists in the United States. Today, CRNAs are directly involved in delivering 30 million anesthetics given 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 as well as providing acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and are the sole anesthesia providers in almost 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 20 years previous. (Kohn L, Corrigan J, Donaldson M, ed. *To Err is Human*. Insti-

tute 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 Pine having recently concluded, "the type of anesthesia provider does not affect inpatient surgical mortality." (Pine, Michael MD et al. "Surgical mortality and type of anesthesia provider." *Journal of American Association of Nurse Anesthetists*. Vol. 71, No. 2, p. 109–116, April 2003.)

Even more recently, a study published in *Nursing Research* indicates that obstetrical anesthesia, whether provided by Certified Registered Nurse Anesthetists (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's data showed that CRNAs and anesthesiologists are substitutes in the production of surgeries, and it is important to note that through continual improvements in research, education, and practice, nurse anesthetists are vigilant in their 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. In May 2003 at the beginning of "Operation Iraqi Freedom," 364 CRNAs were deployed to the Middle East to ensure military medical readiness capabilities. For decades, CRNAs have staffed ships, remote U.S. military bases, and forward surgical teams without physician anesthesiologist support.

#### 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 \$67 million for advanced education nursing from the Title VIII program. We feel that this funding request is well justified, as we are seeing a vacancy rate of nurse anesthetists in the United States impacting people's healthcare. The Title VIII program, which has been strongly supported by members of this Subcommittee in the past, is an effective means to help address the nurse anesthesia workforce demand. This demand for CRNAs is something that the nurse anesthesia profession addresses every day with success and also with the critical assistance of Federal funding through HHS' Title VIII appropriation.

The AANA is very concerned that the President's fiscal year 2009 budget proposal eliminates funding for Advanced Education Nursing Programs, which seek to increase the number of providers in rural and underserved America and are the master's and doctoral prepared providers who are eligible to serve as faculty. Therefore, cuts to this program in Title VIII present a two-fold loss—reducing the number of providers who are trained as clinicians to fill the nursing shortage and reducing the number of eligible faculty to alleviate the faculty shortage.

Increasing funding for advanced education nursing from \$61.8 million to \$67 million is necessary to meet the continuing demand for nursing faculty and other advanced education nursing services throughout the United States. Only a limited number of new programs and traineeships can be funded each year at the current funding levels. 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 meeting the nursing workforce needs of Americans who require healthcare. In 2007, the AANA conducted a nurse anesthesia workforce study that found a 12.6 percent vacancy rate in hospitals for CRNAs, and a 12.5 percent faculty vacancy rate. The supply of clinical providers has increased in recent years, stimulated by increases in the number of CRNAs trained. Between 2003–2007, the number of nurse anesthesia educational program graduates nearly doubled. However, the nurse anesthetist vacancy rate remained steady at around 12 percent, which is likely due to increased demand for anesthesia services as the population ages, growth in the number of clinical sites requiring anesthesia services, and CRNA retirements.

The problem is not that our 108 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 one year serving in an acute care healthcare practice environment. Nurse anesthesia

educational programs are located all across the country including the following States:

State	Number of Accredited Nurse Anesthesia Programs
AL .....	2
IA .....	1
IL .....	5
LA .....	2
NJ .....	2
PA .....	12
RI .....	2
TX .....	5
WA .....	1
WI .....	1

Recognizing the important role nurse anesthetists play in providing quality healthcare, the AANA has been working with the 108 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 programs.

The Council on Certification of Nurse Anesthetists (CCNA) reports that in 1999, our schools produced 948 new graduates. In 2005, that number had increased to 1,790, an 89 percent increase in just five years. This growth is expected to continue. The CCNA projects CRNA programs to produce over 2,000 graduates in 2008. To truly meet the nurse anesthesia workforce challenge, the capacity and number of CRNA schools must continue to expand. 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 study by Pine et al confirms, "the type of anesthesia provider does not affect inpatient surgical mortality." Yet, for what it costs to educate one anesthesiologist, several CRNAs may be educated to provide the same service with the same optimum level of safety. Nurse anesthesia education represents a significant educational cost-benefit for supporting CRNA educational programs with Federal dollars vs. supporting other 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 in 2003 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, who provide care to patients during and following their education. Moreover, they reported producing additional CRNAs that went to serve in rural or medically underserved areas. Under both of these circumstances, an increased number of student nurse anesthetists and CRNAs are providing healthcare to the people of medically underserved America.

We believe it is important for the Subcommittee to allocate \$4 million for nurse anesthesia education for several reasons. First, as this testimony has documented, the funding is cost-effective and very needed. Second, the Title VIII authorization previously providing such a reserve expired in September 2002. Third, this particular funding is important because 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. Lastly, 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 a growing coalition of nursing organizations, including the Americans for Nursing Shortage Relief (ANSR) Alliance and representatives of the nursing community, and others in support of the Subcommittee providing a total of \$200 million in fiscal year 2009 for nursing shortage relief through Title VIII. This

amount is approximately \$44 million over the fiscal year 2008 level and \$90 million above the President's fiscal year 2009 budget.

Every district in America is familiar with the importance of nursing. The AANA appreciates the support for nurse education funding in fiscal year 2008 and past fiscal years from this Subcommittee and from the Congress. The need for increasing nurse educational funding to strengthen our healthcare is clear. According to the Office of the Actuary at the Centers for Medicare & Medicaid Services, America spent about \$2.1 trillion on healthcare in 2006, which is the most recent year for which the agency had records. About \$401 billion of that was from Medicare outlays. Medicaid spending was \$309 billion. It is estimated that Medicare directs over \$8.7 billion of its outlays to Graduate Medical Education (GME), of which more than \$2.3 billion goes to Direct GME. Approximately 99 percent of that educational funding helps to educate physicians and allied health professionals, and about 1 percent is allocated to help educate nurses.

In the interest of patients past and present, particularly those in rural and medically underserved parts of this country, we ask Congress to reject cuts from Federal investments 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 nurse education will improve patient access to quality services and strengthen the Nation's healthcare delivery system. Thank you.

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#### PREPARED STATEMENT OF THE AMERICAN CHEMICAL SOCIETY

The American Chemical Society (ACS) appreciates the opportunity to submit public testimony to the Labor, Health and Human Services, Education, and Related Agencies Subcommittee on the fiscal year 2009 budget for the U.S. Department of Education (DoEd).

The ACS is a nonprofit scientific and educational organization, chartered by Congress in 1937, with more than 160,000 chemical scientists and engineers as members. The world's largest scientific society, ACS advances the chemical enterprise, increases public understanding of chemistry and science, and brings its expertise to bear on state and national matters.

A hardworking and entrepreneurial American workforce, coupled with aggressive federal and private investment in scientific and technological research, sent a man to the moon, harnessed the atom, sequenced the human genome, and built a dynamic, robust, and growing economy that is the envy of the world. As the 21st Century blossoms, we must revitalize our commitment to strengthen the pillars of American innovation and competitiveness—education, basic research, and a business environment to drive innovation.

Last year, Congress showed strong bipartisan support for increased investment to strengthen the U.S. science, technology, engineering, and mathematics (STEM) education pipeline and basic research in the physical sciences by enacting the America COMPETES Act. This groundbreaking legislation authorizes a dramatic expansion of federal investments in many aspects of STEM education from teacher training and recruitment, to educational research, to support for students studying in science and technology fields. As other nations around the globe are quickly advancing scientifically and technologically, it is imperative that the Congress—and especially your Subcommittee—appropriate the funding necessary to fully implement the America COMPETES Act.

#### AMERICAN COMPETITIVENESS INITIATIVE

The ACS supports the \$175 million proposed for fiscal year 2009 by the Administration's American Competitiveness Initiative for math and science education programs at the Department of Education.

We support the proposed funding level of \$70 million for the Advanced Placement/International Baccalaureate as well as \$95 million for the new Math Now program. Both of these new initiatives were authorized by the America COMPETES Act and are broadly supported by the scientific, education, and business communities.

Our Society continues to strongly support the Administration's Adjunct Teacher Corps initiative, proposed at \$10 million in fiscal year 2009, which would encourage up to 30,000 experienced professionals with subject-matter knowledge to enter the classroom to teach part- or full-time in areas of high need, including science and math. We recommend that sufficient funding be provided to ensure adequate teacher development and certification for these professionals.



## K-12 EDUCATION

We profoundly disagree with Administration's decision to flat fund the DoEd Math and Science Partnership program and strongly support a budget increase in fiscal year 2009 toward the fully authorized level of \$450 million. One of the most critical issues facing STEM education today is the supply of qualified K-12 science and mathematics teachers. The Math and Science Partnerships program, authorized in the No Child Left Behind Act at an increasing annual level to reach a sustainable level of \$450 million by fiscal year 2007, is the sole source of dedicated K-12 math and science funding at the Department of Education. It supports valuable long-term, content-based, continuing education for math and science teachers—the type of training that research shows is most effective in improving student achievement.

## VOCATIONAL AND TECHNICAL EDUCATION

We are highly disappointed by the administration's decision to eliminate the Perkins Career and Technical Education program, which was reauthorized by Congress with overwhelming support in 2006. We urge that Congress appropriate full funding for this broadly supported program to aid students in acquiring rigorous academic and technical skills to prepare them for careers in science and technology that will help maintain U.S. competitiveness in the global economy.

## HIGHER EDUCATION

We support the administration's proposal to expand the Graduate Assistance in Areas of National Need (GAANN) program by 10 percent in fiscal year 2009 to \$32.5 million. The budget request for GAANN, which provides graduate students in science and other high-need fields with enhanced fellowship assistance, would support 747 fellowships in 2009, including 529 new fellows. ACS supports expansion of this program to at least 1,200 fellowships. Our Society also believes that the Minority Science and Engineering Improvement program is an effective mechanism to increase the participation of underrepresented minorities in scientific and technological careers.

In closing, we thank you for the opportunity to express our views on the funding priorities of your Subcommittee. We strongly urge you to make the sustained and robust investments in STEM education that will be critical to the success of U.S. global competitiveness and continued economic growth.

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PREPARED STATEMENT OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

The American College of Obstetricians and Gynecologists (ACOG), representing 52,000 physicians and partners in women's health care, 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, ranking member Specter, and the entire subcommittee for their leadership to continually address women's health research at the National Institutes of Health (NIH).

The Nation has made important strides to improve women's health over the past several years, and ACOG is grateful to this Committee for its commitment to ensure that vital research continues to eliminate disease and to ensure valuable new treatment discoveries are implemented. This dedicated commitment to elevate, promote and implement medical research faces an uncertain future at a time when scientists are on the cusp of new cures.

We urge the Committee to support a 6.6 percent increase for the National Institutes of Health (NIH), and all of its institutes, in fiscal year 2009.

## WOMEN'S HEALTH RESEARCH AT THE NIH

NIH institutes work collaboratively to conduct women's health research. The Eunice Kennedy Shiver National Institute of Child Health and Human Development (NICHD) conducts the majority of women's health research, and has made critical accomplishments in preterm birth, contraceptive research, and infertility. The National Cancer Institute (NCI) has made monumental discoveries on gynecologic cancers, and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) works with the NICHD to discover treatments for urinary incontinence. The Office of Research on Women's Health (ORWH) in the NIH Office of the Director coordinates women's health research projects and manages mentoring programs for new investigators.

## MENTORING NEW INVESTIGATORS

Despite the NIH's critical advancements, reduced funding levels have made it difficult for research to continue, largely due to the lack of new investigators. The NIH advanced women's health research during the Congressional doubling between fiscal year 1998 and fiscal year 2003, but funding increases have been so low since fiscal year 2003, the NIH budget is almost same as it was before the doubling.

The Building Interdisciplinary Research Careers in Women's Health (BIRCWH), operated by the ORWH, and the Women's Reproductive Health Research (WRHR) Career Development Program at the NICHD, attract new researchers, but low pay lines make it difficult for the NIH to maintain them. We urge the Committee to significantly increase funding for women's health research at the NIH to maintain a high level of research innovation and excellence, in turn reducing the incidence of maternal morbidity and mortality and discovering cures for other chronic conditions.

OFFICE OF THE DIRECTOR-OFFICE OF RESEARCH ON WOMEN'S HEALTH (ORWH)

*Coordinating and Promoting Women's Health Research throughout NIH*

Established in September 1990, the Office of Research on Women's Health (ORWH) is a focal point for women's health research at the NIH.

The ORWH manages the BIRCWH program, which mentors new investigators at several institutions including the University of Wisconsin, Madison, in Madison, Wisconsin; Tulane University, in New Orleans, Louisiana; Northwestern University and the University of Illinois, Chicago, in Evanston and Chicago, Illinois, respectively; and Pennsylvania State University and Magee Women's Hospital of the University of Pittsburgh Medical Center in University Park, and Pittsburgh, Pennsylvania, respectively.

BIRCWH programs are expanding women's health research through career development, increasing diversity in the field of women's health, promoting interdisciplinary research training and developing independent researchers with backgrounds in high priority women's health research areas.

The ORWH recently launched the NIH Women's Health Fellowships in Intramural Women's Health Research. This intramural program is funded through the Foundation of the NIH, which was established by Congress to maximize the resources at the NIH and support medical research through public-private partnerships. The fellowships are supported by donations from Battelle and AstraZeneca.

An ob-gyn resident at Loyola University, Chicago, Illinois, is one of the first recipients of the fellowship. She is studying the difference in severity and prevalence of fibroids in African American and white women. The Women's Health Fellowship helps new investigators enhance their research skills, and mentor women to senior positions in science.

ACOG urges Congress to increase funding for the ORWH to help prepare the next generation of women's health researchers.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

*Expanding Maternal Health Research*

The Maternal Fetal Medicine Units (MFMU) Network investigates clinical questions in maternal fetal medicine and obstetrics, with a focus on preterm birth, and has advanced women's health research by making several monumental discoveries including using progesterone treatments to reduce preterm birth.

The MFMU is working at 14 sites across the United States (University of Alabama, University of Texas-Houston, University of Texas-Southwestern, Wake Forest University, University of North Carolina, Brown University-Women and Infant's Hospital, Columbia University, Drexel University, University of Pittsburgh-Magee Women's Hospital, University of Utah, Northwestern University, Wayne State University, Case Western University, and Ohio State University), to reduce the risks of pre term birth, cerebral palsy, and preeclampsia (high blood pressure).

In 2006 Congress passed the PREEMIE Act of 2006, Public Law 109-450, increasing research funding on prematurity. In June 2008, the NICHD will hold the Surgeon's Conference on Preventing Preterm Birth, as authorized in Public Law 109-450.

ACOG urges Congress to increase funding for the NICHD, which will fund the research authorized in the PREEMIE Act, and increase funds for the MFMU.

## NATIONAL CANCER INSTITUTE (NCI)

*Developing Gynecologic Cancer Research, Prevention and Education*

The NCI is funding vital women's health research throughout the United States.

—*Effects of Cervical Procedure on Pregnancy.*—At the Washington University School of Medicine, St. Louis, MO, researchers are studying the impact of the Loop Electrosurgical Excision Procedure (LEEP), which is a common treatment for abnormal cells on the cervix, on subsequent pregnancy. This study may determine whether LEEP increases the risk of preterm birth and other adverse pregnancy outcomes.

—*Stress and Ovarian Cancer.*—At the University of Texas, MD Anderson Cancer Center, Houston, TX, researchers are examining the effects of chronic stress on growth and progression of ovarian cancer along with underlying mechanisms. Based on these results, researchers hope to gain a better understanding of the adverse effects of chronic stress and discover new strategies for blocking its harmful effects on cancer patients.

—*Pediatric Cancer Survivor Fertility.*—There are currently over 250,000 childhood cancer survivors in the United States, and while cancer therapies improve long-term survival, such treatments may impair fertility potential and cause premature ovarian failure. Research at the University of Pennsylvania, Philadelphia, PA, will provide preliminary data for the establishment of a long-term study of pediatric cancer survivors and their pregnancy rates, pregnancy outcomes and the occurrence of premature menopause.

*Expanding Ovarian Cancer Research*

Despite the women's health research advancements at the NCI, much more needs to be done. According to the NCI, there will be 22,430 new cases of ovarian cancer and 15,280 deaths from ovarian cancer in the United States in 2007. With more ovarian cancer biomarker research, we may reduce ovarian cancer.

ACOG urges Congress to pass the Ovarian Cancer Biomarker Act, S. 2569/H.R. 3689, which would increase funding for research and clinical centers at the NCI for risk stratification, early detection and screening of ovarian cancer.

*Increasing Gynecologic Cancer Education*

Public and provider education on gynecologic cancers is critical to early detection. When women and their doctors understand the symptoms and risk factors of gynecologic cancers they can find appropriate medical help quickly, increasing the potential for earlier detection.

ACOG urges Congress to fully fund Johanna's Law, Public Law 109-475, at \$10 million in fiscal year 2009, which would increase provider and public education on gynecologic cancers, saving thousands of women's lives.

## NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

*Exploring Treatments for Urinary Incontinence*

The Urinary Incontinence Treatment Network (UITN) at the NIDDK and the NICHD, researches urinary incontinence treatments. The UITN clinical trials compare the outcomes of commonly used surgical procedures, drug therapies, and behavioral treatments for incontinence.

The Trial of Mid-Urethral Slings (TOMUS) researches the outcomes of surgical procedures to treat stress urinary incontinence. Although these surgical procedures are approved by the Food and Drug Administration (FDA), researchers are investigating which are more effective.

The Stress Incontinence Surgical Treatment Efficacy Trial (SISTER) studies the long-term outcomes of commonly performed stress urinary incontinence treatment surgeries. The Burch procedure and the sling produce have estimated cure rates of 60 percent-90 percent, and researchers are determining which produces the best long-term outcome.

The Behavior Enhances Drug Reduction of Incontinence (BE-DRI) studies whether adding behavioral treatment to drug therapy makes it possible to discontinue drug treatment, and still maintain a reduced number of incontinence accidents.

ACOG urges Congress to increase funding for critical women's health research at the NIDDK.

Again, we would like to thank the Committee for its continued support of programs to improve women's health, and urge Congress to increase funding for the NIH and its institutes 6.6 percent above fiscal year 2008 levels in fiscal year 2009.

## PREPARED STATEMENT OF THE AMERICAN DIABETES ASSOCIATION

## INTRODUCTORY REMARKS

Thank you Chairman Harkin, ranking member Specter and members of the committee for your work to provide the first increase since fiscal year 2005 for education and prevention programs at the Centers for Disease Control and Prevention (CDC) and diabetes research at the National Institutes of Health (NIH). As the nation's leading nonprofit health organization providing diabetes research, information and advocacy, we appreciate the opportunity to submit testimony on the importance of federal funding for vital diabetes prevention and research efforts are critical to having on our nation.

## BACKGROUND INFORMATION

There are currently 20.8 million Americans who have diabetes, 7 percent of the population. Of the 20.8 million, 6.2 million are unaware that they have diabetes. Additionally there are 54 million more Americans with pre-diabetes<sup>1</sup> meaning their blood glucose levels are higher than normal and are at increased risk of progressing to diabetes unless they take steps to reduce their risk. Together, this means that 25 percent of the U.S. population either has, or is at risk for developing, this serious disease. Federal funding for diabetes prevention and research efforts are critical to facing this epidemic.

*Diabetes is Serious.*—It is a chronic condition that impairs the body's ability to use food for energy. The hormone insulin, which is made in the pancreas, helps the body change food into energy. In people with diabetes, the pancreas either does not create any insulin, which is type 1 diabetes, or the body doesn't 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. Type 1 individuals account for 5 to 10 percent of all diagnosed cases; type 2 diabetes accounts for 90 to 95 percent of diabetes cases. Diabetes is the leading cause of kidney disease, adult-onset blindness and lower limb amputations as well as a significant cause of heart disease and stroke.<sup>2</sup> Every 21 seconds someone is diagnosed with diabetes. More than 4,000 people will be diagnosed in 24 hours. During this same time frame there will be 230 amputations, 120 people will enter end-stage kidney disease programs, and 55 people will go blind all due to diabetes.<sup>3</sup>

*Diabetes is Costly.*—The total annual economic cost of diabetes in 2007 was estimated to be \$174 billion. Medical expenditures totaled \$116 billion and were comprised of \$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. This is an increase of \$42 billion since 2002. A 32 percent increase, meaning that the dollar amount has grown over \$8 billion each year. In fact, approximately one out of every five health care dollars is spent caring for someone with diagnosed diabetes, while one in ten health care dollars is attributed to diabetes.<sup>4</sup> Additionally, approximately one-third of Medicare expenses are associated with treating diabetes and its complications.<sup>5</sup>

*Diabetes is Deadly.*—It is the fifth leading cause of death by disease, comprising of an estimated 224,092 deaths each year. Diabetes is likely to be under-reported as a cause of death. Studies have found that less than half of individuals with diabetes had it listed on their death certificate. The risk for death among people with diabetes is about twice that of people without diabetes of similar age.<sup>6</sup> Having diabetes lowers the average life expectancy by up to 15 years.<sup>7</sup> Unfortunately, while the death rate due to diabetes has increased by about 45 percent since 1987 while death rates from cancer, heart disease, and stroke have declined.<sup>8</sup>

<sup>1</sup> [www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2005.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2005.pdf)

<sup>2</sup> [www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2005.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2005.pdf)

<sup>3</sup> Frank Vinicor, Associate Director for Public Health Practice at the Centers for Disease Control, qtd. in N.R. Kleinfeld, "Diabetes and Its Awful Toll Quietly Emerges as a Crisis," The New York Times, 9 January 2006.

<sup>4</sup> <http://care.diabetesjournals.org/misc/econcosts.pdf>

<sup>5</sup> <http://www.nih.gov/about/researchresultsforthepublic/Type2Diabetes.pdf>

<sup>6</sup> [www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2005.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2005.pdf)

<sup>7</sup> Portuese E and Orchard T: Mortality in Insulin-Dependent Diabetes. In Diabetes in America (pp. 221–232). Bethesda, MD: National Diabetes Data Group, NIH, 1995.

<sup>8</sup> JAMA 294: 1255, 2005.

## THE AMERICAN DIABETES ASSOCIATION'S FUNDING REQUESTS

Diabetes is one of the greatest U.S. public health crises of the 21st century. To stem the tide of this epidemic, it is essential that diabetes prevention and outreach efforts expand and scientists and researchers be enabled to continue their work towards finding a cure. Therefore, we are requesting:

- \$83.5 million for CDC's Division of Diabetes Translation (DDT).—This would be a \$20.8 million increase, one dollar for each American suffering from diabetes. This program received an \$880,000 increase in fiscal year 2008. This year the Administration has requested a reduction of \$257,000 to this essential prevention and education program.
- \$1.818 billion for the National Institute for Diabetes, Digestive and Kidney Diseases (NIDDK) at the NIH.—This would add \$112.6 million to NIDDK and represent a 6.6 percent increase over fiscal year 2008 funding. The additional funding would provide a 3 percent increase over biomedical inflation which continues to eat into the purchasing power of research funding. The Administration has requested an increase of \$2 million for fiscal year 2009.

## DIABETES INTERVENTIONS AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION

The CDC's Division of Diabetes Translation is critical to our national efforts to prevent and manage diabetes because DDT literally translates research, like that done at NIH, into real solutions and practices. Appropriated funds to DDT are focused on: defining the diabetes burden through the use of public health surveillance; translating research findings into clinical and public health practice; developing and maintaining state-based diabetes and prevention programs; and supporting the National Diabetes Education Program. Our request of \$20.8 million will allow these critical programs at DDT to expand and more adequately meet the growing demands of the diabetes epidemic to prevent or delay this destructive disease.

The research findings that are translated into practice identify and detail the public health implications of results from clinical trials and scientific studies. These findings are applied in health care systems and within local communities. Areas of translational research include: access to quality care for diabetes, especially within managed care organizations; cost-effectiveness of diabetes prevention and control activities; effectiveness of health practices to address risk factors for diabetes; and demonstration of primary prevention of type 2 diabetes.

DDT provides support for 59 state and territorial-based Diabetes Prevention and Control Programs (DPCPs). These programs work to increase outreach and education, and to reduce the complications associated with diabetes. Due to funding constraints, DDT currently funds 28 states at a higher level of support called basic implementation. At this level, states are able to devise and execute community-based programs on a broader scale. The remaining 22 states, 8 territories, and the District of Columbia are funded at the lower, capacity building level. This level of funding establishes a presence in a state, but does not allow them to develop much in the way of intervention. The level of funding proposed by the President's budget would not allow for adequate increases in the amount individual states are provided.

The DDT conducts additional activities which work to eliminate the preventable burden of diabetes and to educate communities. The Diabetes Primary Prevention Initiative, which was created from an initial NIH clinical trial, is an effort to plan and create pilots focusing on health implementation of diabetes primary prevention programs. This program is currently funded in five States as demonstration projects and is expected to end this year. Additional funds would be needed to translate primary prevention in all 50 States.

In a joint cooperative CDC is working with NIH, and over 200 partners, to jointly sponsor the National Diabetes Education Program (NDEP), which seeks to improve the treatment and outcomes of people with diabetes, promote early detection, and prevent the onset of diabetes. In fiscal year 2008 the NDEP focused on minority populations who bear a disproportionate burden of diabetes.

## DIABETES RESEARCH AT THE NATIONAL INSTITUTES FOR HEALTH

The National Institute for Diabetes, Digestive and Kidney Diseases is one of the 27 institutes housed at the NIH. Through its valuable work, NIDDK is poised to make major discoveries that could prevent or reverse the autoimmune destruction of insulin-producing cells. While there is no cure for diabetes, researchers at NIH are working on a variety of projects that represent hope for the millions of individuals with type 1 and type 2 diabetes. The list of advances in treatment and preven-

tion is thankfully long, but it is important to understand what has been, and what can be achieved for Americans with diabetes with additional funding.

A generation ago, 20 percent of individuals diagnosed with type 1 diabetes died within 20 years of diagnosis and over 30 percent died within 25 years. Thanks to research at NIDDK, patients now use a variety of insulin formulations, such as rapid or long acting insulin, insulin pumps, or inhaled insulin to control their blood glucose. Even components of an artificial pancreas are being tested in clinical studies.<sup>9</sup>

Researchers have already learned a great deal about the biology of diabetes, and they now understand much more about the loss of islet cell function. These discoveries have led directly to islet cell transplants, which have given some individuals more than a year of freedom from insulin administration. Scientists are now working on ways to keep the islet cells functioning longer by suppressing the body's natural immune response to the transplanted cells.<sup>10</sup>

Recognizing the growing problem of obesity and its increasing prevalence among youth, the NIDDK is focusing on paths to prevention. The clinical trial, the Diabetes Prevention Program (DPP) focused on discovering whether diet and exercise or an oral diabetes drug could prevent or delay the onset of type 2 diabetes in people with impaired glucose tolerance. The trial found that with modest lifestyle interventions individuals can reduce their risk of developing type 2 diabetes by 58 percent, the oral diabetes medication also reduced risk, although less dramatically.<sup>11</sup>

Additionally, scientists have found that timely laser surgery and appropriate follow-up can reduce the risk of blindness for a person with diabetic retinopathy by 90 percent. This is significant as diabetes is the leading cause of new cases of blindness among adults aged 20–74 years. Another major clinical trial, the Diabetes Control and Complications Trial, showed that intensive glucose control dramatically delays or prevents the eye, nerve, kidney, and heart complications of type 1 diabetes.<sup>12</sup>

#### CONCLUSION

As you are considering the fiscal year 2009 appropriation, we ask you to keep in mind that diabetes is a burgeoning epidemic with a rising morbidity rate that will create a financial and socioeconomic burden of even greater proportion in the very near future. If left unchecked it will overwhelm our healthcare system as well as tragically affect millions of American families. The CDC translational programs and NIH research go hand in hand in the effort to combat the diabetes epidemic. Our Nation can more rapidly move toward curing, preventing, and managing this disease by increasing funding for diabetes education, programs and research.

The American Diabetes Association strongly urges the Subcommittee and the Senate to provide a \$20.8 million increase for the CDC's Division of Diabetes Translation. With 58 percent of type 2 diabetes being preventable this is a smart investment in the well being of our nation. Additionally, we urge the Subcommittee to increase NIH funding by 6.6 percent allowing for a continued and expanded commitment to diabetes research.

We must have a proactive approach to this disease, rather than merely reacting to its consequences. Your continued leadership on this growing epidemic is essential to accomplishing this goal. Again, thank you for your proven commitment to the diabetes community and for the opportunity to submit this testimony. The American Diabetes Association is prepared to answer any questions you might have on these important issues.

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#### PREPARED STATEMENT OF THE AMERICAN HEART ASSOCIATION

Although heart disease and stroke remain our Nation's No. 1 and No. 3 killers respectively, death rates are on the decline. Thanks in large measure to advancements in medical research, treatment and prevention programs, death rates from coronary heart disease have plummeted by almost 26 percent since 1999 and stroke mortality has fallen by 24 percent. If this positive trend holds, a total of 240,000 lives will be spared in 2008 alone.

But while the battle against heart disease and stroke has been successfully joined, the war is far from won. Heart disease, stroke and other forms of cardiovascular disease (CVD) still claim more than 860,000 lives in the United States each year

<sup>9</sup> <http://www.nih.gov/about/researchresultsforthepublic/Type1Diabetes.pdf>

<sup>10</sup> <http://www.nih.gov/about/researchresultsforthepublic/Type1Diabetes.pdf>

<sup>11</sup> <http://diabetes.niddk.nih.gov/dm/pubs/preventionprogram/>

<sup>12</sup> <http://www.nih.gov/about/researchresultsforthepublic/Type2Diabetes.pdf>

and the costs associated with this disease are projected to exceed \$448 billion in 2008. Moreover, any gains we have achieved could be eroded by a rise in often preventable and certainly treatable risk factors, such as high blood pressure, cholesterol, diabetes, obesity and a lack of physical exercise. Continued progress in the fight against CVD is not guaranteed. We must work at it every day through increased research, better access to treatment and reinvigorated prevention efforts.

Sadly, the President's fiscal year 2009 budget turns a blind eye to these challenges. Funding for NIH fails to keep pace with medical research inflation for the sixth year in a row, curtailing work on promising breakthroughs. Increased emphasis on preventing CVD is critical too, but programs that teach Americans how to build healthier lives free of heart disease and stroke are cut or eliminated. Access to quality care and treatment is also jeopardized, by cuts in programs that develop evidence-based information to improve health care outcomes, comparative effectiveness research, and advances in health information technology.

#### FUNDING RECOMMENDATIONS—INVESTING IN THE HEALTH OF OUR NATION

When adjusted for medical research inflation, the NIH budget is roughly 11 percent lower in fiscal year 2008 than in fiscal year 2003, and funding for CVD research is 15 percent lower for that same time period. Prevention also suffers. Funding for the Centers for Disease Control and Prevention's Heart Disease and Stroke Prevention Program and the WISEWOMAN screening and evaluation program are cut. Less than a third of all States receive Federal resources to carry out these critical prevention initiatives.

Where you live could determine if you survive a sudden cardiac arrest. The Rural and Community Access to Emergency Devices Program provides grants to rural areas and communities to buy automated external defibrillators (AEDs), place these life-saving devices in schools, churches, fire stations and other sites, and train lay rescuers and first responders in their use. This successful program is terminated in the President's budget.

With CVD risk factors on the rise, it is clearly not the time to retreat and slash investments that prevent and treat America's leading and most costly killer. If we fail to take deliberate and focused action now, we will pay much more in the future in lost lives and higher health care costs. Our recommendations address this crisis in a comprehensive but fiscally responsible way.

#### *Funding Gap for the National Institutes of Health (NIH)*

NIH-supported research has revolutionized patient care and holds the key to finding new ways to prevent, treat and cure CVD, resulting in longer, healthier lives and lower health care costs. NIH research also generates economic growth and preserves our Nation's position as the world leader in pharmaceuticals and biotechnology. However, the President's fiscal year 2009 budget request for NIH is flat. When adjusted for medical research inflation, the gap between the funding levels achieved with the doubling of NIH's budget between 1999 and 2003 and the current request now approaches a 14 percent decline in support for the NIH.

*The American Heart Association Recommends.*—AHA joins the research and patient advocacy communities in advocating for a fiscal year 2009 appropriation of \$31.1 billion for NIH, representing a 3 percent increase over the 3.5 percent in medical research inflation for a total funding increase of 6.5 percent. This 3 percent increase over medical research inflation is consistent with the average NIH appropriation over the past 30 years (excluding the "doubling" period). Such a sustained and stable funding stream will allow NIH to take advantage of burgeoning scientific opportunities and protect past congressional investments in research that have saved millions of lives.

#### *Increase Funding for NIH Heart and Stroke Research: A Proven and Wise Investment*

The decline in the death rates from CVD can be directly linked to NIH heart and stroke research—with more life-saving treatments and prevention tactics on the horizon. For example, recent NIH research has determined that post-menopausal hormone therapy is not useful in the prevention of heart disease and stroke, has defined the genetic basis of dangerous responses to essential blood-thinners, and funded the early work of the 2007 Nobel Prize winners in Physiology or Medicine for their development of the technology of gene targeting.

Beyond lives saved, NIH research also produces tangible cost savings. For example, the original NIH tPA drug trial resulted in a 10-year net \$6.47 billion reduction in stroke health care costs. And the Stroke Prevention in Atrial Fibrillation Trial 1 produced a 10-year net saving of \$1.27 billion. But despite such solid returns on investments and other successes, NIH heart and stroke research remains disproportional.

tionately under-funded. In fact, only 7 percent of its budget goes to heart disease research, and a mere 1 percent is devoted to stroke. That must change.

*Cardiovascular Disease Research: National Heart, Lung, and Blood Institute (NHLBI)*

Under the President's budget proposal, funding for CVD research does not keep pace with medical research inflation and cannot adequately support current activities or allow investments in promising research opportunities. The loss of purchasing power over the past few years has reduced the ability of the NHLBI to fund meritorious investigator-initiated research and has necessitated cutbacks in Institute programs. Continued cutbacks will limit the pace at which the new NHLBI strategic plan can be implemented. Areas in which research could lag include the ability to translate basic research on human behavior into real world ways to reduce obesity and promote cardiovascular health; studies examining genetic susceptibility in the Framingham population, followed for three generations, and further research into the best methods for saving lives of those suffering from cardiac arrest.

*Stroke Research: National Institute of Neurological Disorders and Stroke (NINDS)*

An estimated 780,000 Americans will suffer a stroke this year, and more than 143,000 will die. Many of the 5.8 million stroke survivors face physical and mental disabilities, emotional distress and huge costs—a projected \$66 billion in medical expenses and lost productivity in 2008.

The NINDS-sponsored Stroke Progress Review Group has issued a long-term, stroke research strategic plan. A variety of research initiatives have since been undertaken, but more funding is needed to fully implement the plan. Indeed, the fiscal year 2009 request for NINDS stroke research falls about 50 percent short of the plan's target and additional resources are needed for programs such as:

- Stroke Translational Research.*—Translational studies are essential to providing cutting-edge stroke treatment, patient care and prevention. However, due to budget shortfalls, NINDS has been forced to scale back by 30 percent its Specialized Programs of Translational Research in Acute Stroke from a planned 10 centers to only 7.
- Genetic Repository.*—NINDS could better understand genetic risk factors associated with stroke by helping more researchers contribute data and findings to an NIH-funded genetic repository and to study available samples.
- Neurological Emergencies Treatment Trials Network.*—NINDS has established a clinical research network of emergency medicine physicians, neurologists and neurosurgeons to develop more and improved treatments for acute neurological emergencies, such as strokes. However, the number of trials will be limited by available funding.

*The American Heart Association Recommends.*—AHA supports an fiscal year 2009 appropriation of \$2.260 billion for NIH heart research; \$3.112 billion for the NHLBI; \$362 million for NIH stroke research; and \$1.644 billion for the NINDS. This represents a 6.5 percent increase over fiscal year 2008—commensurate with the Association's overall recommended funding increase for NIH.

*Increase Funding for the Centers for Disease Control and Prevention (CDC)*

With so many risk factors on the rise, prevention is the best way to protect the health of Americans and ease the economic burden of heart disease and stroke. However, many effective prevention strategies and programs are not being implemented for lack of funds.

For example, CDC's Division for Heart Disease and Stroke Prevention funds only 13 States to implement programs to reduce risk factors for heart disease and stroke, improve emergency response and quality care, and end treatment disparities. An additional 20 States receive funds for planning such prevention programs; however, there are no funds for actual implementation.

This Division also administers the WISEWOMAN program that screens uninsured, under-insured and low-income women ages 40 to 64 in 14 States for heart disease and stroke risk. They receive counseling, education, referral and follow-up as needed. Since January 2000, more than 70,000 women have been screened and more than 170,000 lifestyle interventions have been conducted. The program should be expanded to cover the other 36 States, but the President's budget contains no such funding.

*The American Heart Association Recommends.*—AHA joins with the CDC Coalition in support of an appropriation of \$7.4 billion for CDC, including increases for the Heart Disease and Stroke Prevention and WISEWOMAN programs. Within that total, we recommend \$70 million for the Heart Disease and Stroke Prevention Program, allowing CDC to: (1) add nine unfunded States to develop State-tailored plans; (2) increase funding for up to 18 States with current Heart Disease and



Stroke Prevention Programs; (3) continue to support the remaining funded States; (4) maintain the Paul Coverdell National Acute Stroke Registry; (5) increase the capacity for national, State and local heart disease and stroke surveillance; and (6) provide additional assistance for prevention research and program evaluation. AHA also advocates \$25 million to expand WISEWOMAN to additional States and joins with the Friends of the NCHS in recommending \$125 million for NCHS to restore funding lost and to continue the collection of important public health data.

*Restore Funding for Rural and Community Access to Emergency Devices (AED) Program*

About 94 percent of cardiac arrest victims die outside of a hospital. Receiving immediate CPR and the use of an AED can more than double your chance of survival over CPR alone. Communities with comprehensive AED programs have achieved survival rates of 40 percent or higher. The Rural and Community AED Program provides grants to States to buy and place AEDs and train lay rescuers and first responders to use them. During its first year, 6,400 AEDs were purchased, and placed and 38,800 individuals were trained. Despite this success, the President yet again terminates the program in his proposed fiscal year 2009 budget.

*The American Heart Association Recommends.*—For fiscal year 2009, AHA advocates restoring the 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 helps develop evidence-based information to improve health care decision-making. Through its Effective Health Care Program, AHRQ supports research focused on outcomes, comparative clinical effectiveness and the appropriateness of pharmaceuticals, devices and health care services for conditions such as heart disease, stroke and high blood pressure.

On another front, AHRQ's health information technology (HIT) plan will help bring health care into the 21st century. Through more than \$130 million in grants since 2004, AHRQ and its partners have begun work that can help identify: challenges to HIT adoption and use; solutions and best practices; and tools that aid hospitals and clinicians successfully integrate HIT. This must continue.

*The American Heart Association Recommends.*—AHA joins with Friends of AHRQ in advocating a \$360 million appropriation for the Agency. By restoring AHRQ to fiscal year 2005 levels, we can improve health care, reduce medical errors and expand access to outcomes information.

CONCLUSION

Although heart disease, stroke and other forms of cardiovascular disease are largely preventable, they continue to exact a deadly and costly toll on our nation. However, adequate funding of research, treatment and prevention programs will save lives and reduce rising health care costs. The American Heart Association urges Congress to consider these recommendations during its deliberations on the fiscal year 2009 budget. We believe that they are a wise investment for our nation and the health and well-being of this and future generations of Americans.

PREPARED STATEMENT OF THE AMERICAN INDIAN HIGHER EDUCATION CONSORTIUM

*Summary of Requests.*—Summarized below are the fiscal year 2009 (fiscal year 2009) recommendations for the Nation's 36 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

*A. Higher Education Act Programs*

*Strengthening Developing Institutions.*—Section 316 of Title III-A, specifically supports TCUs through two separate competitive grant programs: (a) basic development grants and (b) facilities/construction grants designed to address the critical facilities needs at TCUs. The TCUs urge the subcommittee to reject the President's fiscal year 2009 budget recommendation to eliminate discretionary funding for this vital program and instead appropriate \$32.0 million and include report language restating that funds not needed to support continuation grants or new planning or implementation grants shall be used for facilities, renovation, and construction grants.

*Pell Grants.*—TCUs urge the subcommittee to fund the Pell Grants Program at the highest possible level.

*B. Perkins Career and Technical Education Programs*

The TCUs urge the subcommittee to reject the funding cut proposed in the President's budget and appropriate \$8.5 million for Sec. 117 of the Carl D. Perkins Career and Technical Education Improvement Act, which funds our two Tribally Controlled Postsecondary Vocational Institutions: United Tribes Technical College and Navajo Technical College. Additionally, TCUs strongly support the Native American Career and Technical Education Program (NACTEP) authorized under Sec. 116 of the Act.

*C. Relevant Title IX Elementary and Secondary Education Act (ESEA) Programs*

*Adult and Basic Education.*—Although Federal funding for tribal adult education was eliminated in fiscal year 1996, TCUs continue to offer much needed adult education, GED, remediation and literacy services for American Indians, yet their efforts cannot meet the demand. The TCUs request that the subcommittee direct \$5.0 million of the Adult Education State Grants appropriated funds to make awards to TCUs to support their ongoing and essential adult and basic education programs.

*American Indian Teacher and Administrator Corps.*—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 support these programs at \$10.0 and \$5.0 million, respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES PROGRAM

*D. 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 are working to meet the mandate that Head Start teachers earn degrees in Early Childhood Development or a related discipline. The TCUs request that \$5.0 million be designated for the TCU-Head Start partnership program, to ensure the continuation of current programs and the resources needed to support additional TCU-Head Start partnership programs.

DETAILED JUSTIFICATIONS FOR FISCAL YEAR 2009 APPROPRIATIONS REQUESTS FOR  
TRIBAL COLLEGES AND UNIVERSITIES

*Higher Education Act*

The Higher Education Act Amendments of 1998 created a separate section (§316) within Title III—A 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. Although TCUs, which are truly developing institutions, are providing access to quality higher education opportunities to some of the most rural and impoverished areas of the country, the President's fiscal year 2009 budget proposes eliminating all discretionary funding for the TCU Title III grants program. TCUs recognize and are grateful for the positive step that Congress took by including in the fiscal year 2008 Reconciliation Act much needed supplemental funding for Title III and Title V programs, including the TCU program. The fiscal year 2009 budget recommendation effectively negates this progress by eliminating discretionary funding needed to fund multi-year development grants. We believe it was the intent of Congress to supplement the Title III program funds, NOT to supplant discretionary funding for the very institutions that disproportionately educate low-income chronically underserved populations. A clear 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 program is specifically designed to address the critical, unmet needs of their American Indian students and communities, in order to effectively prepare them for the workforce of the 21st Century. The TCUs urge the subcommittee to reject the President's budget recommendation to eliminate discretionary funding and appropriate \$32.0 million in fiscal year 2009 for Title III—A section 316, an increase of \$8.8 million over fiscal year 2008 and \$32.0 million over the President's request. These funds will afford these developing institutions the resources necessary to continue their ongoing grant programs and address the needs of their historically underserved students and communities. Additionally, we request that report language be restated clarifying that funds not necessary to support continuation grants or new planning or implementation grants shall be used for facilities, renovation, and construction grants to ensure TCUs will be able to operate in adequate and safe facilities.

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 tribal college 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 fund this critical grants program at the highest possible level.

*B. Carl D. Perkins Career & Technical Education Act*

Tribally-Controlled Postsecondary Vocational Institutions: Section 117 of the Perkins Act provides basic operating funds for two of our member institutions: United Tribes Technical College in Bismarck, North Dakota, and Navajo Technical College in Crownpoint, New Mexico. The TCUs urge the subcommittee to reject the President's budget proposal to eliminate funding for this program and to appropriate \$8.5 million.

*Native American Career and Technical Education Program.*—The Native American Career and Technical Education Program (NACTEP) under Sec. 116 of the Act reserves 1.25 percent of appropriated funding to support Indian vocational programs. The TCUs strongly urge the subcommittee to continue to support NACTEP, which is vital to the survival of vocational education programs being offered at Tribal Colleges and Universities.

*C. 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 TCUs, State and local education agencies, Indian tribes, institutions, and agencies. Despite a lack of funding, TCUs must find a way to continue to provide 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. The number of students in need of remedial education before embarking on their degree programs is considerable at TCUs. There is a broad need for basic adult educational programs and TCUs need adequate funding to support these essential activities. TCUs respectfully request that the subcommittee direct \$5.0 million of the Adult Education State Grants appropriated funds to make awards to TCUs to help meet the ever increasing demand for basic adult education and remediation program services.

*American Indian Teacher/Administrator Corps (Special Programs for Indian Children).*—American Indians are severely under represented in the teaching and school administrator ranks nationally. These competitive programs are designed to produce new American Indian teachers and school administrators for schools serving American Indian students. These grants support recruitment, training, and in-service professional development programs for Indians to become effective teachers and school administrators and in doing so become excellent role models for Indian children. We believe that the TCUs are the 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 awarding institutions. The TCUs request that the subcommittee support these two programs at \$10.0 million and \$5.0 million, respectively, to increase the number of qualified American Indian teachers and school administrators in Indian Country.

DEPARTMENT OF HEALTH AND HUMAN SERVICES/ADMINISTRATION FOR CHILDREN & 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. Graduates of these programs help meet the degree mandate for all Head Start program teachers. More importantly, this program has afforded American Indian children Head Start programs of the highest quality. A clear impediment to the ongoing success of this partnership program is the erratic availability of discretionary funds made available for the TCU-Head Start Partnership. In fiscal year 1999, the first year of the program, some colleges were awarded 3-year grants, others 5-year grants. In fiscal year 2002, no new grants were awarded. In fiscal year 2003, funding for eight new TCU grants was made available, but in fiscal year 2004, only two new awards could be made because of the lack of ade-

quate funds. The President's fiscal year 2009 budget includes a total request of \$7,026,571,000 for Head Start Programs. The TCUs request that the subcommittee direct the Head Start Bureau to designate a minimum of \$5.0 million, of the over \$7.0 billion recommended in the budget, for the TCU-Head Start Partnership program, to ensure that this critical program can continue and expand so that all TCUs have the opportunity to participate in the TCU-Head Start partnership program.

#### CONCLUSION

Tribal Colleges and Universities are providing access to 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 investment makes sound moral and fiscal sense. TCUs need your help if they are to sustain and grow their programs and achieve their missions to serve their students and communities.

Thank you again for this opportunity to present our funding recommendations. 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 2009 appropriations needs and recommendations.

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#### PREPARED STATEMENT OF THE AMERICAN LIVER FOUNDATION

Mr. Chairman and members of the subcommittee, thank you for giving the American Liver Foundation the opportunity to testify as the subcommittee begins to consider funding priorities for fiscal year 2009. My name is Dr. James L. Boyer and I am the Chairman of the Board of Directors of the American Liver Foundation (ALF), a national voluntary health organization dedicated to the prevention, treatment and cure of hepatitis and other liver diseases through research, education and advocacy. I am also the Ensign Professor of Medicine and Director of the Liver Center at Yale University School of Medicine.

ALF has 25 Chapters nationwide and provides information to 300,000 patients and families. Over 70,000 physicians, including primary care practitioners and liver specialists and scientists also receive information from ALF. The ALF Board of Directors is composed of scientists, clinicians, patients and others who are directly affected by liver diseases. Every year ALF handles over 100,000 requests for information, helping patients and their families understand their illnesses, informing them about available services, and showing them that there are knowledgeable and concerned individuals to assist them in every possible way.

Mr. Chairman, ALF joins the Ad Hoc Group for Medical Research Funding, a coalition of some 300 patient and voluntary health groups, medical and scientific societies, academic research organizations and industry, in recommending \$31.1 billion (6.5 percent increase) for the National Institutes of Health in fiscal year 2009. The fiscal year 2009 Administration budget request for NIH is flat compared to fiscal year 2008 funding levels, which due to the effects of biomedical inflation, translates to a cut. If the President's budget were implemented, this funding level would mean NIH's ability to conduct and support life-saving research will be cut by more than 11 percent in inflation-adjusted dollars since fiscal year 2003.

While the ALF 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 than proposed by the Administration. To ensure that NIH's momentum is not further eroded, and to ensure the fight against diseases and disabilities that affect millions of Americans can continue, ALF supports a minimum increase of 6.5 percent for the NIH in fiscal year 2009 and a minimum increase of a 6.5 percent for the National Institute for Diabetes and Digestive and Kidney Diseases and for liver disease research across all NIH Institutes.

In addition to the NIH, there are a number of programs within the jurisdiction of the subcommittee that are important to ALF including the Centers for Disease Control's Division of Viral Hepatitis and HRSA's Division of Transplantation. Mr. Chairman, our specific recommendations for these and other areas of interest are summarized in a table at the end of this statement.

#### RECOGNIZING THE LEADERSHIP OF THE SUBCOMMITTEE

Mr. Chairman, ALF appreciates your leadership and the leadership of this subcommittee in supporting NIH in a time of fiscal austerity. Your leadership in supporting CDC and HRSA's Division of Transplantation are also greatly recognized and appreciated. These programs are important to our shared goals of improving the

public health response to the threats of hepatitis and liver disease and to increasing the rate of organ donation. We applaud the Committee's leadership in making progress in these important areas and to allocating increased funding to these programs during periods of fiscal austerity.

#### RECOGNIZING THE LEADERSHIP OF THE NIH

Mr. Chairman, I would also like to take this opportunity to commend the leadership of NIH, and especially the leadership of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for their strong support of liver disease research. In the summer of 2002, a member of the House Labor-HHS Subcommittee, Congressman Dan Miller, introduced a piece of legislation titled the Liver Disease Research Enhancement Act. The legislation, reintroduced in the 110th Congress by Congressmen Stephen Lynch and Peter King, was introduced after several months of deliberation and consultation with the leadership of NIH, with the intention of creating a center within NIDDK focused solely on liver and liver-related diseases. This bill will streamline the study and funding of liver disease research by creating a Liver Disease Research Advisory Board that will include preeminent scientists at the NIH, and from across the country to develop a Liver Disease Research Action Plan to guide future NIH funding decisions and help the liver research community prioritize research efforts. In addition the bill provides new authorities necessary to help insure that the scientific opportunities identified by the Liver Disease Research Action Plan are adequately funded.

After the bill was first introduced, the NIH independently implemented many of the provisions of this legislation, including the establishment of a Liver Disease Branch and the creation of a Liver Disease Research Action Plan, which the NIH continues to update each year. The Research Action Plan is an important blueprint for the future of liver disease research; however, ALF is concerned that without the authorities included in the legislation, implementation of the plan will proceed slowly. We recommend the Liver Research Enhancement Act to the subcommittee as necessary steps needed to improve the rate of scientific discovery thus leading to cures and better treatment for liver disease.

We would also like to commend the leadership of the NIDDK on their decision to host a consensus conference focused on best treatment practices for individuals with hepatitis B. The growing number of treatment options is encouraging and suggests a strong rationale for conducting a consensus conference to provide state of the art treatment guidelines for the practicing physician community.

#### FUNDING THE LIVER DISEASE RESEARCH ACTION PLAN

Mr. Chairman, in December 2004, the NIDDK released the Liver Disease Research Action Plan outlining major research goals for the various aspects of liver disease. Working with the leading scientific experts in the field, the plan is organized into 16 chapters and identifies numerous areas of research important to virtually every aspect of liver disease, including: improving the success rate of therapy of hepatitis C; developing noninvasive ways to measure liver fibrosis; developing sensitive and specific means of screening individuals at high risk for early hepatocellular carcinoma; developing standardized and objective diagnostic criteria for major liver diseases and their grading and staging; and decreasing the mortality rate from liver disease. Each year, the plan is reviewed and updated. The ALF urges the Committee to provide adequate funding and policy guidance to NIH to urge continued implementation of the plan.

#### CDC'S DIVISION OF VIRAL HEPATITIS

ALF joins with the CDC Coalition, a nonpartisan coalition of more than 100 groups, in supporting \$7.4 billion for the Centers for Disease Control and Prevention in fiscal year 2009. The CDC programs are crucial to the health of millions of Americans, they are key to maintaining a strong public health infrastructure, and are essential in protecting us from threats to our health. At a time when the CDC is facing unprecedented challenges and responsibilities ranging from chronic disease prevention, eliminating health disparities, bioterrorism preparedness, to combating the obesity epidemic the administration's budget has cut the CDC's budget by \$412 million. We urge the committee to restore this cut and fund the CDC at \$7.4 billion. Within that amount, we further request that the Committee provide a \$5 million increase for the Division of Viral Hepatitis.

The Division of Viral Hepatitis (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, a disease which impacts over 6 million Americans and often leads to liver cancer and liver failure. The DVH provides the

scientific and programmatic foundation for the prevention, control and elimination of hepatitis virus infections in the United States and also assists the international public health community in these activities. DVH works with State and local health departments to provide the guidance and technical expertise needed to integrate hepatitis prevention services such as hepatitis A and B vaccine, hepatitis B and C counseling, and testing and referral to existing public health programs serving individuals at high risk.

Mr. Chairman, ALF requests that an increase of \$5 million, be included to address the public health crisis of Hepatitis A, B & C and the large growing HIV co-infection rates.

#### INCREASING THE SUPPLY OF ORGANS FOR DONATION

As the subcommittee knows, even with advances in the use of living liver donors, the increase in the demand for livers needed for transplantation will continue to exceed the number available. The need to increase the rate of organ donation is critical. Each day approximately 78 people receive an organ transplant, but another 18 people die because organ demand far outweighs the supply and the gap continues to widen. For example, in 2007, while 5,940 liver transplants were performed, there were over 17,122 individuals on the list waiting for liver transplantations and about 1,421 people died due to the lack of a donor liver. Despite this demonstrated need, the Division of Transplantation has received cuts or level funding over the past four fiscal years.

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, no additional funding has been provided to implement this legislation. To address these needs, ALF recommends that the Division of Transplantation receive a \$2 million increase in fiscal year 2009.

#### SUMMARY AND CONCLUSION

Mr. Chairman, again we wish to thank the subcommittee for its past leadership. Significant progress has been made in developing better treatments and cures for the diseases that affects mankind due to your leadership and the leadership of your colleagues on this subcommittee. Significant progress has also similarly been made in the fight against liver disease. For fiscal year 2009 we recommend a 6.5 percent, increase for NIH above the level of the fiscal year 2008 funding levels, with the level of liver disease research also increased by at least 6.5 percent. We also urge a \$5 million increase for CDC to strengthen the public health response to hepatitis and liver disease and a \$2 million increase to HRSA's Division of Transplantation necessary to increase the rate of organ donation. Mr. Chairman, if this country is to maintain its leadership role in health maintenance, disease prevention, and the curing of diseases, adequate funding for NIH, CDC and HRSA is paramount. The ALF appreciates the opportunity to provide testimony to you on behalf of our constituents and yours.

#### ALF RECOMMENDATIONS FOR FISCAL YEAR 2009 FUNDING

##### *NIH and the Liver Disease Research Action Plan*

- 6.5 percent increase for NIH overall and 6.5 percent for the National Institute of Diabetes and Digestive and Kidney Diseases;
- +\$25 million to implement the Liver Research Action Plan

##### *CDC: National Hepatitis C Prevention Strategy, Public Health Information, HAV & HBV Vaccinations*

- +\$5 million to support expansion of CDC's National Hepatitis C Prevention program;
- +\$1 million to increase the public health information regarding liver diseases.

##### *HRSA: Expanding the supply of organs*

- +\$2 million to start funding the Organ Donation and Recovery Act provisions.

## PREPARED STATEMENT OF THE AMERICAN LUNG ASSOCIATION

## SUMMARY.—FUNDING RECOMMENDATIONS

[In millions of dollars]

	Amount
National Institutes of Health .....	31,129
National Heart, Lung, and Blood Institute .....	3,114
National Cancer Institute .....	5,117
National Institute of Allergy and Infectious Disease .....	4,675
National Institute of Environmental Health Sciences .....	683
National Institute of Nursing Research .....	146
Fogarty International Center .....	70
Centers for Disease Control and Prevention .....	10,700
Chronic Disease Prevention & Health Promotion: COPD Activities .....	6
National Institute for Occupational Safety and Health .....	285
Office on Smoking and Health .....	145
Environmental Health: Asthma Activities .....	70
Tuberculosis Control Programs .....	300
Influenza Pandemic .....	1,169

The American Lung Association is pleased to present our recommendations to the Labor Health and Human Services and Education Appropriations Subcommittee. These programs will improve and extend the lives of millions of Americans who suffer from lung disease.

The American Lung Association is one of the oldest voluntary health organizations in the United States, with a National Office and local associations around the country. Founded in 1904 to fight tuberculosis, the American Lung Association today fights lung disease in all its forms.

## THE TOLL OF LUNG DISEASE

Each year, close to 400,000 Americans die of lung disease. Lung disease is America's number three killer, responsible for one in every six deaths. More than 35 million Americans suffer from a chronic lung disease. Each year lung disease costs the economy an estimated \$157.8 billion. Lung diseases include: asthma, chronic obstructive pulmonary disease, lung cancer, tuberculosis, pneumonia, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease and sarcoidosis.

## CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Chronic Obstructive Pulmonary Disease, or COPD, is a growing health problem. Yet, it remains relatively unknown to most Americans. COPD refers to a group of largely preventable diseases, including emphysema and chronic bronchitis that generally gradually limit the flow of air in the body. COPD is the fourth leading cause of death in the United States and worldwide. In 2007, the annual cost to the nation for COPD was \$42.6 billion. This includes \$26.7 billion in direct health care expenditures, \$8.0 billion in indirect morbidity costs and \$7.9 billion in indirect mortality costs. Medicare expenses for COPD beneficiaries were nearly 2.5 times that of the expenditures for all other patients.

It has been estimated that 12.6 million patients have been diagnosed with some form of COPD and as many as 24 million adults may suffer from its consequences. In 2004, 118,171 people in the U.S. died of COPD. Women have exceeded men in the number of deaths attributable to COPD since 2000. Over the past 30 years, the death rate due to COPD has doubled while the death rates for heart disease, cancer and stroke have decreased by over 50 percent.

Today, COPD is treatable but not curable. Fortunately, promising research is on the horizon for COPD patients. Research on the genetic susceptibility underlying COPD is making progress. Research is also showing promise for reversing the damage to lung tissue caused by COPD. Despite these promising research leads, the American Lung Association believes that research resources committed to COPD are not commensurate with the impact COPD has on the United States and the World.

The American Lung Association strongly supports the establishment of a national COPD program within CDC's National Center for Chronic Disease Prevention and Health Promotion with a funding level of \$6 million for fiscal year 2009 to expand surveillance activities and create a comprehensive national action plan for com-

bating COPD. This must occur if the nation is to begin to address this critical public health problem.

The American Lung Association strongly recommends that the NIH and other Federal research programs commit additional resources to COPD research programs. We support increasing the National Heart, Lung and Blood Institute budget to \$3,114 billion.

#### TOBACCO USE

Tobacco use is the leading preventable cause of death in the United States, killing more than 438,000 people every year. Smoking is responsible for one in five U.S. deaths. The direct health care and lost productivity costs of tobacco-caused disease and disability are also staggering, an estimated \$167 billion each year.

The CDC's Office on Smoking and Health provides significant technical assistance to States to develop comprehensive and effective tobacco prevention programs, in addition to providing a small, yet essential, amount of Federal assistance directly to State tobacco control and prevention programs. Funds for tobacco prevention at CDC also are used to maintain comprehensive information on smoking and health and to support ongoing research on tobacco-related issues.

We believe Congress should fund the type of youth tobacco prevention programs that science tells us are essential to counter the impact of tobacco company marketing to our kids. The American Lung Association strongly supports a minimum level of \$145 million in fiscal year 2009 funding for the Office on Smoking and Health.

#### ASTHMA

Asthma is a chronic lung disease in which the bronchial tubes become swollen and narrowed, preventing air from getting into or out of the lung. An estimated 34.1 million Americans have ever been diagnosed with asthma by a health professional. Approximately 22.9 million Americans currently have asthma, of which 12.4 million had an asthma attack in 2006. Asthma prevalence rates are almost 24 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 Hispanic subgroups.

Asthma is expensive. Asthma incurs an estimated annual economic cost of \$14.7 billion to our nation. Asthma is the third leading cause of hospitalization among children under the age of 15. It is also the number one cause of school absences attributed to chronic conditions. The Federal response to asthma has three components: research, programs and planning. We are making progress on all three fronts but more must be done:

##### *Asthma Research*

Researchers are developing better ways to treat and manage chronic asthma. The NHLBI has shown that using corticosteroids to treat children with mild to moderate asthma is safe and effective. Genetic research is also providing insights into asthma. Researchers in the NHLBI-supported Asthma Clinical Research Network have discovered that a genetic variation determines how well asthma patients will respond to the most common asthma medication, inhaled beta-agonists. This discovery will help physicians better target the drugs they prescribe.

##### *Asthma Programs*

Last year, Congress provided approximately \$31.3 million for the CDC to conduct asthma programs. The American Lung Association recommends that CDC be provided \$70 million in fiscal year 2009 to expand its asthma programs. This funding includes State asthma planning grants, which leverage small amounts of funding into more comprehensive State programs.

##### *Asthma Surveillance*

In addition to public education programs, the CDC has been piloting programs to determine how to establish a nationwide health-tracking system. Congress needs to increase funding to create a nationwide health-tracking system, based on the localized pilots that are underway now.

#### LUNG CANCER

An estimated 351,344 Americans are living with lung cancer. During 2007, an estimated 213,380 new cases of lung cancer will be diagnosed. Also, 160,390 Americans will die from lung cancer. Survival rates for lung cancer tend to be much lower than those of most other cancers. Men have higher rates of lung cancer than women.



However, over the past 30 years, the lung cancer age-adjusted incidence rate has decreased 9 percent in males compared to an increase of 143 percent in females. Further, African Americans are more likely to develop and die from lung cancer than persons of any other racial group.

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 research programs. We support increasing the National Cancer Institute budget to \$5.117 billion.

#### INFLUENZA

Influenza is a highly contagious viral infection and one of the most severe illnesses of the winter season. It is responsible for an average of 200,000 hospitalizations and 36,000 deaths each year. Further, the emerging threat of a pandemic influenza is looming. Public health experts warn that over half a million Americans could die and over 2.3 million could be hospitalized if a moderately severe strain of a pandemic flu virus hits the United States. To prepare for a potential pandemic, the American Lung Association supports funding the Federal Pandemic Influenza Plan at the recommended level of \$1.169 billion.

#### 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 2007, there were 13,293 cases of active TB reported in the United States. While declining overall TB rates are good news, the emergence and spread of multi-drug 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 to \$300 million for fiscal year 2009.

The NIH also has a prominent role to play in the elimination of TB. Currently there is no highly effective vaccine to prevent TB transmission. However, the recent sequencing of the TB genome and other research advances has put the goal of an effective TB vaccine within reach. In addition, the American Lung Association encourages the subcommittee to fully fund the TB vaccine blueprint development effort at the NIAID.

#### *Fogarty International Center TB Training Programs*

The Fogarty International Center 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 care professionals in the area of TB treatment and research. The American Lung Association recommends Congress provide \$70 million for FIC to expand the TB training grant program from a supplemental grant to an open competition grant.

#### ENVIRONMENTAL HEALTH

The National Institute of Environmental Health Sciences funds vital research on the impact of environmental influence on disease. The American Lung Association supports increasing the appropriation from this subcommittee to \$680 million.

#### RESEARCHING AND PREVENTING OCCUPATIONAL LUNG DISEASE

The American Lung Association recommends that the subcommittee provide \$285 million for the National Institute for Occupational Safety and Health (NIOSH) at the CDC.

#### CONCLUSION

In conclusion, Mr. Chairman, lung disease is a continuing, growing problem in the United States. It is America's number three killer, responsible for one in seven deaths. The lung disease death rate continues to climb. Mr. Chairman, 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 AND THE UNITED NATIONS FOUNDATION

Chairman Harkin, Senator Specter, 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.

In 2001, CDC—along with the American Red Cross, the United Nations Foundation, the World Health Organization, and UNICEF—became one of the spearheading partners of the Measles Initiative, a partnership committed to reducing measles deaths globally. The current U.N. goal is to reduce measles deaths by 90 percent by 2010 compared to 2000 estimates. The Measles Initiative is committed to reaching this goal by providing technical and financial support to governments and communities worldwide.

The Measles Initiative has achieved “spectacular”<sup>1</sup> results by supporting the vaccination of more than 500 million children. Largely due to the Measles Initiative, global measles mortality dropped 68 percent, from an estimated 757,000 deaths in 2000 to 242,000 in 2006. During this same period, measles deaths in Africa fell by 91 percent, from 396,000 to 36,000.

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 \$635 million and provided technical support in more than 50 developing countries on vaccination campaigns, surveillance and improving routine immunization services. During the period 2001–2006, the donor investment of 429 million USD resulted in the prevention of 2.3 million deaths, i.e. 184 USD per 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 opportunities 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 undernourished children), de-worming medicine, 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 31 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.

Countries are well positioned to achieve the 2010 goal and to take a bold step towards achievement of the 2015 Millennium Development Goal #4 of reducing under-five child mortality. The Measles Initiative is now supporting the full implementation of measles mortality reduction activities in South Asia, where the measles burden remains high. In addition, The Initiative is continuing efforts in Africa to sustain and improve on the current success. Achieving these goals will require the continued and expanded support of CDC for the purchase of vaccine and the provision of technical expertise.

By controlling measles cases in other countries, U.S. children are also being protected from the disease. A major 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 ROLE OF CDC IN GLOBAL MEASLES MORTALITY REDUCTION

Since fiscal year 2001, Congress has provided approximately \$42 million annually in funding to CDC for global measles control activities. These funds were used toward the purchase of more than 400 million doses of measles vaccine for use in large-scale measles vaccination campaigns in more than 50 countries in Africa and Asia, and for the provision of technical support to Ministries of Health in those countries. Specifically, this technical support includes:

<sup>1</sup>The Lancet, Volume 8, page 13 (January 2008).

- 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 6 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 provide solutions to complex problems that help critical work get done faster and more efficiently.

In fiscal year 2008, Congress has appropriated approximately \$41.8 million to fund CDC for global measles control activities. The American Red Cross and the United Nations Foundation thank Congress for the financial support that has been provided to CDC in the past and this year. We respectfully request a total of \$51.8 million for fiscal year 2009 funding for CDC's measles control activities so that the gains made to date can continue and the 2010 goal of a 90 percent reduction in measles deaths can be achieved.

The additional funds we are seeking for CDC are critical for:

- Sustaining the great progress in measles mortality reduction in Africa by strengthening measles surveillance and strengthening the delivery of measles vaccine through routine immunization services to protect new birth cohorts;
- Conducting large-scale measles vaccination campaigns in South Asia, especially in India, thus protecting millions of children;
- Conducting nationwide measles vaccination campaigns in countries, such as the Philippines, lacking access to traditional and new funding sources.

Your commitment has brought us unprecedented victories in reducing measles mortality around the world. Measles can cause severe complications and death. It's important to note that measles control globally also protects children in the United States from the disease. The Americas as a region eliminated endemic measles in 2002, but each year countries in the region have outbreaks of imported measles cases. These outbreaks cause needless suffering and accrue public health costs which in the United States are upwards of \$150,000 to respond to each case. Therefore, 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 AMERICANS FOR NURSING SHORTAGE RELIEF

The undersigned organizations of the ANSR Alliance greatly appreciate the opportunity to submit written testimony regarding fiscal year 2009 appropriations for Title VIII—Nursing Workforce Development Programs. The ANSR Alliance is comprised of 51 national nursing organizations that united in 2001 to identify and promote creative strategies for addressing the nursing and nurse faculty shortages, including passage of the Nurse Reinvestment Act of 2002.

The ANSR Alliance stands ready to work with lawmakers to advance programs and policy that will sustain and strengthen our Nation's nursing workforce. To ensure that our Nation has a sufficient and adequately prepared nursing workforce to provide quality care to all well into the 21st century, ANSR urges Congress to:

- Appropriate at least \$200 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 2009.
- Restore the Advanced Education Nursing program (Sec. 811) and fund it at a level on par with the proposed fiscal year 2009 increase for the other Title VIII programs.

## NURSING SHORTAGE

Nursing is one of the largest health care professions with an estimated 2.9 million licensed RNs in the United States.<sup>1</sup> Nurses work in a variety of settings, including public health, long-term care, and hospitals. Advanced practice nurses (nurse practitioners, nurse midwives, clinical nurse specialists, and certified registered nurse anesthetists) practice in numerous settings, including primary care, hospitals, and surgical care facilities. Approximately three out of five jobs are in hospitals.<sup>2</sup> A Federal report published in 2004 estimates that by 2020 the national nurse shortage will increase to more than 1 million full-time nurse positions. According to these projections, which are based on the current rate of nurses entering the profession, only 64 percent of projected demand will be met.<sup>3</sup> A 2007 study that uses different assumptions published in *Health Affairs* has adjusted the demand projection to 340,000 nurses by 2020.<sup>4</sup> In either scenario, the shortage presents an extremely serious challenge to health care access and quality patient care. Even considering only the smaller projection of vacancies, this shortage still results in a frightening gap in nursing service, essentially three times the 2001 nursing shortage.

## DESPERATE NEED FOR NURSE FACULTY

Nursing vacancies exist throughout the entire health care 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 2005, the American Hospital Association reported that hospitals needed 118,000 more RNs to fill immediate vacancies, and that this 8.5 percent vacancy rate is hampering the hospitals' ability to provide emergency care.<sup>5</sup> 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 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 they are accepted. In the 2005–2006 academic year, research reported by the National League for Nursing found that schools of nursing rejected more than 88,000 qualified applications because of shortages of faculty, classroom space, and clinical placement for students.<sup>6</sup> 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 health care facilities.

The current and deepening nurse faculty shortfall is a critical reason that the Advanced Education Nursing line item in the Title VIII programs must be fully funded. This program supported 13,877 graduate nursing students in fiscal year 2006. The students that are supported by this funding are the pool of future faculty for the nursing profession. Whether supporting students in clinical education or as faculty in schools of nursing, it is essential that advanced education nursing funding be restored.

## NURSING SUPPLY IMPACTS AMERICA'S EMERGENCY PREPAREDNESS

The National Center for Health Workforce Analysis at HRSA's Bureau of Health Professions reports that the nursing shortage makes it challenging for the health care sector to meet current service needs. Nursing shortfalls exacerbating capacity insufficiencies throughout the health care system have ripple effects, for example,

<sup>1</sup>Steiger, D.M., Bausch, S., Johnson, B., Peterson, A. (2006) The Registered Nurse Population: Findings from the March 2004 National Sample Survey of Registered Nurses. Health Resources and Services Administration, U.S. Department of Health and Human Services.

<sup>2</sup>Bureau of Labor Statistics, U.S. Department of Labor. Occupational Outlook Handbook, 2006–2007 Edition, Registered Nurses.

<sup>3</sup>Health Resources and Services Administration. (2004) What is Behind HRSA's Projected Supply, Demand, and Shortage of Registered Nurses?

<sup>4</sup>Auerbach, D.I., Buerhaus, P.I., & Staiger, D.O. (2007). Better late than never: Workforce supply implications of later entry into nursing. *Health Affairs*. 26(10): 178–185.

<sup>5</sup>American Hospital Association. (2005). Prepared to care: The 24/7 Role of American's full-service Hospitals.

<sup>6</sup>National League for Nursing. (2008). Nursing Data Review Academic Year 2005–2006, Executive summary.

seen in the problems encountered by most communities' day-to-day emergency care services. Facing a pandemic flu or other natural or man-made disaster of significant proportions makes the nursing shortage an even greater national concern, as well as an essential part of national preparedness and response planning.

Nurses play a critical role as front-line, first-responders. When word of the devastation caused by Hurricanes Katrina and Rita reached nurses across the country, they immediately volunteered in American Red Cross shelters, medical clinics, and hospitals throughout that widespread region. Nurses and advanced practice registered nurses (e.g., nurse midwives, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists) are particularly critical national resources in an emergency, able to provide clinical nursing care as well as primary care. During Katrina and Rita, nurse midwives delivered babies in airplane hangars, and nurses trained in geriatric care assisted in caring for those traumatized by their evacuation from the comforts of their homes, assisted living facilities, or nursing homes. Nurse practitioners diligently staffed temporary and permanent health care clinics to provide needed primary care to hurricane victims. Many nurses contributed not just through their clinical expertise, but also by offering psychological support as they listened to survivors recount their stories of pain and tragedy.

These stories seem particularly relevant in demonstrating the essential assistance nurses provide during tragedies, and reinforce the need to ensure an adequate supply of all types of nurses. Unless steps are taken now, the Nation's ability to respond to disasters will be further hindered by the growing nursing shortage. An investment in the nursing workforce is a reasonable and cost-effective investment toward rebuilding the public health infrastructure and increasing our Nation's health care readiness and emergency response capabilities.

#### FUNDING REALITY

Enacted in 2002, the Nurse Reinvestment Act (Public Law 107-205) addressed new and expanded initiatives, including loan forgiveness, scholarships, career ladder opportunities, and public service announcements to advance nursing as a career. Despite the enactment of this critical measure, HRSA fails to have the resources necessary to meet the current and growing demands for our Nation's nursing workforce. The President's proposed budget for fiscal year 2009 reduces overall funding of Title VIII by \$46.1 million, a 30 percent decrease compared to fiscal year 2008. This cut is achieved by zeroing out funding for "Advanced Education Nursing." This funding cut, if implemented, will further diminish training and potentially jeopardizes the delivery of health care. Funding of all of the Title VIII programs make a difference. For example:

- fiscal year 2006 Nursing Education Loan Repayment Program: Of the 4,222 applicants, 615 awards were made. This translates to 14.6 percent of applicants receiving awards.
- fiscal year 2007 Nursing Education Loan Repayment Program: Whereas last fiscal year, only 12 percent of the 4,845 nursing student applications reviewed were awarded loans in this program (i.e., 586 applicant awards).

The ANSR Alliance requests that the Subcommittee provide a minimum of \$200 million in fiscal year 2009 to fund the Title VIII—Nursing Workforce Development Programs. We also urge the restoration of the Advanced Education Nursing program (Sec. 811) funded at a level on par with the proposed fiscal year 2009 increase for the other Title VIII programs.

This funding can be used to restore the Advanced Education Nursing program and fund a higher rate of Nurse Education Loan Repayment and Nursing Scholarship applications, as well as implement other essential endeavors to sustain and boost our Nation's nursing workforce. We thank you for considering our request.

#### SUMMARY

Programmatic area	Final fiscal year 2008	President's budget fiscal year 2009	ANSR Alliance fiscal year 2009 request
Title VIII—Nursing Workforce Development Programs at HRSA .....	\$156,046,000	\$109,853,000	\$200,000,000

Academy of Medical-Surgical Nurses, American Academy of Ambulatory Care Nursing, American Academy of Nurse Practitioners, American Association of Critical-Care Nurses, American Association of Nurse Anesthetists, American Association of Nurse Assessment Coordinators, American Association of Nurse Executives, American Association of Occupational Health Nurses, Inc., American College of Nurse Practitioners, American Society of PeriAnesthesia Nurses, American Society

of Plastic Surgical Nurses, Association of periOperative Registered Nurses, Association of Rehabilitation Nurses, Association of Women's Health, Obstetric and Neonatal Nurses, Emergency Nurses Association, Infusion Nurses Society, International Society of Nurses in Genetics, National Association of Clinical Nurse Specialists, National Association of Neonatal Nurses, National Association of Nurse Massage Therapists, National Association of Nurse Practitioners in Women's Health, National Association of Orthopaedic Nurses, National Association of Pediatric Nurse Practitioners, National Association of Registered Nurse First Assistants, National Black Nurses Association, National Conference of Gerontological Nurse Practitioners, National Council of State Boards of Nursing, National Gerontological Nursing Association, National League for Nursing, National Nursing Centers Consortium, National Organization for Associate Degree Nursing, National Student Nurses' Association, Oncology Nursing Society, RN First Assistants Policy & Advocacy Coalition, Society of Trauma Nurses, Society of Urologic Nurses and Associates, and Wound, Ostomy and Continence Nurses Society.

#### PREPARED STATEMENT OF THE AMERICAN OCCUPATIONAL THERAPY ASSOCIATION

Mr. Chairman and members of the subcommittee, thank you for giving the American Occupational Therapy Association (AOTA) the opportunity to testify as the subcommittee begins to consider funding priorities for fiscal year 2009. My name is Fred Somers and I am the executive director of the American Occupational Therapy Association, a nationally recognized professional association of more than 35,000 occupational therapists, occupational therapy assistants, and students of occupational therapy. AOTA has affiliate programs in all 50 States.

#### ABOUT OCCUPATIONAL THERAPY

Occupational therapy addresses the activity limitations of people experiencing health problems such as stroke, spinal cord injuries, cancer, congenital conditions, developmental disabilities, and mental illness. With interventions to develop and restore skills that are essential for independent functioning, health, well-being, and participation in society therapy interventions are available for people of all ages and occur in a wide range of settings including schools, hospitals, skilled nursing facilities, home health, outpatient rehabilitation clinics, psychiatric facilities, and community health programs. Occupational therapy programs promote healthy lifestyles for individuals who are at risk for health conditions and prevent secondary problems associated with chronic conditions or disabilities. The outcome of occupational therapy promotes independence in individuals who may otherwise require institutionalization or other long-term care and enables people with disabilities to be productive and contributing members of society. Lower health care costs and improved quality of life for individuals, families, and caregivers are also evident byproducts of occupational therapy services.

#### RECOGNIZING THE LEADERSHIP OF THE SUBCOMMITTEE

AOTA's testimony is in support of four major programs under the subcommittee's jurisdiction: the Center for Disease Control and Prevention, especially the Center on Injury Control and Prevention's National Falls Prevention Program; the National Institutes of Health; the Health Resources and Services Administration's Health Professions Programs; and the administration on Aging. Mr. Chairman, our specific recommendations for these and other areas of interest are summarized in a table at the end of this statement.

Mr. Chairman, AOTA appreciates your leadership and the leadership of this subcommittee in supporting NIH in a time of fiscal austerity. Your leadership in supporting all of the programs mentioned in our statement are also greatly recognized and appreciated. These programs are important to our shared goals of improving the health and well being of the Nation. We applaud the subcommittee's leadership in addressing the needs of all of the programs under the jurisdiction of this subcommittee during this time of fiscal constraints.

#### CENTERS FOR DISEASE CONTROL AND PREVENTION

AOTA joins with the CDC Coalition, a nonpartisan coalition of more than 100 groups, in supporting \$7.4 billion for the Centers for Disease Control and Prevention in fiscal year 2009. The CDC programs are crucial to the health of millions of Americans, they are key to maintaining a strong public health infrastructure, and are essential in protecting us from threats to our health. At a time when the CDC is faced with unprecedented challenges and responsibilities ranging from chronic disease

prevention, eliminating health disparities, bioterrorism preparedness, to combating the obesity epidemic the administration's budget has cut the CDC's budget by \$412 million. We urge the committee to restore this cut and fund the CDC at \$7.4 billion. Within that amount, we further request that the committee provide a \$20.7 million increase for the Falls Prevention Program in the Center for Injury Prevention and Control.

Mr. Chairman, AOTA applauds the CDC's Center for Injury Prevention and Control's initiative of preventing falls among older adults. Falls are a leading cause of mortality among adults age 65 and older; one of every three older Americans falls each year, and about 30 percent of those who fall require medical treatment. In 2005, in the United States, more than 16,000 older adults died from falls, approximately 1.8 million were treated in hospital emergency departments for unintentional fall-related injuries, and more than 430,000 of those were subsequently hospitalized. Falls and fall-related injuries represent an enormous burden to individuals, society, and to our health care system. CDC reports that the mortality rate from falls among older Americans has increased 39 percent between 1999 and 2005. Furthermore, a recent analysis by CDC determined that in 2000, among adults aged 65 and older, direct medical costs totaled \$19.2 billion for nonfatal fall-related injuries.

Occupational therapy evaluates and treats many older adults who are at risks for falls. Both prevention and rehabilitation programs are available as part of occupational therapy services. Occupational therapy addresses the physical and sensory impairments of aging, eliminates environmental barriers by promoting "universal design" and recommends safety practices in people's homes. But occupational therapy can also deal with the fear of falling, which contributes to isolation and seriously limits many older adults' participation in full community life.

CDC's ability to reduce the rate of falls among older Americans is substantially leveraged and increased by collaboration with States and organizations, such as Area Aging Agencies, and other partners with special access and expertise. AOTA, for example, with 35,000 national members and affiliates in all 50 States, we believe, is an ideal partner for effective program collaboration. In order to enhance CDC's outreach and collaboration with appropriate organizations, AOTA recommends a \$20.7 million be appropriated to the CDC for elder falls prevention.

#### THE NATIONAL INSTITUTES OF HEALTH

Mr. Chairman, for the National Institutes of Health in fiscal year 2009, we recommend an increase of \$1.9 billion over the fiscal year 2008 funding level. AOTA joins the Ad Hoc Group for Medical Research Funding, a coalition of some 300 patient and voluntary health groups, medical and scientific societies, academic research organizations and industry in making this recommendation. The administration's fiscal year 2009 request would provide \$29.2 billion for NIH, representing the sixth consecutive year that the NIH budget has failed to keep pace with biomedical inflation. In the 5 years through 2008, a series of nominal increases and cuts has amounted to flat funding for NIH, and NIH has lost approximately 11 percent in purchasing power due to inflation. If the President's fiscal year 2009 request becomes law, NIH will have lost one-seventh of its purchasing power due to inflation. Furthermore, we urge the subcommittee to provide a 6.5 percent base adjustment for medical rehabilitation research across all Institutes and Centers.

The National Center for Medical Rehabilitation Research (NCMRR), within NICHD, provides important leadership within the NIH for the 15 NIH Institutes and Centers which fund medical rehabilitation research. For fiscal year 2009 the NIH projects that it will spend \$344 million for medical rehabilitation research, which is the same as the fiscal year 2007 actual NIH expenditure for this category of programs. AOTA recommends that these programs be increased to allow for a heightened focus on institutional and career development awards aimed at increasing the applicant success rate of the several under-represented health professions that contribute significantly to the field, such as occupational therapists.

The National Institute for Neurological Disorders and Stroke (NINDS) is providing important leadership in efforts to develop a consensus rehabilitation treatment protocol for stroke victims that will help insure the fullest possible recovery. AOTA strongly supports NINDS leadership to convene a Scientific Workshop to identify the scientific questions that must be answered before such a consensus rehabilitation treatment protocol can be developed and we would urge the committee to support this effort as well.

The Institute of Medicine report, *Enabling America: Assessing the Role of Rehabilitation Science and Engineering*, highlighted the national need for research advances to improve the effectiveness of rehabilitation services and the practices for

promoting the health of people with disabilities. The incidence and prevalence of people with disabilities continue to mount in parallel with dramatic increases in medicine's ability to prevent deaths due to injury, disease, and conditions associated with aging. An estimated 49 million Americans, about 1 out of every 7, have disabling conditions so severe that they are unable to carry out the major activities of their age group, such as attending school, working, or providing self-care. Occupational therapy, as part of a medical rehabilitation team, provides the means for reducing the effects and societal costs of disability.

#### HRSA HEALTH PROFESSIONS PROGRAM

The AOTA urges the restoration of the funding reductions proposed by the Administration to HRSA's Health Professions programs. Many of these programs, such as the Area Health Education Centers Program, the Health Careers Opportunity Program, and the Centers of Excellence Program are all particularly effective in addressing faculty shortages, institutional barriers and other programs needed to support the cost of educating under-represented minority health practitioners and addressing the needs of underserved areas. These programs are particularly advantageous to Historically Black Colleges and Universities, where Departments of Occupational Therapy, for example, are at constant risk of closure. Adequate support from HRSA's health professions program is important for all institutions of higher education to meet our workforce needs.

#### ADMINISTRATION ON AGING

Mr. Chairman, the administration on Aging (AoA) has developed a commendable vision and program structure that focuses on the importance of community based organizations to help adults as they age maintain their independence and well being in the community. AoA is to be commended for its development of a national network of Aging and Disability Resource Centers (ADRC). The ADRC initiative supports State efforts to develop "one stop shop" programs that help seniors make informed decisions about service and support options. AOTA is disappointed, however, in the very limited and diminishing discretionary program needed to fund and promote new and innovative options to help seniors remain independent. For example, AOTA is aware of the exciting and large array of pre-market assistive device technologies that need further research, development and testing before they can be appropriately promoted and used by our seniors. AOTA recommends increased funding for AoA in fiscal year 2009.

#### DEPARTMENT OF EDUCATION

As the national association representing occupational therapy, a profession dedicated to maximizing independence and function for people throughout the lifespan, AOTA supports NIDRR's Long Range Plan's emphasis on rapidly transitioning research knowledge into policy and best practices that will improve the quality of life for people with disabilities. We urge Congress to fully fund these activities. Two issues of particular interest for AOTA in this area are the Disability Rehabilitation Research Projects (DRRP) related to rehabilitation of children with traumatic brain injury and reducing obesity and obesity-related secondary conditions in adolescents and adults with disabilities.

AOTA also recognizes the translational research being conducted by the Institute of Educational Science, particularly the National Center for Special Education Research (NCSE) which published a request for proposals on the topic of special education related services. AOTA believes Congress should increase support for NCSE in order to promote research that delivers more evidence-based interventions into classrooms.

#### SUMMARY AND CONCLUSION

Mr. Chairman, we appreciate the opportunity to testify on the many important programs funded by this subcommittee. A summary of our specific funding recommendations follows:

##### *CDC: +\$20.7 Million for the Center for Injury Prevention and Control*

—Increased funding needed for CDC's Falls Prevention Program and Older Drivers Initiative.

##### *NIH and Medical Rehabilitation Research*

—6.5 percent increase for NIH overall and a 6.5 percent increase for Medical Rehabilitation Research;



*HRSA: +\$50.74 million to Restore Administration Cuts*

—Area Health Education Centers Program, the Health Careers Opportunity Program and the Centers of Excellence Programs

*AoA: +\$5 million for programs to fund innovative options to help seniors remain independent.*

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PREPARED STATEMENT OF THE AMERICAN PSYCHOLOGICAL ASSOCIATION (APA)

The APA, in Washington, DC, is pleased to submit these recommendations. APA is the largest scientific and professional organization representing psychology in the United States and is the world's largest association of psychologists. APA's membership includes more than 148,000 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 human welfare.

Many of the programs in this appropriations bill directly impact the health and quality of life of populations that are now underserved by the health care and education systems. Ethnic and linguistic minorities and rural and urban families in poverty are especially vulnerable to the current economic downturn and would benefit from targeted research and services. In addition, special populations including children and the elderly have specific health needs. Below are APA's recommendations for funding for needed research and services to improve health and education for all, but particularly for these underserved populations.

*National Institutes of Health.*—APA supports the recommendation of the Coalition for Health Funding of a 6.5 percent increase for NIH in fiscal year 2009. APA is concerned about falling success rates, falling grant application rates, and the increasing age of first-time grant recipients that have been exacerbated by sub-inflationary funding increases over the past 5 years.

Research on behavior and health is an integral part of the NIH research portfolio, and must remain so to reduce the complications of the chronic conditions that are such large contributors to health care costs. Behavioral research on diabetes is a case in point. Diabetes can lead to devastating complications such as heart disease, stroke, blindness, and premature death. Diabetes is growing at an epidemic rate, with more than 20 million Americans currently affected, and 54 million with pre-diabetes. For many years, scientists believed that medication was the only tool to prevent and treat diabetes. Medication can prevent some complications, but does not eliminate all the adverse consequences. A landmark study called the Diabetes Prevention Program<sup>1</sup> demonstrated that lifestyle interventions—modest weight loss and regular physical activity—can reduce the risk of developing Type 2 diabetes in high-risk adults by 58 percent, compared to 31 percent reduction with medication alone. These findings led to “Small Steps, Big Rewards”, the first national diabetes prevention campaign.

NIH funding of research on substance abuse is key to realizing the national goal of eliminating health disparities. The consequences of drug abuse disproportionately impact minorities, especially African American populations. The National Institute of Drug Abuse (NIDA) encourages research in this population, particularly in geographic areas where HIV/AIDS rates are high and or growing among African Americans, including in criminal justice settings. NIDA's promising research among the Native American community has the potential to make an impact on methamphetamine abuse in those rural populations.

*Increase the power of research on HIV–AIDS: Speed translation of research to the affected communities.*—NIH-supported behavioral research aimed at reducing the likelihood of HIV infection should include the necessary structural, environmental, and socio-economic variables to ensure that the end product can be evaluated as appropriate for racial and ethnic minority populations.

Congress needs better data in order to track which NIH programs train minority scientists most effectively, and which disciplines are best attracting minority trainees. APA recommends that Congress (a) urge the National Center for Minority Health and Health Disparities (NCMHD) to collaborate with all Institutes and Centers to produce an integrated and coordinated NIH-wide science trainee data tracking system, and (b) suggest that NCMHD engage trainees actively in the data track-

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<sup>1</sup> Knowler WC, Barrett-Connor E, Fowler SE, et al.; Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med*. 2002 Feb 7;346(6):393–403.

ing process to document trainee outcomes such as funding awards for trainees or fellows, including those programs that are targeted to underrepresented minorities. APA also recommends that Congress urge the Center to continue its efforts to build a foundation of talented researchers who will create the knowledge base needed to address the many complex issues underlying health disparities in communities of color, and to collaborate with other I/Cs on existing efforts to enhance recruitment and retention of underrepresented minority scientists.

*Health Resources and Services Administration: improve access to care for the underserved.*—The Graduate Psychology Education (GPE) Program is the nation's only Federal program dedicated solely to the education and training of psychologists. The activity is authorized by 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. Established 6 years ago, GPE provides grants to accredited psychology doctoral, internship and postdoctoral training programs. An exemplary “two-for-one” Federal program, GPE supports the interdisciplinary training of psychology graduate students while they provide supervised mental and behavioral health services to underserved populations, such as older adults, children, the chronically ill, and victims of abuse and trauma, including returning military personnel and their families, especially in rural and urban communities. GPE currently supports 18 grants across the country at academic institutions and training sites. Prior to recent budget cuts, one major program component had been devoted to geropsychology—the area of practice focusing on needs of the elderly. Providing \$7 million in fiscal year 2009 will restore funding to allow HRSA to run a national competition to produce approximately 30 general GPE training grants and 10 new geropsychology grants.

*National Health Service Corps (NHSC): address health professions shortages, particularly in mental and behavioral health.*—There are currently 2,724 mental health professional shortage areas (HPSAs) across the country accounting for an estimated underserved population of over 56 million. Psychologists, as health professionals eligible to participate in the NHSC Loan Repayment Program, are a critical component in meeting the mental and behavioral health needs of these underserved populations. While the NHSC supports a field strength of over 4,000 practitioners, HRSA estimates that an additional 30,000 practitioners are needed to achieve the target HPSA practitioner/population ratios. However, in the past 5 years funding for the NHSC has been cut by \$47 million, over 27 percent of a budget that was already insufficient in fiscal year 2003. Consequently, the NHSC has reduced annual scholarship and loan repayment awards by over 25 percent during that period (from 1,351 awards in fiscal year 2003 to 1,012 in fiscal year 2007). At its current funding level, the NHSC is unable to award qualified loan repayment applicants, and 13 practitioners in underserved areas are turned away for every 1 accepted. To address the deficiencies and to ensure an increase in psychologists serving in the NHSC, we strongly urge a steady and sustainable increase starting with a \$200 million appropriation for the NHSC in fiscal year 2009.

*Substance Abuse and Mental Health Services Administration (SAMHSA): protect students at risk of suicide.*—The APA urges the Committee to increase funds for the Campus Suicide Prevention program. This program, administered by SAMHSA and authorized as part of the Garrett Lee Smith Memorial Act, has made 56 grants to 2- and 4-year colleges and universities throughout the nation. Still, with nearly 4,000 institutions of post-secondary study in the United States, \$5 million cannot meet the needs that exist.

Those needs are significant. The most recent National College Health Assessment noted, “the rate of students reporting ever being diagnosed with depression has increased 56 percent in the last six years, from 10 percent in spring 2000 to 16 percent in spring 2005.” A 2007 Survey of College Counseling Center Directors found that the greatest concerns facing centers was finding referrals for students requiring long term help (62 percent), followed administrative considerations of handling of students with more serious psychological problems (61 percent), and the growing demand for services without an increase in resources (59 percent). Finally, and of great significance, suicide is the 2nd leading cause of death among college students. When students receive help for their psychological problems, counseling can have a positive impact on personal well-being, academic success, and retention. A survey conducted by the University of Idaho Student Counseling Center (2000) found that 77 percent of students who responded reported that they were more likely to stay in school because of counseling and that their school performance would have declined without counseling.

*Center for Mental Health Services: Expand the Minority Fellowship Program (MFP).*—There is an urgent need to address health disparities as the demographics of our nation are changing dramatically. While minorities are projected to comprise

40 percent of the U.S. population by 2025, only 23 percent of recent doctorates in psychology, social work, and nursing were awarded to minorities. The MFP's mission is to address this need by increasing the number of minority mental health professionals and by training mental health professionals to become culturally competent. APA recommends the Committee include \$6 million for the MFP.

*Emergency Mental Health and Traumatic Stress Services Branch: increase attention to child trauma.*—Traumatic events can have a significant impact on the physical, mental, emotional, and behavioral health of children and families. SAMHSA has made tremendous efforts in this area through the outstanding National Child Traumatic Stress Network (NCTSN) program and its coordinating center, the UCLA-Duke University National Center for Child Traumatic Stress. APA recommends increased funding for NCTSN programs supporting the recovery of children, families and communities impacted by a wide range of trauma. APA also encourages SAMHSA to strengthen the expertise of this critical program through programmatic support of experienced child trauma professionals, and to increase attention to the needs of children and families affected by trauma.

*Center for Substance Abuse Prevention (CSAP): train providers to identify substance use and mental disorders of persons with HIV.*—According to recent reports, almost half of persons with HIV/AIDS screened positive for illicit drug use or a mental disorder, including depression and anxiety disorder. APA encourages SAMHSA and CDC to collaborate with HRSA to train health care providers to screen HIV/AIDS patients for mental health and substance use problems.

*CDC's National Center for Health Statistics (NCHS): improve surveillance of eating disorders.*—Eating disorders are a significant public health problem for individuals across the lifespan. They may have serious, chronic effects on one's quality of life and often co-occur with significant physical and mental health problems. However, the impact of these disorders has not yet been appropriately investigated. Therefore, APA urges the Committee to encourage the CDC to increase support for surveillance and research efforts regarding the incidence, morbidity, and mortality rates of eating disorders, including anorexia nervosa, bulimia nervosa, binge eating disorder, and eating disorders not otherwise specified across age, ethnicity and gender subgroups.

*Administration on Aging (AoA)'s National Family Caregiver Support Program (NFCSP): fund critical program for family caregivers.*—Family caregivers play an essential role in providing a significant proportion of our nation's health and long-term care for those who are chronically ill and aging. Research suggests that respite provides family caregivers with the relief necessary to help maintain their own health, bolster family stability, keep marriages intact, and avoid or delay more costly nursing home or foster care placements. APA urges Congress to fund the Lifespan Respite Care Act at its authorized level of \$53.3 million.

*Administration for Children and Families (ACF): increase attention to prevention of maltreatment of Children with Disabilities.*—APA is committed to preventing child maltreatment and ameliorating its adverse health effects. In particular, children with disabilities are a distinct high-risk group for abuse and neglect. An estimated 300,000 children with disabilities are maltreated each year, which is approximately two to three times more than children without disabilities. APA recommends targeted support for appropriate research, and the implementation of evidence-based prevention and early intervention efforts for children with disabilities.

*The Department of Education's Office of Safe and Drug-Free Schools (OSDFS): expand use of threat assessments.*—Research shows that threat assessment techniques are more effective in preventing school violence and shootings than zero tolerance measures and similar disciplinary strategies. Threat assessment is a process of evaluating the threat, and the circumstances surrounding the threat, to uncover any facts or evidence that indicate the threat is likely to be carried out. APA recommends the adoption of standardized, research-based threat assessment techniques, including the creation of interdisciplinary school-based threat assessment teams that address threats on a case-by-case basis.

*Enhance Culturally and Linguistically Appropriate Education.*—APA urges the strengthening of programs that meet the unique cultural, linguistic and educational needs of ethnic minority and American Indian/Alaska Native students from preschool to graduate-level education. Ethnically diverse children and American Indian/Alaska Native children are performing at far lower levels than other students. APA recommends support for educational systems that reflect the unique needs of these populations.

## PREPARED STATEMENT OF THE AMERICAN PHYSIOLOGICAL SOCIETY

The American Physiological Society (APS) thanks the subcommittee for its sustained support for the National Institutes of Health (NIH). The doubling of the agency's budget that took place between 1998 and 2003 allowed the NIH to explore new and innovative ways to address challenges in biomedical research. The increased funding has allowed researchers to investigate scientific opportunities on an unprecedented scale, creating significant momentum and excitement in the research community. To maximize and build upon that momentum, the NIH must be able to continue to provide support for scientists and researchers around the country. For the last 5 years, the NIH budget has failed to keep pace with inflation, resulting in a loss of purchasing power of more than 10 percent. The Administration's fiscal year 2009 budget proposal would fund the NIH at \$29.3 billion, the same as in fiscal year 2008. The APS urges you to make every effort to provide the NIH with \$31.1 billion in fiscal year 2009 so we can take advantage of scientific opportunities and strengthen the Nation's scientific workforce to face future challenges.

The APS is a professional society dedicated to fostering research and education as well as the dissemination of scientific knowledge concerning how the organs and systems of the body work. The Society was founded in 1887 and now has more than 10,000 member physiologists. Our members conduct NIH-supported research at colleges, universities, medical schools, and other public and private research institutions across the United States. The APS offers these comments on the budget recognizing both the enormous financial challenges facing our Nation and the enormous opportunities before us to make progress against disease.

## RESEARCH CHALLENGES AND SOLUTIONS

Looking ahead, the scientific and medical communities see many challenges on the horizon including an aging population, the growing incidence of obesity, diabetes and heart disease, and new and emerging infectious diseases. The NIH has taken a forward-thinking approach to these challenges, and developed a vision for the future of health care that focuses on predicting who will develop diseases with the goal of developing personalized prevention and treatment strategies that will preempt disease onset before symptoms appear.<sup>1</sup> The goal of this approach is to minimize health care expenses by keeping Americans healthier longer, instead of the current model of health care, which is based on intervention once symptoms occur. In order to make this vision a reality, extensive research is needed to increase our understanding of the basic mechanisms of disease and pursue the most effective intervention strategies.

An example of this proactive approach is beginning to take shape in Alzheimer's disease research. Alzheimer's is a devastating neurological disease that afflicts a growing number of older Americans. Researchers have used both basic and clinical research to begin to determine who is at risk for developing the disease, identify the underlying genetic variants, and understand the molecular pathology in the brains of those who are affected. This work has led to several new targets for drug development that will be explored in the coming years, hopefully leading to the development of new ways to prevent and treat Alzheimer's disease.

Another recent breakthrough that holds the promise of saving many lives through disease prevention is the development of a vaccine that protects against cervical cancer. Scientists have known for some time that human papilloma virus (HPV) infection can in some cases lead to the development of cervical cancer in women. While effective screening methods for early detection are available, the disease remains a significant cause of death in the United States and around the world, where health care systems are not able to provide routine screening for precancerous cells. The recently released cervical cancer vaccine is designed to prevent infection by several of the viruses that cause most of the cancers and by vaccinating young women it is hoped that the incidence of cervical cancer will decline.

## THE SCIENTIFIC WORKFORCE

In addition to supporting research, the NIH must also address workforce issues to be sure that our nation's researchers are ready to meet the challenges they will face in the future. Recent data from the NIH shows that the average age of NIH supported principal investigators (PI) is now 50.8 years, up from an average of 39.1 years in 1980.<sup>2</sup> In addition, the average age of the new NIH PI has increased to

<sup>1</sup> <http://www.nih.gov/strategicvision.htm> (accessed March 19, 2008).

<sup>2</sup> [http://grants.nih.gov/grants/new\\_investigators/resources.htm#data](http://grants.nih.gov/grants/new_investigators/resources.htm#data) (accessed March 21, 2008).

42.4 years. As the scientific workforce ages and researchers retire, there is concern that there will not be an adequate number of young scientists who are trained to replace them. NIH has undertaken several programs to encourage and fund early-career investigators, but falling success rates may discourage trainees from pursuing careers in academic science. The fiscal year 2009 budget request would result in an overall success rate for grant applications of just 18 percent, the lowest figure in decades. As funding falters, the best and brightest minds will turn away from careers in medical science. If NIH cannot fund new ideas, this will not only hamper efforts to find cures, it will also discourage up and coming researchers who could become the next generation of basic and clinical scientists.

#### RECOMMENDATIONS

The APS joins the Federation of American Societies for Experimental Biology (FASEB) and the Ad Hoc Group for Medical Research Funding in urging that NIH be provided with \$31.1 billion in fiscal year 2009 to permit the agency to maintain its current wide-ranging and important research efforts. Because the majority of the NIH budget is distributed to scientists who carry out their research in all 50 States, the investment that Congress makes in biomedical research creates jobs and contributes to economic vitality in communities throughout the country. The continued health and prosperity of our Nation's people depends on a robust and consistent investment in basic, translational and clinical research.

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#### PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) wishes to submit the following statement in support of increased funding for the Centers for Disease Control and Prevention (CDC). The ASM strongly believes that the CDC must receive sustained and sufficient funding to support its mission as the Nation's principal public health agency. The administration's proposed fiscal year 2009 budget for CDC falls 7.5 percent below the fiscal year 2008 level and clearly is inadequate to support CDC's science based programs which are so critical to preserving public health.

The recently released World Health Organization's (WHO) report of higher than expected incidences of extensively drug-resistant tuberculosis (XDR-TB), illustrates the consequences of underestimating the global threat from infectious diseases. In the United States, recent recalls of contaminated ground beef, peanut butter and produce, along with other events like the spread of drug-resistant staph infections in medical facilities and communities, also warn us against under funding of CDC programs in infectious disease surveillance and prevention.

The ASM believes that the administration's fiscal year 2009 proposed budget for CDC would undermine essential CDC capabilities. We recommend instead that Congress appropriate \$7.4 billion for the fiscal year 2009 CDC budget. With annual U.S. healthcare costs projected by Federal economists to exceed \$4 trillion by 2017, it seems prudent to invest now in preventing diseases, present and future. We need to make increased investments in the CDC to slow or stop disease outbreaks through education, prevention, preparedness and research.

#### CDC INFECTIOUS DISEASE PROGRAMS SAFEGUARD UNITED STATES AND GLOBAL PUBLIC HEALTH

The administration's proposed funding cuts for the fiscal year 2009 CDC budget will weaken the agency's key infectious disease programs. The \$1.87 billion allocated for infectious diseases is a decrease of \$30 million, or 5.1 percent below the fiscal year 2008 level. CDC's diverse programs include research and surveillance activities that must be sustained, long term, not suddenly created in response to some unexpected disease outbreak. CDC initiatives that focus on preparing against emerging infectious diseases or slowing the spread of antimicrobial resistant (AR) pathogens are wisely investing Federal resources in cost effective prevention. All these programs rely on adequate Congressional appropriations that recognize infectious disease control as central to the CDC's overall mission of protecting the public. Unfortunately, the proposed individual program levels for fiscal year 2009 would constrict these CDC activities, which is shortsighted given the ever changing nature of pathogens and patient populations.

*Antimicrobial Resistance.*—Across the CDC, any program related to infectious disease must now consider potential pathogens that have evolved sufficiently to resist traditional drug therapies. Last year's media reports of highly virulent staph infections among sports teams and international travelers infected with XDR-TB were snapshots of the reality that AR infections are steadily increasing in incidence and

severity. A CDC study released in October determined that in the United States during 2005, methicillin-resistant *Staphylococcus aureus* (MRSA) caused more than 94,000 life threatening infections and nearly 19,000 deaths, the first national baseline of MRSA's impact on public health. Earlier CDC studies had determined that more than 70 percent of bacterial hospital-acquired infections are resistant to at least one of the antimicrobial drugs most commonly used to treat them. In 2007, the CDC made new treatment recommendations for gonorrhea after finding that rising numbers of cases are resistant to commonly used and previously highly effective antimicrobials. Surveillance data had shown that between 2001 and 2006, fluoroquinolone-resistant cases rose from less than 1 percent of reported infections to over 13 percent. Gonorrhea, the Nation's second most commonly reported infectious disease, causes an estimated 700,000 new infections annually. Additionally, oseltamivir-resistant H1N1 was recognized in Europe and the United States this year. Continued emergence of this strain could be a potential threat in the context of pandemic flu preparedness and the stockpiling of Tamiflu.

Another year of shrinking support for the CDC will undercut the nationwide strategy begun in 1999 with creation of the interagency Antimicrobial Resistance Task Force, co-chaired by the CDC. In 2001, the Task Force launched its Public Health Action Plan to Combat Antimicrobial Resistance, outlining an ambitious agenda to improve surveillance, prevention and control, and research and product development. Last fall, ASM commented on the Strategies to Address Antimicrobial Resistance Act (STAAR Act; H.R. 3697, S. 2313), which encourages greater Federal efforts against AR infections, and recommended that the CDC be appointed the lead agency for the Task Force and the Action Plan. The agency's infectious disease programs integrate proven CDC expertise that ranges from case reporting networks to research on faster diagnostic tests for field use. Monitoring outbreaks like those caused by MRSA, pathogenic *E. coli*, or XDR-TB, is optimized through CDC surveillance systems that include the National Healthcare Safety Network. However, as more and more hospitals are required via State mandates to report nosocomial infections including MRSA, they will have to register with the National Healthcare Safety Network database, causing a strain on this network. Additional resources will be necessary to for the database to support this growth.

ASM recommends that Congress appropriate additional resources for CDC antimicrobial resistance programs of \$65 million in fiscal year 2009. The administration's fiscal year 2009 CDC budget would instead cut allocations for AR activities to \$16.5 million, 2.5 percent below last year. This is an unfortunate backward approach to a public health problem that is growing nationally and internationally.

*Emerging Infectious Diseases.*—Funding for emerging infectious diseases (EID) would be cut under the proposed fiscal year 2009 budget which decreases funding to "All Other Infectious Diseases" by \$26.6 million, or 20 percent under last year's appropriation. ASM recommends that at a minimum, funding for this group of diseases should be restored to the fiscal year 2007 or fiscal year 2008 level of \$130–132 million, with an adjustment for inflation. Failure to do so could impinge on the CDC's capacity to quickly respond to EID outbreaks in the United States and abroad. Rapid responses rely upon a well funded infrastructure of special pathogens expertise and laboratories, training programs for State and local laboratory personnel, and domestic or global case reporting computer networks. Weak fiscal support of EID-related programs could slow what has been to date, very rapid CDC reaction, typified by the SARS, West Nile virus and foodborne outbreaks that mobilized CDC resources in recent years.

Unpredictable emerging and re-emerging infectious diseases are a constant in public health and must not be ignored. The viruses causing HIV infection and Ebola fever were once unknown pathogens eventually linked by scientists to newly emergent diseases. Long familiar diseases like dengue fever and cholera are today spreading to new geographic regions or reappearing in areas once thought freed of the diseases. CDC assisted studies reported in 2007 included discovery of a new, potentially deadly bacterial species isolated from a U.S. traveler to Peru and related to trench fever. Researchers using a new molecular typing test developed by CDC reported that a viral strain typically tied to common colds and stomach flu, adenovirus 21, is becoming more virulent and more common in the United States, with half of the patients requiring hospitalization. The agency prepares for the unexpected through its time tested blend of ongoing surveillance, education and training programs, prevention protocols, and basic research on best methods. CDC uses these science based tools in an impressive range of activities that could be curtailed by the administration's inopportune budget cuts for fiscal year 2009.

If Congress does not reverse the downturn in CDC funding, another specific budget category to be reduced is the National Center for Zoonotic, Vector-Borne and Enteric Diseases (NCZVED), which addresses a broad range of relatively rare emerging

pathogens and diseases like SARS, hantavirus, Ebola, and “mad cow” disease. The program also includes activities on far more prevalent disease like Lyme disease and foodborne diseases such as salmonellosis and *E. coli* 0157, as well as the growing threat of drug-resistant malaria, the reemergence of yellow fever in South America, and the increasing threat of dengue and dengue hemorrhagic fever throughout much of Asia and the Americas. The CDC 2009 request includes \$60.6 million for NCZVED, a decrease of \$7.2 million below fiscal year 2008, despite the continual call for CDC expertise in special pathogens and food safety. For example, CDC recently confirmed test results from the national lab in Uganda that identified a new virus subtype causing an outbreak of Ebola fever. CDC also responded last year to outbreaks of Marburg hemorrhagic fever in Uganda and Rift Valley fever in Kenya, where it led efforts to establish a Rift Valley fever veterinary diagnostic laboratory. The agency also updated traveler advisories based on rising reports of mosquito-borne dengue fever in Latin America and the Caribbean. Disease patterns in this category can be altered by diverse elements like farming practices, human or vector migration, and climate patterns. Public health responses undoubtedly benefit from CDC’s skillful collaboration among scientific disciplines and across national borders.

Additionally, Federal investment in the WNV program over the years has created a strong infrastructure assisting States in the prevention, detection and response to WNV and other vector-borne diseases. Since fiscal year 2007, however, program funding has dwindled causing concern that the infrastructure will not be able to support the core capacity of activities, including lab capacity and national, State and local expertise in all vector-borne diseases. Appropriate support for this program in fiscal year 2009 and beyond is critical as WNV becomes more endemic in this country.

Finally, as foodborne disease outbreaks continue to rise, CDC needs additional resources to support databases such as PulseNet and FoodNet. Last year’s investigation of over 700 cases of *Salmonella* infection in 48 States which were linked to contaminated peanut butter, is an example of CDC’s real time surveillance and control efforts. Large multiple State investigations, however, are a strain on CDC’s limited databases. Additional resources will help to improve and enhance these data collection networks.

*HIV/AIDS, Viral Hepatitis, STDs and TB Prevention.*—The CDC budget category covering HIV/AIDS, hepatitis, sexually transmitted diseases (STDs), and tuberculosis characterizes the breadth of CDC responsibilities in protecting public health. Unfortunately, funding on these programs would stagnate under the fiscal year 2009 budget, losing \$2 million, or 0.2 percent of its fiscal year 2008 level. The recent report of hepatitis C infections traced by public health officials to outpatient procedures at a Las Vegas clinic is a timely reminder that the various types of viral hepatitis, which kill more than 5,000 Americans annually, are not a minor health problem. New infections with sexually transmitted pathogens are rising in the United States. In 2006, more than 1 million cases of chlamydia broke the unenviable U.S. record for annual reports of a sexually transmitted disease, but officials believe that actual case numbers are closer to 2.8 million. CDC surveillance networks also reveal that cases of syphilis and gonorrhea are increasing, complicated by drug resistant forms.

At the end of 2007, there were about 33.2 million persons worldwide living with HIV infection, including over 1 million in the United States. Co-infection with TB is becoming more prevalent (an estimated one third of persons living with HIV), and TB is the cause of death in up to half of AIDS cases. The concurrent spread of drug resistant forms of tuberculosis, especially in areas hard hit by HIV/AIDS, deeply worries public health experts. CDC should work towards assuring necessary laboratory support for tuberculosis diagnosis and sensitivity testing in areas where antiretroviral therapy and anti-tuberculosis therapy are being distributed in HIV endemic areas that are co-endemic with TB. Without such laboratory support, we are at risk of contributing to the MDR and XDR-TB epidemic through the use of ineffective drugs. Any advances made in diagnosis and controlling tuberculosis and HIV/AIDS must be preserved with sufficient Federal funding. The administration’s proposed CDC fiscal year 2009 budget does correctly recognize the opportunity offered by estimates that up to 25 percent of U.S. cases are unaware of their infection, providing increased funds to expand domestic HIV testing and early diagnosis in high risk United States locations and populations.

#### ASM ASKS CONGRESS TO REVERSE EROSION OF CDC FUNDING

ASM recommends that Congress approve \$7.4 billion for CDC funding in fiscal year 2009. This request to significantly increase the CDC budget acknowledges the major contributions made by the agency to disease prevention in the United States

and elsewhere. Whether focusing on influenza, bioterrorism, quarantine stations, or other priorities, ongoing CDC programs bring together agency and other scientists, along with health care officials and governments, to find science based solutions to complex situations. The CDC surveillance networks and field research teams can detect and help contain disease outbreaks anywhere in the world. The strength of CDC's many infectious disease programs lies in steady sources of talented personnel and sufficient funding. Eroding Federal support with flat or declining appropriations is not the best advised approach to preserving the Nation's public health.

#### PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) appreciates the opportunity to submit a written statement on the fiscal year 2009 budget proposal for the National Institutes of Health (NIH). The ASM is seriously troubled by the continuing shrinkage of appropriations for the National Institutes of Health (NIH), with inflation-adjusted funding flat or declining since fiscal year 2003. The President's proposed fiscal year 2009 budget for NIH continues a disturbing trend that risks losing our scientific edge in biomedical research. With annual health spending in the United States likely to exceed \$4 trillion by 2017, innovative medical research is critical to improvements in both public health and the national economy. Increasing biomedical research is key to finding new cures, treatments and preventions for infectious and chronic diseases that threaten our future.

For 5 years the NIH budget has lost ground to biomedical research inflation, estimated at 3.5–3.7 percent. Since fiscal year 2004 this situation has cost NIH and biomedical research approximately 11 percent in purchasing power. At the same time, annual funding has fallen far short of that needed to adequately support and build on opportunities in basic and clinical research. The fiscal year 2008 NIH budget of \$29 billion, minus the set-aside for the Global Fund for HIV/AIDS, Malaria and TB, is a meager 0.5 percent increase over fiscal year 2007. The administration's proposed \$29 billion budget for fiscal year 2009 regrettably flatlines NIH funding for the sixth year in a row. This budget request will clearly weaken fiscal support for NIH, which expends more than 80 percent of its budget on research at about 3,100 institutions and is the largest single funding source for research at U.S. universities and colleges.

Because of flat budgets and expanding research opportunities, the success rates for NIH research grant applications continue to fall. The total number of grant recipients also will decline under the fiscal year 2009 request. This is a sobering predictor of slower technical innovation and fewer medical advances. At the National Institute of Allergy and Infectious Diseases (NIAID), the number of research grant requests rose from 1,993 in 1997 to 4,900 in 2007, while success rates slipped from about 43 percent to 23 percent. The Institute's fiscal year 2008 funding level was 2.3 percent below fiscal year 2007. The fiscal year 2009 NIAID request is only 0.2 percent above fiscal year 2008 levels, before \$300 million is transferred to the Global Fund. This downward trend will continue to undercut research that is the foundation of future biomedical successes and the fight against infectious diseases.

#### ASM RECOMMENDS THE NIH BUDGET BE INCREASED BY \$1.9 BILLION

The NIH Reform Act of 2006 authorized a funding level of \$32.8 billion for the NIH's fiscal year 2008 budget, which illustrates how far the NIH budget, currently at \$29 billion in fiscal year 2008, has fallen behind congressionally authorized levels of growth. Continuing fiscal shortfalls will weaken efforts of NIH to develop new therapies, vaccines, and diagnostics for a myriad of infectious and chronic diseases. To help reverse the ongoing erosion of biomedical research, the ASM recommends that the fiscal year 2009 NIH budget be increased by \$1.9 billion, an increase of 6.6 percent. This increase will help restore purchasing power that has been eroded by 5 years of flat funding and would provide some measure of growth for biomedical research.

#### TAKING ADVANTAGE OF RESEARCH OPPORTUNITIES TO IMPROVE PUBLIC HEALTH AND ADDRESS INFECTIOUS DISEASES

Federal investment in basic and applied research has had enormous payoff in medical advances against chronic and infectious diseases. The following are just several examples of the changeable nature of both pathogens and their human hosts, evidence that strong biomedical research programs must be sustained:

—Seasonal influenza kills about 36,000 Americans each year and is an ever present concern. Even more worrisome is the potential for pandemic influenza



if current bird flu viruses mutate into forms easily spread from human to human. Since the avian influenza virus H5N1 resurfaced in 2003, it has spread to more than 60 countries and infected more than 350 people, with over 60 percent mortality. NIAID scientists are collaborating with others worldwide to prevent a possible pandemic. Last year, for example, NIAID researchers identified genetic changes on the H5N1 surface that could permit easier entry into human cells, thereby suggesting potential approaches to improved surveillance and vaccines.

- Antimicrobial resistance is a significant challenge to biomedical researchers trying to understand the mechanisms involved and to develop countermeasures. Recent surveillance studies report yet another newly emerging antimicrobial resistant pathogen, a multiple-drug resistant variant of the already problematic methicillin-resistant *Staphylococcus aureus* (MRSA). In 2005, MRSA was responsible for an estimated 94,000 life-threatening infections in the United States and more than 18,000 deaths. The newly described variant of MRSA is resistant to even more drugs and causes more-virulent skin infections. NIAID-supported research is providing key information on resistant staph infections, like the just published studies identifying specific proteins secreted by MRSA that determine disease severity in humans. NIAID-funded scientists also have used comparative genome sequencing to reveal the origins of epidemic community-associated MRSA, a growing problem in this country.
- Infectious diseases, whether naturally occurring or deliberately spread, are among the greatest security challenges to the United States. Research to develop effective medical countermeasures to detect prevent and treat infectious diseases is a key responsibility of the NIAID. The NIAID has updated its Strategic Plan for Biodefense to address a broad spectrum strategy to prevent and respond to traditional and new types of threats that will require the capability to rapidly identify unknown and poorly defined agents, quickly evaluate the efficacy of available interventions and develop and deploy novel treatments. In recent years, the NIAID has expanded its basic and applied research portfolio and established a comprehensive infrastructure with extensive resources that support all levels of research. Examples of this infrastructure include the following:
  - Regional Centers of Excellence (RCEs) for Biodefense and Emerging Infectious Diseases, ten centers, located nationwide, provide resources and communication systems that can be rapidly mobilized and coordinated with regional and local systems in response to an urgent public health event.
  - Cooperative Centers for Translational Research on Human Immunology and Biodefense further knowledge of human immune responses against infectious pathogens and elucidate molecular mechanisms responsible for both short-term immunity and long-term immune memory. The ultimate goal of these eight centers is to translate research on immunity to infection into clinical applications to protect against bioterrorist threats.
  - National Biocontainment Laboratories (NBLs) and Regional Biocontainment Laboratories (RBLs), 2 NBLs and 13 RBLs are available or under construction for research requiring high levels of containment and are prepared to assist national, State and local public health efforts in the event of a bioterrorism or infectious disease emergency.
  - Expanded Vaccine and Treatment Evaluation Units, multiple sites allow for more extensive clinical trials capacity and expertise.
  - The Biodefense and Emerging Infections Research Resources Repository offers reagents and information essential for studying emerging infectious diseases and biological threats.
  - Genomics and proteomics centers include the Microbial Sequencing Centers, the Pathogen Functional Genomics Resource Center, the Bioinformatics Resource Centers, and the Biodefense Proteomics Research Centers.
  - The In Vitro and Animals Models for Emerging Infectious Diseases and Biodefense resource provides screening of potential therapeutics and the development of in vitro animal efficacy models for evaluating drugs and vaccines.
  - The NIAID has supported a number of biodefense workshops and multiple training opportunities ranging from basic introductory courses to 2-year fellowships to provide professional training in biosafety and biocontainment. These programs are available through the National Biosafety and Biocontainment Training Program, the RCEs, and NIAID Institutional Training Grants.
- The NIH routinely reevaluates its research priorities and adjusts programs to address changing disease threats, national priorities, or appropriated resources. An example is the agency-wide Roadmap for Medical Research, a strategy to leverage waning resources through interdisciplinary teams, state-of-the-art technologies, and harmonization of clinical research efforts. The NIH's singular abil-

ity to impact biomedical research broadly is epitomized by the recent launch of a new Roadmap initiative: the multi-center Human Microbiome Project to map the genomes of all microorganisms present in or on the human body, to better understand host-microbe interactions in both sickness and health. With next-generation DNA technologies, researchers will eventually sequence 1,000 microbial genomes, results to be deposited in public databases for use in designing new treatments and better methods to prevent disease.

Constant changes here and abroad, in populations, disease pathogens and vectors, climates, economies, cultures, and governments, all have potential to influence the global burden of human disease. Emerging threats like West Nile fever or Nipah virus coexist with global successes like polio or smallpox immunization campaigns. Persistent challenges like HIV/AIDS and foodborne illnesses continue to confound public health officials. It is imperative that the NIH maintain its science based agility to respond appropriately to both the anticipated and the unexpected health threat.

#### BIOMEDICAL RESEARCH IS THE FOUNDATION OF RESEARCH COMPETITIVENESS IN A GLOBAL ECONOMY

Past investments in biomedical research have returned exceptional benefits to the American people, but there are troubling indicators that our scientific edge is slipping. Globalization is now increasing worldwide competition in scientific discovery, technological innovation, and scientific talent. The United States has declined to near parity with the EU-15 in recent years in biology publications. U.S. Federal support for academic R&D is falling for the first time in a quarter century. It is critical to note that the Federal Government supports the majority of basic research conducted by academic institutions. Basic research funded by the NIH fuels technological innovations and fosters the vitality of the U.S. scientific enterprise. It helps create new industries and jobs, improves the quality of life of people and provides technology that contributes to national security.

The ASM strongly recommends that Congress end the past 5 years of fiscal neglect for NIH. It is absolutely essential that the United States increase support for biomedical research, which is an essential foundation for future U.S. scientific competitiveness, knowledge based industries, and highly skilled jobs in this country. Biomedical innovation is key to economic competitiveness and technological breakthroughs that improve our lives.

#### ASM URGES CONGRESS TO INCREASE FISCAL YEAR 2009 FUNDING FOR NIH

The United States cannot afford to neglect greater investment in biomedical research. The continuing complacency that has led to the leveling off and erosion of support for biomedical research can diminish our defenses against both expected and unpredictable diseases. Also at risk are the nation's high quality scientific workforce, the tradition of technological innovation, and competitiveness in global markets, all nurtured by NIH supported research, laboratories and institutions. To assure continued public health benefits from biomedical research, the ASM strongly recommends that Congress increase the NIH budget by \$1.9 billion for fiscal year 2009.

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#### PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR NUTRITION

The American Society for Nutrition (ASN) appreciates this opportunity to submit testimony regarding fiscal year 2009 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 research to very broad societal applications. ASN respectfully requests \$31.2 billion for NIH, and we urge you to adopt the President's request of \$125 million for NCHS in fiscal year 2009.

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 health care costs has highlighted the need for improved information on dietary components, dietary intake, strategies for dietary change and nutritional therapies. Preventable chronic diseases related to diet and physical activity cost the economy over \$117 billion annually, and this cost is predicted to rise to \$1.7 trillion in the next 10 years. 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 the nation's premier sponsor of biomedical research and is the agency responsible for conducting and supporting 90 percent (nearly \$1 billion) of federally-funded basic and clinical nutrition research. Nutrition research, which makes up about four percent of the NIH budget, is truly a trans-NIH endeavor, being conducted and funded across multiple Institutes and Centers. Some of the most promising nutrition-related research discoveries have been made possible by NIH support.

In order to fulfill the extraordinary promise of biomedical research, including nutrition research, ASN recommends an fiscal year 2009 funding level of \$31.2 billion for the agency, which is a \$1.9 billion increase over fiscal year 2008.

Over the past 50 years, NIH and its grantees have played a major role in the explosion of knowledge that has transformed our understanding of human health, and how to prevent and treat human disease. Because of the unprecedented number of breakthroughs and discoveries made possible by NIH funding, scientists are 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 age-related macular degeneration.

During the next 25 years, the number of Americans with chronic disease is expected to reach 46 million, and the number of Americans over age 65 is expected to be the largest in our nation's history. Sustained support for basic and clinical research is required if we are to confront successfully the health care challenges associated with an older, and potentially sicker, population.

Unfortunately, over the last 5 years the NIH budget has failed to keep up with inflation and subsequently, the percentage of dollars funding nutrition-focused projects has declined. Flat budgets have reduced the purchasing power of the agency by 13 percent, and the success rate for research proposals to NIH likely will be reduced by half from that of 6 years ago. New opportunities for ground-breaking research are going unfunded, and there is a chance that the number of new therapies under development will begin to decrease. It is imperative that we renew our commitment to biomedical research and to fulfill the hope of the American people by making the NIH a national priority. Otherwise, we risk losing our nation's dominance in biomedical research.

#### 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 health care system, and it is responsible for monitoring the nation's health and nutrition status. Nutrition and health data, largely collected through the National Health and Nutrition Examination Survey (NHANES), is essential for tracking the health and well being of the American population, and it is especially important for observing health trends in our nation's children. Knowing both what Americans eat and how their diets directly affect their health provides valuable information to guide policies on food safety, food labeling, food assistance, military rations and dietary guidance.

Over the past few years, flat and decreased funding levels have threatened the collection of this important information, most notably vital statistics and the NHANES. To address this problem, ASN recommends an fiscal year 2009 funding level of \$125 million for the agency, which is an \$11 million increase over fiscal year 2008. This recommendation is consistent with the funding level recommended by President Bush in his fiscal year 2009 budget proposal.

Current funding levels for NCHS are precarious. Before the modest increase Congress provided last year, NCHS had lost \$13 million in purchasing power since fiscal year 2005 due to years of flat funding, coupled with inflation and the increased costs of technology and information security. These shortfalls forced the elimination of data collection and quality control efforts, threatened the collection of vital statistics, stymied the adoption of electronic systems and limited the agency's ability to modernize surveys to reflect changes in demography, geography, and health delivery.

Moreover, nearly 30 percent of the funding for NHANES comes from other Federal agencies such as the NIH and the Environmental Protection Agency. When

these agencies face flat budgets or cuts, they withdraw much-needed support for NHANES, placing this national treasure in even greater jeopardy.

The obesity epidemic is a case in point that demonstrates the value of the work done by NCHS. It is because of NHANES that our nation became aware of this growing public health problem, and as obesity rates have increased to 31 percent of American adults (which we know because of continued monitoring), so too have rates of heart disease, diabetes and certain cancers. It is only through continued support of this program that the public health community will be able to stem the tide against obesity. Continuous collection of this data will allow us to determine not only if we have made progress against this public health threat, but also if public health dollars have been targeted appropriately. A recent report from the Institute of Medicine recognized the importance of NHANES and called for the enhancement of current surveillance systems to monitor relevant outcomes and trends with respect to childhood obesity.<sup>1</sup>

In addition to our fiscal year 2009 request, we urge the Committee to consider a path to boost funding for the NCHS to \$175 million by 2013. Reaching this level over 5 years, through annual increases of \$11 million, would allow the agency to reach what its supporters call “blue sky.” Such an increase would ensure uninterrupted collection of vital statistics and sustain over-sampling of vulnerable populations.

ASN thanks your committee for its support of the NIH and NCHS in previous years. If we can provide any additional information, please contact Mary Lee Watts, ASN Director of Public Affairs, at (301) 634-7112 or mwatts@nutrition.org.

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PREPARED STATEMENT OF THE AMERICAN SOCIETY OF TROPICAL MEDICINE AND  
HYGIENE

OVERVIEW

The American Society of Tropical Medicine and Hygiene (ASTMH) appreciates the opportunity to submit written testimony to the House Labor, Health and Human, Services, and Education Appropriations Subcommittee. With nearly 3,500 members, ASTMH is the world’s largest professional membership organization dedicated to the prevention and control of tropical diseases. We represent, educate, and support tropical medicine scientists, physicians, clinicians, researchers, epidemiologists, and other health professionals in this field.

We respectfully request that the subcommittee provide the following allocations in the fiscal year 2009 Labor, Health and Human, Services, and Education Appropriations bill to support a comprehensive effort to enhance malaria control programming globally:

- \$18 million to the Centers for Disease and Control and Prevention (CDC) for malaria research, control, and program evaluation efforts with a \$6 million set-aside for program monitoring and evaluation;
- \$31.1 billion to National Institutes of Health (NIH);
- \$4.3 billion to the National Institute of Allergy and Infectious Diseases (NIAID);
- and
- \$71 million to the Fogarty International Center (FIC).

We very much appreciate the subcommittee’s consideration of our views, and we stand ready to work with subcommittee members and staff on these and other important global health matters.

ASTMH

ASTMH plays an integral and unique role in the advancement of the field of tropical medicine. Its mission is to promote global health by preventing and controlling tropical diseases through research and education. As such, the Society is the principal membership organization representing, educating, and supporting tropical medicine scientists, physicians, researchers, and other health professionals dedicated to the prevention and control of tropical diseases. Our members reside in 46 States and the District of Columbia and work in a myriad of public, private, and non-profit environments, including academia, the U.S. military, public institutions, Federal agencies, private practice, and industry.

The Society’s long and distinguished history goes back to the early 20th century. The current organization was formed in 1951 with the amalgamation of the National Malaria Society and the American Society of Tropical Medicine. Over the

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<sup>1</sup>Institute of Medicine. Progress in Preventing Childhood Obesity Washington, DC: National Academies Press, 2006.

years, the Society has counted many distinguished scientists among its members, including Nobel laureates. ASTMH and its members continue to have a major impact on the tropical diseases and parasitology research carried out around the world.

ASTMH aims to advance policies and programs that prevent and control those tropical diseases which particularly impact the global poor. ASTMH supports and encourages Congress to expand funding for—and commitments to—national and international malaria control initiatives. As part of this effort, ASTMH recently conducted an analysis of federally funded tropical medicine and disease programs and developed fiscal year 2009 funding requests based on this assessment.

#### TROPICAL MEDICINE AND TROPICAL DISEASES

The term “tropical medicine” refers to the wide-ranging clinical work, research, and educational efforts of clinicians, scientists, and public health officials with a focus on the diagnosis, mitigation, prevention, and treatment of diseases prevalent in the areas of the world with a tropical climate. Most tropical diseases are located 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.

The field of tropical medicine encompasses clinical work treating tropical diseases, work in public health and public policy to prevent and control tropical diseases, basic and applied research related to tropical diseases, and education of health professionals and the public regarding tropical diseases.

Tropical diseases are illnesses that are caused by pathogens that are prevalent in areas of the world with a tropical climate. These diseases are caused by viruses, bacteria, and parasites which are spread through various mechanisms, including airborne routes, sexual contact, contaminated water and food, or an intermediary or “vector”—frequently an insect (e.g. a mosquito)—that transmits a disease between humans in the process of feeding.

#### MALARIA

Malaria is a global emergency affecting mostly poor women and children; it is an acute and sometimes fatal disease caused by the single-celled *Plasmodium* parasite that is transmitted to humans by the female *Anopheles* mosquito.

Malaria is highly treatable and preventable. The tragedy is that despite this, malaria is one of the leading causes of death and disease worldwide. According to the CDC, as many as 2.7 million individuals die from malaria each year, with 75 percent of those deaths occurring in African children. In 2002, malaria was the fourth leading cause of death in children in developing countries, causing 10.7 percent of all such deaths. Malaria-related illness and mortality exact a significant human toll as well as cost Africa’s economy \$12 billion per year perpetuating a cycle of poverty and illness. Nearly 40 percent of the world’s population lives in an area that is at high risk for the transmission of malaria.

Fortunately, malaria can be both prevented and treated using four types of relatively low-cost interventions: (1) the indoor residual spraying of insecticide on the walls of homes; (2) long-lasting insecticide-treated nets; (3) Artemisinin-based combination therapies; and (4) intermittent preventive therapy for pregnant women. However, limited resources preclude the provision of these interventions and treatments to all individuals and communities in need.

#### REQUESTED MALARIA-RELATED ACTIVITIES AND FUNDING LEVELS

##### *CDC Malaria Efforts*

ASTMH calls upon Congress to fund a comprehensive approach to malaria control, including adequately funding the important contributions of the CDC. The CDC originally grew out of the WWII “Malaria Control in War Areas” program, and since its founding the Atlanta-based agency has maintained a strong role in efforts to research and mitigate malaria. Although malaria has been eliminated as an endemic threat in the United States for over 50 years, CDC continues to be on the cutting edge of global efforts to reduce the toll of this deadly disease.

CDC efforts on malaria falls into three broad areas—prevention, treatment, and vaccines—and CDC performs a wide range of basic research within these categories. This includes investigations of the biology of host-parasite relationships; immune response to malaria; host genetic factors associated with malaria; parasite genetic diversity and drug resistance; HIV and malaria interaction; the efficacy of insecticide-treated nets in preventing illness and deaths; malaria and pregnancy; public health strategies for improving access to antimalarial treatment and delaying the appear-

ance of antimalarial drug resistance; improved transmission reduction strategies; vaccine development and evaluation; and many other topics.

Although endemic malaria has been eradicated in the United States it remains one of the leading causes of death and disease around the world, and a significant proportion of CDC's malaria-focused work involves working in and with foreign countries to prevent the spread of malaria, and to assist in the treatment of those who have contracted the disease. CDC funding in fiscal year 2008 for global malarial activities is \$8.7 million, which includes CDC's contribution to the \$1.2 billion President's Malaria Initiative.

CDC participates in several global efforts, including: The President's Malaria Initiative (PMI), the Amazon Malaria Initiative (AMI), the West Africa Network Against Malaria During Pregnancy, Preventing and Controlling Malaria During Pregnancy in Sub-Saharan, and the International Red Cross and the Expanded Program for Immunizations.

CDC collaborations support treatment and prevention policy change based on scientific findings; formulation of international recommendations through membership on World Health Organization (WHO) technical committees; and work with Ministries of Health and other local partners in malaria-endemic countries and regions to develop, implement, and evaluate malaria programs. In addition, CDC has provided direct staff support to the WHO; UNICEF; the Global Fund to Fight AIDS, Tuberculosis, and Malaria; and the World Bank—all stakeholders in the Roll Back Malaria (RBM) Partnership.

#### NIH MALARIA PROGRAMS

As the Nation's and world's premier biomedical research agency, the NIH and its Institutes and Centers play an essential role in the development of new anti-malarial drugs, better diagnostics, and an effective malaria vaccine. NIH estimates that its fiscal year 2007 spending on malaria research will total \$101 million while malaria vaccine efforts will receive \$45 million. ASTMH urges that NIH malaria research portfolio and budget be increased by at least 6.6 percent in fiscal year 2009. To support a comprehensive effort to control malaria, ASTMH respectfully requests the following funding:

- \$31.1 billion to NIH
- \$4.3 billion NIAID
- \$71 million to the Fogarty International Center for training that supports U.S. efforts targeting malaria and other neglected tropical diseases.

*National Institute of Allergy and Infectious Diseases (NIAID).*—Malaria continues to be among the most daunting global public health challenges we face. A long-term investment is needed to achieve the drugs, diagnostics and research capacity needed to control malaria. NIAID, the lead institute for malaria research, plays an important role in developing the drugs and vaccines needed to fight malaria. ASTMH urges the committee to increase NIAID funding so that present malaria research efforts be maintained and new areas explored such as: increasing fundamental understanding of the complex interactions among the malaria parasites, the mosquito vectors responsible for their transmission and the human host; developing new diagnostics, drugs, vaccines, and vector management approaches; and enhancing both national and international research and research training infrastructure to meet malaria research needs.

*Fogarty International Center (FIC).*—While biomedical research has provided major advances in the treatment and prevention of malaria, these benefits are often slow to reach the people who need them the most. While highly-effective anti-malarial drugs exist and when patients receive these drugs promptly their lives can be saved. The FIC plays a critical role in strengthening science and public health research institutions in low-income countries, specifically in malaria, TB, and neglected tropical diseases. By promoting applied health research in developing countries, the FIC can speed the implementation of new health interventions for malaria, TB, and neglected tropical diseases.

The FIC works to strengthen research capacity in countries where populations are particularly vulnerable to threats posed by malaria and neglected tropical diseases. FIC's efforts strengthen the research workforce in-country—including collaborations with U.S.-supported global health programs—and help to ensure that programs are continuously improved and adapted to local conditions, and that the impact of U.S. investments is maximized, are critical to fighting malaria and other tropical diseases.

The FIC addresses global health challenges and supports the NIH mission through myriad activities, including: collaborative research and capacity building projects relevant to low- and middle-income nations; institutional training grants

designed to enhance research capacity in the developing world, with an emphasis on institutional partnerships and networking; the Forum for International Health, through which NIH staff share ideas and information on relevant programs and develop input from an international perspective on cross-cutting NIH initiatives; the Multilateral Initiative on Malaria, which fosters international collaboration and cooperation in scientific research against malaria; and the Disease Control Priorities Project, which is a partnership supported by the FIC, The Gates Foundation, the WHO, and the World Bank to develop recommendations on effective health care interventions for resource-poor settings.

ASTMH urges the subcommittee to allocate additional resources to the FIC in fiscal year 2009 to increase these efforts, particularly as they address the control and treatment of malaria.

#### CONCLUSION

Thank you for your attention to these important global health matters. We know that you face many challenges in choosing funding priorities and we hope that you will provide the requested fiscal year 2009 resources to those agencies programs identified above. ASTMH appreciates the opportunity to share its views, and we thank you for your consideration of our requests.

#### PREPARED STATEMENT OF THE AMERICAN THORACIC SOCIETY

##### SUMMARY.—FISCAL YEAR 2009 FUNDING RECOMMENDATIONS

[In millions of dollars]

	Amount
National Institutes of Health .....	30,537
National Heart, Lung & Blood Institute .....	3,112
National Institute of Allergy & Infectious Disease .....	4,675
National Institute of Environmental Health Sciences .....	683
Fogarty International Center .....	70
National Institute of Nursing Research .....	146
Centers for Disease Control and Prevention .....	10,700
National Institute for Occupational Safety & Health .....	253
Environmental Health: Asthma Activities .....	70
Div. of Tuberculosis Elimination .....	300
Chronic Disease Prev. & Health Promotion: COPD .....	6

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. The American Thoracic Society, founded in 1905, is an independently incorporated, international education and scientific society that focuses on respiratory and critical care medicine. With approximately 18,000 members who help prevent and fight respiratory disease around the globe, through research, education, patient care and advocacy, the Society's long-range goal is to decrease morbidity and mortality from respiratory disorders and life-threatening acute illnesses.

#### LUNG DISEASE IN AMERICA

Lung disease is a serious health problem in the United States. One in seven deaths is caused by lung disease, making it America's number three cause of death. In 2005, lung diseases cost the U.S. economy an estimated \$157.8 billion in direct and indirect costs. Lung diseases include chronic obstructive pulmonary disease, lung cancer, tuberculosis, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease, sarcoidosis, asthma and severe acute respiratory syndrome (SARS).

The ATS is concerned that the President's fiscal year 2009 budget proposes to freeze NIH spending at the fiscal year 2008 level and would impose a significant funding cut for the Centers for Disease Control and Prevention (CDC). We ask that this subcommittee recommend a 6.5 percent increase for NIH so that the institute can respond to biomedical research opportunities and public health needs. In order to stem the devastating effects of lung disease, research funding must continue to grow to sustain the medical breakthroughs made in recent years. We also ask that the CDC budget be adjusted to reflect increased needs in chronic disease prevention, infectious disease control, including strengthened TB control to prevent the spread

of drug-resistant TB, and occupational safety and health research and training. There are three lung diseases that illustrate the need for further investment in research and public health programs: Chronic Obstructive Pulmonary Disease, pediatric lung disease, asthma and tuberculosis.

#### COPD

Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death in the United States and the third leading cause of death worldwide. It is estimated that 11.2 million patients have COPD while an additional 12 million Americans are unaware that they have this life threatening disease. According to the National Heart, Lung and Blood Institute (NHLBI), COPD cost the U.S. economy an estimated \$37 billion per year. We recommend the subcommittee encourage NHLBI to devote additional resources to finding improved treatments and a cure for COPD.

Today, COPD is treatable but not curable. Fortunately, promising research is on the horizon for COPD patients. Despite these leads, the ATS feels that research resources committed to COPD are not commensurate with the impact the disease has on the United States and that more needs to be done to make Americans aware of COPD, its causes and symptoms. The ATS commends the NHLBI for its leadership on educating the public about COPD through the National COPD Education and Prevention Program. As this initiative continues, we encourage the NHLBI to maintain its partnership with the patient and physician community.

While additional resources are needed at NIH to conduct COPD research, CDC has a role to play as well. To address the increasing public health burden of COPD, the ATS encourages the CDC to create a COPD program the Center for Chronic Disease Prevention and Health Promotion with a recommended funding level of \$6 million for fiscal year 2009. We are hopeful that the program will include development of a national COPD response plan, expansion of data collection efforts and creation of other public health interventions for COPD. The ATS also encourages the CDC to add 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). By collecting information on the prevalence of COPD, researchers and public health professionals will be better able to understand and control the disease.

#### PEDIATRIC LUNG DISEASE

The ATS is pleased to report that infant death rates for various lung diseases have declined for the past 10 years. However, of the seven leading causes of infant mortality, four are lung diseases or have a lung disease component. In 2003, lung diseases accounted for 18 percent of all deaths under 1 year of age. The ATS encourages the NHLBI to continue with its research efforts to study lung development and pediatric lung diseases.

The pediatric origins of chronic lung disease extend back to early childhood factors. For example, many children with respiratory illness are growing into adults with COPD. In addition, it is estimated that close to 20.5 million people suffer from asthma, including an estimated 6.8 million children. While some children appear to outgrow their asthma when they reach adulthood, 75 percent will require life-long treatment and monitoring of their condition. Asthma is the third leading cause of hospitalization among children under the age of 15 and is the leading cause of chronic illness among children.

#### ASTHMA

The ATS believes that the NIH and the CDC must play a leadership role in assisting individuals with asthma. National statistical estimates show that asthma is a growing problem in the United States. Approximately 22.2 million Americans currently have asthma, of which 12.2 million had an asthma attack in 2005. African Americans have the highest asthma prevalence of any racial/ethnic group. The age-adjusted death rate for asthma in the African-American population is three times the rate in whites.

#### ASTHMA SURVEILLANCE

There is a need for more data on regional and local asthma prevalence. In order to develop a targeted public health strategy to respond intelligently to asthma, we need locality-specific data. CDC should take the lead in collecting and analyzing this data and Congress should provide increased funding to build these tracking systems.



In fiscal year 2008, Congress provided approximately \$30.7 million for CDC's National Asthma Control Program. The goals of this program are to reduce the number of deaths, hospitalizations, emergency department visits, school or work days missed, and limitations on activity due to asthma. We recommend that CDC be provided with \$70 million in fiscal year 2009 to expand the program and establish grants to community organizations for screening, treatment, education and prevention of childhood asthma.

#### SLEEP

Sleep is an essential element of life, but we are only now beginning to understand its impact on human health. Several research studies demonstrate that sleep illnesses and sleep disordered breathing 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 traffic accidents, lost work and school productivity, cardiovascular disease, obesity, mental health disorders, and other sleep-related comorbidities. We cannot appropriately address these problems if we do not consider how chronic sleep loss contributes to them. Despite the increased need for study in this area, research on sleep and sleep-related disorders has been underfunded. The ATS recommends funding level of \$2 million in fiscal year 2009 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 a global public health crisis that remains a concern for the U.S. Globally, one-third of the world's population is infected with the TB germ, 9.2 million active cases develop each year and 1.7 million people die of tuberculosis annually. The rapid spread of drug resistant TB and the emergence of extensively drug-resistant (XDR) TB has created a global health emergency. According to a February 2008 World Health Organization (WHO) report on drug resistant TB, about 5 percent of all new TB cases are drug resistant. The highest rates of drug resistance can be found in former Soviet bloc countries such as Azerbaijan and Ukraine and areas where HIV/AIDS is endemic, such as South Africa. Because it is resistant to most of the drugs used to treat TB, XDR-TB is virtually untreatable and has an extremely high fatality rate. Because of the ease with which TB can spread, drug resistant TB will continue to pose a serious risk to the United States as long as it exists anywhere else in the world.

According to the CDC, although the overall rate of new TB cases is declining in the United States, the annual rate of decrease in TB cases has slowed significantly, from about 7.3 percent (1993 to 1999) to 3.8 percent currently (2000–2007). This rate represents one of the smallest declines since 1992, when over \$1 billion was spent in New York City alone to regain control of TB. The ATS is concerned that TB rates in African Americans remain high and that TB rates in foreign-born Americans are growing.

While we urge immediate action in response to the drug resistant TB global health crisis, we also recognize the best way to prevent the future development of other resistant strains of tuberculosis is through supporting effective tuberculosis control programs in the United States and throughout the globe. We ask the subcommittee to take the first steps to eliminating TB in the United States and prevent further outbreaks of drug resistant forms of TB. The ATS, in collaboration with Stop TB USA, recommends a funding level of \$300 million in fiscal year 2009 for CDC's Division of TB Elimination.

The NIH has a prominent role to play in the elimination of tuberculosis through the development of new tools to fight the disease, however the ATS is concerned that the NIH has cut funding for TB research from \$158 million in 2005 to \$150 million in 2006–2008. We encourage the NIH to expand efforts to develop new tools to reduce the rising global TB burden, including faster diagnostics that effectively identify TB in all populations, new drugs to shorten the treatment regimen for TB and combat drug resistance, and an effective vaccine.

#### *Fogarty International Center TB Training Programs*

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 inter-

national health care professionals in the area of TB treatment and research. These training grants should be expanded and offered to all institutions. The ATS recommends Congress provide \$70 million for FIC, which would allow the expansion 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 \$253 million in fiscal year 2009 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. It is this country's third leading cause of death. The lung disease death rate continues to climb. Overall, lung disease and breathing problems constitute the number one killer of babies under the age of 1 year. Worldwide, tuberculosis is one of the leading infectious disease killers. 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. Please contact Nuala S. Moore, Sr. Legislative Representative, at 202.296.9770, or Nmoore@thoracic.org, with any questions concerning this statement.

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#### PREPARED STATEMENT OF THE ARTHRITIS FOUNDATION

The Arthritis Foundation greatly appreciates the opportunity to submit testimony in support of the continued federal commitment to arthritis research at the National Institutes of Health and arthritis public health initiatives at the Centers for Disease Control and Prevention, which are aimed at improving the lives of 46 million adults and 294,000 children living with arthritis in the United States.

The medical and societal impact of arthritis in the United States is staggering. Arthritis costs the economy \$128 billion, which was equivalent to 1.2 percent of the U.S. gross domestic product in 2003. These costs include \$81 billion in direct costs for expenses like physician visits and surgical interventions, and \$47 billion in indirect costs for missed work days. Arthritis is the most common cause of disability in the United States, and nearly one-third of adults with arthritis experience work limitations.

The Arthritis Foundation strongly believes that in order to prevent or delay arthritis from impacting people and to mitigate the effects of arthritis that an investment both from the private and public sector must be made today. Research shows that the pain and disability of arthritis can be decreased through early diagnosis and appropriate management, including evidence based self-management activities such as 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 interventions are recognized by the Centers for Disease Control and Prevention to reduce health care expenditures. The Arthritis Foundation offers and partners with other organizations to offer the Self-Help Program, and an Aquatic Program, and an Exercise Program as part of our Life Improvement Series. Each of these programs is proven to reduce pain and physician visits, decrease stiffness and increase function.

The public sector investment at the Federal Government level entails the Centers for Disease Control and Prevention's arthritis program. In early 1998, the Arthritis Foundation joined forces with the CDC to develop the National Arthritis Action Plan—an innovative public health strategy. Among the goals are improving the scientific information base on arthritis, increasing awareness that arthritis is a national health problem, and encouraging more individuals with arthritis to seek early intervention and treatment to reduce pain and disability. Due to the subcommittee's support and leadership, the CDC was provided with \$10 million in fiscal year 1999 to begin to make this vision a reality. Ten years later, the CDC's arthritis program has not kept pace and in fact, has seen a decline in funding from just a few years ago. In fiscal year 2008, the arthritis program was funded at \$13 million.

Approximately half of the CDC's arthritis program funding is distributed through a competitive grant process, to 36 State health departments. Over the past 5 years, these 36 State health departments in partnership with other State organizations have successfully used CDC funding to increase public awareness of the burden of arthritis and increase the availability of interventions that have been proven to improve the quality of life and health care of people with arthritis. In 2007, a CDC convened expert panel recommended that individual State health departments receive larger financial grants in order to maximize the impact of the State program. The CDC is currently reviewing grant submissions from the States and will announce later this summer which 10–18 States will receive CDC funding this year. From the previous number of 36 States funded, this will result in between 18–26 States losing CDC support for their arthritis program. While more efficient and effective programs are desired in all States, the loss of programs in a significant number of States comes at a time when the prevalence of arthritis continues to climb. The CDC estimates 67 million or 25 percent of the adult population will have arthritis by 2030. More than 57 percent of adults with heart disease and more than 52 percent of adults with diabetes also have arthritis. Arthritis limits the ability of people to effectively manage other chronic diseases. It is not the time to withdraw support, but rather a significant investment must be made now to sustain and improve the reach of these interventions.

The Arthritis Foundation strongly recommends Congress appropriate \$23 million in fiscal year 2009 for CDC's arthritis program, which is equivalent to 50 cents per person with arthritis. This is a \$10 million increase from fiscal year 2008, which will ensure that qualified, participating States can continue the vital work of lessening the burden of arthritis on Americans and the American work force.

As the Arthritis Foundation celebrates our 60th anniversary of working to prevent, control, and cure arthritis, we have reached several critical milestones, which have included new treatment options and the aforementioned proven strategies in preventing the onset and progression of the disease. However, as we take stock of these accomplishments, it is important to remember the challenges still faced in helping to improve the quality of life for Americans living with arthritis, and ultimately finding a cure.

Research funded by the National Institutes of Health and the Arthritis Foundation has produced a revolutionary class of biological therapies that alleviate painful inflammation and prevent disability. While these advances have changed the lives of Americans living with arthritis significantly, there is still no cure for the disease and its prevalence and impact continues to grow.

The Arthritis Foundation firmly believes research holds the key to tomorrow's advances and provides hope for a future free from arthritis pain. From its inception in 1948, a core mission of the Arthritis Foundation is to raise funds each year to support peer-reviewed research. Last year in 2007, the Arthritis Foundation invested \$13 million in research through 179 grants, including 69 new and 110 continuing grants to researchers in over 100 academic institutions.

As the largest non-profit contributor 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. To date, the Arthritis Foundation has funded more than 2,200 researchers with more than \$380 million in grants. By supporting researchers in the early stages of their careers, the Arthritis Foundation makes important initial discoveries possible that lead to ultimate breakthrough results. However, even with this commitment every year grants that rate "stellar" in our peer review process go unfunded. These are potential cures without the funding to be realized.

An increased public investment in biomedical research holds the real promise of improving the lives of millions of Americans with arthritis. This investment will reduce the burden of arthritis on the U.S. economy with less missed work days, disability payments, and expensive surgical interventions. To illustrate this point, less than 50 percent of working age adults with rheumatoid arthritis are still employed 10 years after disease onset. Nearly two-thirds of people diagnosed with arthritis are under the age of 65—750,000 hospitalizations and 36 million outpatient visits annually are due to arthritis.

Promising research in the broad field of arthritis includes the following examples: Osteoarthritis currently impacts 23 million Americans and is the leading cause of hip and knee replacement. The Osteoarthritis Initiative at NIH is a comprehensive effort to use multiple imaging modalities, biomarkers, and genetic data to characterize osteoarthritis incidence and progression. Importantly, it represents a successful partnership between industry and the National Institute of Arthritis and Mus-

culoskeletal and Skin Diseases, which will lead to the identification of novel biomarkers of diagnostic and prognostic significance and to the development of new therapies.

Last year a former Arthritis Foundation grant recipient, Peter K. Gregersen, M.D., of the Feinstein Institute for Medical Research in Manhasset, New York, who has spent years of his professional life analyzing the human genome, and a huge international team of investigators, which included scientists from NIAMS, announced two genes that impart an increased risk of developing rheumatoid arthritis.

Researchers supported in part by the Arthritis Foundation uncovered a pathway that regulates joint destruction associated with inflammatory arthritis. Researchers David M. Lee, M.D., Ph.D., and Michael Brenner, M.D., of Brigham and Women's Hospital, Harvard Medical School in Boston, along with an international team of scientists, found that blocking the action of a protein called cadherin-11 prevents the joint destruction that characterizes inflammatory arthritis in laboratory mice. They are hopeful that their success in mice will lead to a new treatment option for people with rheumatoid arthritis and other inflammatory joint diseases.

Although cartilage is a relatively simple tissue, scientists still face challenges in engineering and growing replacement material that behaves like natural tissue. Arthritis Foundation-funded researcher Farshid Guilak, Ph.D., of Duke University Medical Center, and colleagues at Duke and at the Massachusetts Institute of Technology have taken an important step toward surmounting these obstacles. The team created a new framework structure upon which cartilage tissue can be grown by developing a microscopic technology that weaves fibers in three directions. This three-dimensional scaffold is porous so the fabric can be seeded with cells that have been suspended in a gel. The cell-infused fabric can then be transplanted into a damaged joint. The plan is that the gel and fabric will eventually degrade and be absorbed by the body, leaving only healthy, strong cartilage. If everything progresses according to plan, a new form of engineered cartilage will be available to treat joints damaged by osteoarthritis or other cartilage injuries.

The mission of the National Institute of Arthritis and Musculoskeletal and Skin Diseases is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases, the training of basic and clinical scientists to carry out this research, and the dissemination of information on research progress in these diseases. Research opportunities at NIAMS are being curtailed due to the stagnating and in some cases declining numbers of new grants being awarded for specific diseases. 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 in pursuit of other more successful endeavors.

Sustaining the field of pediatric rheumatology is essential to the care of 294,000 children under the age of 17 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 treated with the most effective treatment protocols known for their particular disease. The establishment of a national data collection system to ensure that the safety and effectiveness of these treatments is essential and that they are applied in the most beneficial manner, especially for children.

A 2007 Health Resources and Services Administration report to Congress found that there are fewer than 200 practicing pediatric rheumatologists in the United States, and 10 States have no specialists at all who are qualified to diagnose and treat children with arthritis. With this critical 75 percent shortage, it is even more important for the existing pediatric rheumatologists to be supported and to share their expert knowledge across the country through a national network of cooperating clinical centers for the care and study of children with arthritis. The Arthritis Foundation has given substantial financial support to the development of the Childhood Arthritis and Rheumatology Research Alliance (CARRA). However, in addition, NIAMS has a unique opportunity to leverage its public research funds through CARRA's capabilities, and the Arthritis Foundation urges Congress to express support for a national network of cooperating clinical centers for the care and study of children with arthritis.

The Arthritis Foundation is dedicated to finding a cure for arthritis. However, the investment in NIH research is absolutely crucial to realize this dream. With continued and increased investment in research, the Arthritis Foundation believes a cure is on the horizon. The Arthritis Foundation urges Congress to expand funding and provide a \$1.9 billion increase in fiscal year 2009 for NIH to continue to fuel innovation and discoveries that could put an end to the pain of arthritis.

The Arthritis Foundation has labored under many myths surrounding arthritis. —Arthritis is an inevitable part of the aging process.

- It cannot be prevented.
- There are no effective treatment options apart from taking a few aspirin.
- Exercise is harmful for individuals with arthritis.
- Children do not get arthritis.

Today, the Arthritis Foundation is prepared with the necessary tools, expertise, and energy to shatter these myths and capitalize on the fruits of our collective research to help improve the lives of Americans living with arthritis. On behalf of the 46 million adults and nearly 300,000 children with arthritis, I urge the members of the subcommittee and Congress to help us win the war against arthritis by increasing critical funding for the National Institutes of Health and the Centers for Disease Control and Prevention.

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#### PREPARED STATEMENT OF THE ASSOCIATION OF AMERICAN CANCER INSTITUTES

The Association of American Cancer Institutes (AACI), representing 91 of the Nation's premier academic and free-standing cancer centers, appreciates the opportunity to submit this statement for consideration as the Labor, Health and Human Services Appropriations Subcommittee plans the fiscal year 2009 appropriations for the National Institutes of Health (NIH) and the National Cancer Institute (NCI).

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. Years of flat funding for the NIH and NCI have eroded these institutions' ability to maintain their robust research programs. For fiscal year 2009, the AACI joins its colleagues in the biomedical research community in supporting the highest possible appropriation NIH. We encourage Senators to honor the commitment to biomedical research they made in voting for the Specter-Harkin amendment to the Budget Resolution that would bring the total increase for NIH to \$3 billion over fiscal year 2008 levels. Further, AACI respects the professional judgment of the NCI in requesting an appropriation of \$5.26 billion (an increase of \$455 over fiscal year 2008 levels).

#### THE GROWING CANCER BURDEN

In 2008, there will be approximately 1.44 million new cases of cancer in the United States and approximately 565,650 deaths due to the disease.<sup>1</sup> The human toll of cancer is staggering, as is its financial toll; the NCI reports that in 2006, \$206.3 billion was spent on healthcare costs for cancer alone. Additionally, NCI acknowledges that the burdens of cancer—physical, emotional, and financial—are “unfairly shouldered by the poor, the elderly, and minority populations.”<sup>2</sup> The number of cancer diagnoses will only continue to climb as our population ages, with an estimated 18.2 million cancer survivors (those undergoing treatment, as well as those who have completed treatment) alive in 2020.<sup>3</sup> By comparison, an estimated 11.9 million survivors were living in the United States in 2007.<sup>2</sup>

#### CANCER RESEARCH: BENEFITING ALL AMERICANS

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. While these 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 across the United States.

Though over a half-million Americans will die this year from the many diseases defined as cancer, progress is being made. Because of continued progress made by the Nation's researchers, cancer death rates have continued to decline; between 1991 and 2004, the death rates for cancer in men and women declined 18.4 percent and 10.5 percent, respectively.<sup>4</sup>

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

<sup>1</sup> Cancer Facts and Figures 2008. American Cancer Society; 2008.

<sup>2</sup> The Nation's Investment in Cancer Research: An Annual Plan and Budget Proposal for Fiscal Year 2009. National Cancer Institute, 2008.

<sup>3</sup> Future Supply and Demand for Oncologists. *Journal of Oncology Practice* 2007; 3(2): 79–86.

<sup>4</sup> Cancer Statistics, 2008. *CA: Cancer Journal for Clinicians* 2008; 58(2): 71–96.

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. Another initiative, the Childhood Cancer Therapeutically Applicable Research to Generate Effective Treatments Initiative, is identifying targets that can lead to better treatments for young people with cancer.

These projects—along with the work being performed by dedicated physicians and researchers across the United States every day—have the potential to radically change the way cancer, as a collection of diseases, affects the people who live with it every day. Every discovery contributes to a future without cancer as we know it today.

#### A GENERATION OF SCIENCE AT RISK

The Nation's investment in cancer research is in jeopardy. Since 2004, the budget of the NCI has—through actual cuts and the effects of biomedical inflation—lost 12 percent of its spending power.<sup>2</sup> The current success rate for R01 applications—the R01 is the cornerstone grant of medical research—submitted to NIH is 25 percent; only one in four applications submitted to NIH are funded. These funds are often approved only after the researcher has resubmitted the application several times. In 1999, the success rate for a first R01 submission was 29 percent; in 2007, that rate was 12 percent. The low approval rate and lengthy delays in receiving funds have combined to raise the average age of receiving a first R01 grant from age 39 in 1990 to age 43 in 2007.<sup>5</sup>

Because of this, young researchers—the next generation of scientists whose novel ideas will build upon those of their seasoned mentors—may be lost. As NIH itself states, “New investigators are the innovators of the future—they bring fresh ideas and technologies to existing biomedical research problems, and they pioneer new areas of investigation. Entry of new investigators into the ranks of independent, NIH-funded researchers is essential to the health of this country's biomedical research enterprise.”<sup>6</sup>

Research projects that are funded are often more conservative in scope than those of a few years ago. Scientists who perform the invaluable task of evaluating R01 proposals are electing to fund conventional projects that will lead to incremental progress; these reviewers are also less likely to fund truly “out-of-the-box” ideas that may not bear fruit—but if they were successful, these ideas could move the pace of research exponentially.<sup>5</sup> In years past, funding has been available to support both of these types of projects, a mix that led to the rapid progress to which we have become accustomed—and that has contributed to lengthening and improving the lives of cancer patients around the world.

#### THE NATION'S CANCER CENTERS

The nexus of cancer research in the United States is the Nation's network of cancer centers that are 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 \$3.17 billion<sup>7</sup> from NCI to conduct cancer research; this represents 66 percent of NCI's total budget. In fact, 85 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 is dependent on Fed-

<sup>5</sup> A Broken Pipeline? Flat Funding of the NIH Puts a Generation of Science at Risk. A Follow-up Statement by a Group of Concerned Universities and Research Institutions, 2008.

<sup>6</sup> NIH Office of Extramural Research Website: [http://grants.nih.gov/grants/new\\_investigators/](http://grants.nih.gov/grants/new_investigators/). Retrieved 3/28/08.

<sup>7</sup> National Cancer Institute 2007 Fact Book. U.S. Department of Health and Human Services, U.S. National Institutes of Health, 2007.

eral dollars, via training grants and other funding from NCI. Decreasing Federal support will significantly undermine 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.

Stagnant funding prevents expansion at existing centers but also prevents new centers from achieving NCI designation. While most major metropolitan areas in the United States have easy access to an NCI-designated cancer center, several States and many underserved areas do not. Without enhanced funding to establish and nurture cancer centers in these areas, far too many Americans face the burden of cancer without the benefit of the cutting-edge care available only at a dedicated cancer center.

#### ENSURING THE FUTURE OF CANCER CARE AND RESEARCH

Because of an aging population, an increasing number of cancer survivors require ongoing monitoring and care from oncologists, and new therapies that tend to be complex and often extend life. As a result, demand for oncology services is projected to increase 48 percent by 2020. However, the supply of oncologists expected to increase by only 20 percent and 54 percent of currently practicing oncologists will be of retirement age within that timeframe. Also, alarmingly, there has been essentially no growth over the past decade in the number of medical residents electing to train on a path toward oncology as a specialty.<sup>8</sup>

Cancer physicians—while essential—are only one part of the oncology workforce that is in danger of being stretched to the breaking point. The Health Resources and Services Administration predicted that by 2020, over 1 million nursing positions will go unfilled, and a 2002 survey by the Southern Regional Board of Education projected a 12 percent shortage of nurse educators by last year.<sup>9</sup>

Without immediate action, these predicted shortages will prove disastrous for the State of cancer care in the United States. The discrepancy between supply and demand for oncologists will amount to a shortage of 9.4 to 15.1 million visits, or a shortage of 2,550 to 4,080 oncologists.<sup>8</sup> The Department of Health and Human Services projects that today's 10-percent vacancy rate in registered nursing positions will grow to 36 percent, representing more than 1 million unfilled jobs by 2020.<sup>10</sup>

Greater Federal support for training oncology physicians, nurses, and other professionals who treat cancer must be enacted to prevent a disaster within our healthcare system when demand for oncology services far outstrips the system's ability to provide adequate care for all.

#### AMERICANS SUPPORT FEDERAL FUNDING FOR RESEARCH

The research community has long understood the obstacles that are facing cancer research. Though the nuances of R01 grants and oncology workforce training may not be well understood by the average American, the people of the United States believe in supporting the disparate activities that make up America's biomedical research infrastructure.

In a 2007 Research!America poll, 91 percent of those surveyed believed it was somewhat or very important for policymakers to create more incentives to encourage individuals to pursue careers as nurses, while 89 percent believed the same for encouraging careers as physicians. Forty-seven percent of those surveyed agreed that the United States must increase investment in NIH to ensure our future health and economic security, and 54 percent favored annual 6.7-percent increases in funding for NIH in 2008, 2009, and 2010. An overwhelming majority—70 percent—agreed that the United States is losing its global competitive edge in science, technology, and innovation.<sup>11</sup>

<sup>8</sup>Forecasting the Supply of and Demand for Oncologists: A Report to the American Society of Clinical Oncology (ASCO) from the AAMC Center for Workforce Studies. American Society of Clinical Oncology, 2007.

<sup>9</sup>ONS: Ready to Collaborate with Other Policymakers to Ensure Future of Quality Cancer Care. *Oncology Times*, August 25, 2007; (29): 8–9.

<sup>10</sup>Oncology Nursing Society Website: <http://www.ons.org/lac/pdf/correspondence/110/082807.pdf>. Retrieved 3/28/08.

<sup>11</sup>Your Congress—Your Health Survey, 2007. Charlton Research Company for Research!America, 2007.

We encourage our Representatives in Congress to respond to the concerns of the American people by enhancing support for biomedical research that will lead to improved health for everyone in the United States and around the world.

#### CONCLUSION

These are exciting times in science and, particularly, in cancer research. Discoveries made today can translate to prevention methods, treatments and even cures in the future. Research funding through the NIH and NCI make these discoveries possible.

AACI urges the members of the Senate Committee on Appropriations, Subcommittee on Labor, Health & Human Services, Education, and Related Agencies to dedicate the highest possible appropriation for the NIH in fiscal year 2009. We ask that the Senate honor the efforts of 95 of its members who voted in favor of the Specter-Harkin Amendment to the Budget Resolution in March. We request your support in increasing this critical funding that will help set the pace for cancer research for years to come.

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#### PREPARED STATEMENT OF THE ASSOCIATION FOR CLINICAL RESEARCH TRAINING

##### SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2009

At least a 6.5 percent funding increase for the National Institutes of Health, including the National Center for Research Resources.

\$700 million for the Clinical and Translational Science Awards Program.

Continuation of the K-30 Clinical Research Curriculum Awards Program.

\$360 million for the Agency for Healthcare Research and Quality.

The Association for Clinical Research Training (ACRT) is committed to improving the Nation's health by increasing the amount and quality of clinical research through the expansion and improvement of clinical research training. This training is funded by both the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ).

##### NATIONAL INSTITUTES OF HEALTH

As you are aware, recent years of near level-funding at the National Institutes of Health (NIH) have negatively impacted the mission of the National Center for Research Resources (NCRR). For this reason, ACRT applauds efforts like Senators Tom Harkin (D-IA) and Arlen Specter's (R-PA) adopted amendment to the fiscal year 2009 Senate Budget Resolutions which calls on appropriators to provide NIH with a 10.3 percent funding increase. ACRT urges this Subcommittee to show strong leadership in pursuing such a substantial funding increase.

For fiscal year 2009 ACRT is recommending a funding increase of at least 6.5 percent for NIH and NCRR.

One of the programs hardest hit by the loss of resources that has resulted from recent years of level funding at NIH is the Clinical and Translational Science Awards (CTSA) program. The CTSA program aims to meet one of the profound challenges of 21st Century medicine, namely that the ever increasing complexities involved in conducting clinical research are making it more difficult to translate new knowledge from the bench to the bedside. The CTSA program transforms basic research into clinical practice, advances information technology, integrates research networks and improves workforce training. As Dr. Elias Zerhouni, the Director of NIH, wrote in the October 13, 2005 edition of the *New England Journal of Medicine*, "it is the responsibility of those of us involved in today's biomedical research enterprise to translate the remarkable scientific innovations we are witnessing into health gains for the Nation."

The CTSA program is intended to assist institutions in creating a home for clinical and translational science that has the resources necessary to train and advance the next generation of investigators. Originally, the program was designed to begin with 12 academic health centers located throughout the Nation, and ultimately link 60 institutions together to energize the discipline of clinical and translational science. However, budgetary constraints are presently affecting the scheduled implementation of this program by reducing the size of awards. In an effort to reach the targeted goal of 60 institutions with a continually diminished resource pool, NCRR has begun reducing the size of awards to institutions by as much as 40 percent in some instances. This has created a disparity between the size of awards given to the 12 initial institutions and those awards given to other institutions in subsequent rounds of grants. Additionally, it now appears that NCRR may not even have the necessary resources to ultimately provide 60 awards.



For fiscal year 2009 ACRT is recommending a funding level of \$700 million for the CTSA program, an increase of \$220 million over fiscal year 2008.

It is important to note that implementation of the CTSA program is intended to subsume other programs, most notably the General Clinical Research Centers (GCRC) program. Furthermore, many of the clinical training mechanisms currently offered through the GCRC program are scheduled to sunset or be replaced by CTSA mechanisms. Once again, the impact of inadequate resources on the implementation of the CTSA program has created significant challenges to maintaining clinical research training mechanisms while transition occurs between the CTSA and GCRC programs.

Nowhere are these challenges more apparent than within the K-30 Clinical Research Curriculum Awards (CRCA) mechanism. K-30 awards have a track record as an exceedingly cost-effective approach to improving the quality of training in clinical research. Presently, the CRCA mechanism is scheduled for phase out by 2010 to reduce redundancies with the CTSA program. However, due to the slowed implementation of the CTSA program and the reductions in the size of awards, the CRCA program remains essential to ensuring that a cadre of well trained clinical researchers is maintained in order to capitalize on the many profound developments and discoveries in basic science and to translate them to clinical settings at research institutions.

For fiscal year 2009 and beyond ACRT is recommending continuation of the K-30 Clinical Research Curriculum Awards mechanism for those institutions not given an opportunity to convert to a CTSA.

Additionally, to further protect our Nation's clinical research infrastructure, ACRT strongly opposes cuts to K-12, K-23, and K-24 Career Development Awards. These awards are crucial to generating a pool of highly trained clinical researchers.

For fiscal year 2009 ACRT is recommending that K-12, K-23, and K-24 Career Development Awards be funded at an increased level, consistent with biomedical research inflation.

#### AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AHRQ is the lead Federal agency charged with supporting research to improve healthcare quality, reduce costs, advance patient safety, decrease medical errors, eliminate disparities and broaden access to essential services. AHRQ supports health services research that will improve the quality of healthcare and improve evidence-based decision making. The agency also transforms innovative research into cutting-edge practices in order to facilitate wider access to effective healthcare services.

By providing funds to train clinical researchers, AHRQ ensures that there continues to be individuals who are able to provide the Nation with high quality, unbiased information about healthcare. Once consumers have this information, they will then be able to make effective, evidence based healthcare choices. A Center for Comparative Effectiveness Research would further leverage AHRQ's expertise in providing this information to consumers. Subsequently, additional resources would be required in order to train an expanded cohort of skilled clinical researchers with expertise in the field of comparative effectiveness.

For fiscal year 2009 ACRT is recommending a funding level of \$360 million for AHRQ, an increase of \$26 million over fiscal year 2008.

For fiscal year 2009 ACRT supports the appropriation of such sums as needed to fund a robust and meaningful Comparative Effectiveness Research initiative at AHRQ which should include clinical research training in the area of healthcare quality, cost-effectiveness, patient safety, access, and health disparities.

I thank you for the opportunity to present the views of ACRT.

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#### PREPARED STATEMENT OF THE ASSOCIATION OF FARMWORKER OPPORTUNITY PROGRAMS

Good morning Chairman Harkin and members of the subcommittee. My name is David Strauss and I represent the 51 nonprofit and public agencies that provide job training and related services to our Nation's migrant and seasonal farmworkers. They perform these tasks with grants from the United States Department of Labor pursuant to section 167 of the Workforce Investment Act. As you know, the administration has tried to eliminate this program for the last 7 years. You and the members of your subcommittee have led the way in maintaining it each year, and we thank you for your leadership.

About 2.5 million people labor in the fields and farms of America, from Hawaii to Florida and Puerto Rico, from Maine to California. Estimates are that 85 percent

of the fruits and vegetables we eat are hand harvested by farmworkers. The pay is extremely low: most farmworkers earn less than \$12,000 per year. Few farmworkers receive the job-related benefits, such as health insurance and sick pay, which we all take for granted. In many States, agricultural workers are not even eligible for unemployment compensation. While Federal law guarantees them the minimum wage, they are exempt from overtime provisions, regardless of how many hours per week they labor in the fields.

They live a tough life. Many workers travel hundreds, sometimes thousands of miles in search of work. They get paid only when they perform the work: if the weather is bad or the crop is not as plentiful as the farmer had hoped, they simply do not receive wages. They typically cannot afford decent housing. Their children have to struggle mightily to even complete their public school education. The drop-out rate for farmworker youth, especially those who migrate with their parents, is enormous.

For over 37 years the Federal Government has made and kept a commitment to these hardworking people. Special Federal programs were created to recognize the reality that farmworkers often cross State lines to work and live. Thus, we have migrant head start, migrant health, migrant education, and the job training effort called the National Farmworker Jobs Program. These all are federally funded and have guidelines that acknowledge that Governors should not be placed in a position of deciding whether or not agricultural workers qualify for these services under State residency or other localized requirements.

Today, I want to explain the results of this program since you and your colleagues in the Senate and the House of Representatives decided to retain the National Farmworker Jobs Program over the White House's opposition.

From Program Years 2001–2006, Department of Labor reports show that 123,039 eligible migrant and seasonal farmworkers enrolled and exited the program. I might add that to be eligible, a person must have earned a majority of his/her income in agricultural work, must be a United States citizen or have proof of work authorization, and must have earnings no greater than the Federal poverty level. And as a measure of their dedication to work as their means of livelihood, a very small percentage receives TANF or other forms of cash assistance.

Of the 123,039 enrolled, some received a service or item that allowed them to survive until their next payday. Many enrolled to get help to find a better job. Most of that group found that they need considerable training to really increase their earning power. During the period 2001–2006, 38,201 farmworkers got good jobs with benefits and some measure of job security. Most of these workers were unemployed and took rigorous training into new professions, such as over the road driving, welding, health care, or other non-agricultural work. About 8 percent were trained into higher-level jobs in agriculture in which they received better pay and benefits. Almost 80 percent stayed in those jobs during the 6 months following placement and on average they earned over \$10,000 more in their first year of new employment than they had the previous year. When you consider how low the poverty level is, that is an astounding increase in living standard.

Those retention and earnings data are incredible figures for any job-training program, but are especially noteworthy when you consider the barriers that so many farm laborers face. They typically have less than an 8th grade education. Most report that their primary language is Spanish. Many migrate from State to State in search of work, making it difficult to participate in a training program that may last several months. Their extremely low incomes also make it a challenge to participate, even though they can receive a minimum wage stipend during training. It can be a daunting task to participate in English language classes, learn a new trade, purchase special clothing or equipment, while still providing basic necessities so that their families can survive during the training period.

Our member agencies provide the supportive services and counseling that farmworkers need to learn their new skills and market themselves to new employers. They do all this with skill, passion and energy. Those come from within—many people who staff the National Farmworker Jobs Program were once farmworkers themselves, and they can identify with and understand the needs, hopes and fears of their “customers.”

However, no matter how dedicated and skilled these staff people may be, they could not do the life-changing work they perform every day without the grants their agencies receive from the Department of Labor. And these agencies must compete for these grants every 2 years. There is no job security for the staff that operates this program, but they nonetheless continue to perform their jobs with the dedication and perseverance necessary to properly serve the people who provide the food for America's tables.

In turn, the grants could only be possible with a national program, for the reasons stated earlier. And you are the people who have made those grants a reality by refusing to accept the Bush administration's position that this program is not needed. The 38,201 farmworkers whose lives have dramatically changed because the National Farmworker Jobs Programs was there when they needed it are grateful to you and your colleagues for recognizing and supporting their fight to achieve the American Dream.

And on behalf of our 51 member agencies that operate this successful program, I thank you as well. I ask that you continue to retain this program in the appropriations bill for the Department of Labor for Program Year 2009 and expand the funding to \$107 million to permit more young farmworkers to break the cycle of poverty into which they were born.

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#### PREPARED STATEMENT OF THE ASSOCIATION OF INDEPENDENT RESEARCH INSTITUTES

The Association of Independent Research Institutes (AIRI) respectfully submits this written statement for the fiscal year 2009 Public Record to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies.

AIRI is a national organization of approximately 90 independent, non-profit research institutes that perform basic and clinical research in the biological and behavioral sciences. Our member institutes are private, stand-alone research centers that set their sights on the vast frontiers of medical science. 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 be structurally nimble and capable of adjusting their research programs to emerging areas of inquiry. While the primary function of AIRI institutes is research, most are strongly involved in training the next generation of biomedical researchers. In a testament to the quality of research and innovative ideas that AIRI institutes bring to the national biomedical enterprise, our institutions consistently exceed the success rates of the overall National Institutes of Health (NIH) grantee pool, and receive about 11 percent of NIH's peer reviewed, competitively awarded extramural grants. On average, AIRI member institutes receive a total of \$1.6 billion in extramural grants from NIH in any given year.

The doubling of the NIH budget over 1998-2003 allowed the biomedical research community to accelerate solutions to human disease and disability. We have blazed new trails for medical research, delving into the intricacies of how the human body musters its defenses and of how those responses can be evaluated, enhanced, and modified. In addition, increased funding at NIH has helped us to realize new scientific management strategies such as fostering interdisciplinary research and creating new robust teams of scientists that, before the doubling, did not have scientific common ground. These research teams navigate the fast progressing research environment where there is an increasing need to integrate and aggregate basic research, computational capabilities, and clinical evidence into new therapies and cures more quickly. Further, Federal investment in NIH has helped us to redefine health and healthcare goals based on scientific discoveries that were out of reach prior to the doubling. We now discuss disease and healthcare in terms of developing new predictive, preventative and pre-emptive tactics.

Last year, AIRI endorsed the fiscal year 2008 Ad Hoc Group for Medical Research proposal to increase the NIH budget by 6.7 percent over each of the next three fiscal years, fiscal year 2008-fiscal year 2010. At the time, we recognized that competing budget priorities put pressure on Congress to face difficult funding trade-offs yet we asked the subcommittee to adopt a long-term commitment to NIH. As you are aware, the final fiscal year 2008 appropriation for NIH was a disappointment to your subcommittee and the rest biomedical research community. For the fifth straight year, NIH funding failed to match even the pace of biomedical inflation.

Unfortunately, the President's fiscal year 2009 budget request for NIH continues this flat funding trend for the agency for the sixth straight year. If the President's fiscal year 2009 request is enacted, the agency will have lost over 13.4 percent of its purchasing power during this time period when taking into account the antici-

pated 3.5 percent biomedical inflation rate for this year. As such, AIRI joins its colleagues in the biomedical community in calling for a \$1.9 billion (6.6 percent) increase in NIH's total discretionary budget for fiscal year 2009.

The NIH-funded research conducted at independent research institutes and other institutions across the Nation is important for curbing projected dramatic increases in U.S. healthcare costs over the long term. Sustained, multi-year Federal funding commitments will be critical to forestalling the onset of diseases such as heart disease and stroke, Alzheimer's disease, mental health disorders, and cancer as 80 million baby boomers begin to retire and face the diseases of aging. NIH-funded research has had an enormous impact and remains a cornerstone in the Nation's battle against existing and emerging diseases. Flat funding for the agency reduces NIH's ability to meet the research demands of the Nation and slows the medical advances that can be made by the entire research community.

In addition to funding for NIH biomedical research overall, AIRI hopes that the subcommittee will continue to support programs and policies championed by NIH Director Dr. Zerhouni that foster a sustainable, biomedical research workforce. The biomedical research community is dependent upon a knowledgeable and skilled workforce to address current and future critical health research challenges. The cultivation and preservation of this workforce is dependent upon several factors, including the ability to: recruit scientists and students globally; train researchers both in basic and clinical biomedical research; develop and retain researchers at critical stages during their early careers; support new and young investigators; and maintain the NIH extramural investigator salary cap at Executive Level I. As we work to enhance biomedical research capabilities, we should not impose barriers that would discourage talented people from committing to careers in research. The recruitment and development of these scientists will be a key to sustaining our national competitiveness.

Additionally, AIRI urges Congress to support NIH extramural shared instrumentation and equipment grant programs. As the investment in medical research and the national biomedical research agenda have expanded, the need for acquisition and modernization of laboratory equipment and infrastructure has become critical. NIH equipment grants meet the specific infrastructure needs of research institutions to maximize productivity of their research grants. These grants aid in the attainment of state-of-the-art research tools that allow U.S. laboratories to investigate biomedical questions on the cutting edge of science.

Medical research is a long-term process and, in order to meet the challenges of improving human health, curbing rising healthcare expenditures, and securing a global leadership role in the life sciences, we must increase our Federal commitment and investment in NIH. It is essential to sustain the momentum of NIH-funded research so that it continues to meet the goal of improving the health of all Americans.

AIRI would like to thank the subcommittee for its important work to ensure the health of the Nation, and we appreciate this opportunity to present recommendations concerning the fiscal year 2009 Appropriations bill in the fiscal year 2009 Public Record.

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PREPARED STATEMENT OF THE ASSOCIATION OF MATERNAL AND CHILD HEALTH PROGRAMS

The Association of Maternal and Child Health Programs (AMCHP) is pleased to submit this testimony in support of fully funding the Maternal and Child Health (MCH) Services Block Grant at \$850 million in fiscal year 2009. When our children are healthy, they are more likely to succeed. MCH programs help promote our children's success by identifying emerging and urgent health needs, while continuing to assure services like prenatal care, immunizations and access to health services. The MCH Block Grant provides funding to State MCH agencies, which directly serve almost 35 million women and children in the U.S. State MCH programs reach millions more through support of population-wide programs that reach all women and children, such as newborn screening for genetic disorders, lead poisoning prevention, injury prevention, and public education.

AMCHP supports full funding of the MCH Block Grant to enable States to:

- Provide and enable access to comprehensive preconception, prenatal and postnatal health care and public health services that reduce infant mortality and improve the overall health of mothers and children
- Ensure access to quality health care through enabling services such as transportation and translation

- Increase the number of children receiving health assessments and follow-up diagnostic and treatment services
- Provide and ensure access to preventive and rehabilitative services for children, including immunizations, screenings, nutrition and dental education and mental health services
- Implement family-centered and community-based systems of coordinated health care for children and youth with special health care needs
- Partner with schools, youth service groups, and other agencies and organizations to prevent behaviors that place youth at risk.

In 2002, funding for the MCH Block Grant peaked at \$731 million and has been level funded or reduced ever since. The fiscal year 2008 omnibus appropriations bill cut funding to \$666 million. This alarming reduction threatens the progress States have made in improving the health of mothers, children, and families. When Title V of the Social Security Act was passed in 1935, the Federal Government pledged its support of State efforts to extend and improve health and welfare services for mothers and children. The MCH Block Grant today remains the only Federal program that focuses solely on improving the health of all mothers and children. The reduction of Federal support for this vital program in recent years represents an alarming gap in the Federal-State partnership needed to assure the health of all women, children, and families in the America.

AMCHP members report that reductions to the MCH Block Grant require cutbacks in needed services at the State and local level. Reductions to the MCH Block Grant erode the remarkable successes that have been made in improving the health of mothers and children over the past half century. For example, today the infant mortality rate is 77 percent lower than in 1950, immunization rates have reached historic highs, childhood deaths from injuries are down dramatically, and most children report having a usual source of health care. Despite this substantial progress, consider the following troubling trends in the health of our Nation's mothers and children:

- Over the past decade, improvements in reducing maternal and infant mortality have stalled and preterm and low birth weight births have increased. Today the United States ranks 29th in infant mortality rates in international comparisons.
- Racial and ethnic disparities persist across several health status indicators, and the black infant mortality rate is double the rate for whites.
- Teen pregnancy rates rose in 2007 for the first time in 14 years.
- Childhood obesity is a national epidemic requiring urgent public health intervention, with some age groups experiencing a threefold obesity rate increase over the past two decades.

Considering these and many other urgent health needs, we ask for your leadership in supporting full funding for the MCH Block Grant at \$850 million in fiscal year 2009.

The MCH Block Grant improves the health of America's women and children by:

- Supporting programs that work. The MCH Block Grant earned the second highest program rating by the Office of Management and Budget (OMB)'s Program Assessment Rating Tool (PART). OMB found that MCH 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. The program has performance measures and evaluations that document the effective impact of this modest investment in innovative approaches. Reduction to the MCH Block Grant threatens the ability of these programs to carry on this work.
- Addressing the growing needs of women, children and families. As States face economic hardships and face limits on their Medicaid and SCHIP programs, more women and children seek care and services through MCH-funded programs. Resources are needed to reduce infant mortality, provide mental health care to those in need, improve oral health care, reach more children and youth with special health care needs, and reduce racial disparities in health care.
- Supporting health systems and leveraging Federal funding for other health programs such as community health centers, Healthy Start, WIC, Combating Autism, SCHIP and Medicaid. The MCH Block Grant invests in State needs assessments, planning and policy development, quality assurance and standards development, training, collection of health care data and analysis, and development of information systems that complement health care services and promote prevention for all populations. Close coordination with other health programs assures that funding is maximized and services are not duplicated.

Over the years, the achievements of MCH Block Grant-supported projects have been integrated into the ongoing care system for children and families. Landmark

projects have produced guidelines for child health supervision from infancy through adolescence; influenced the nature of nutrition care during pregnancy and spread the message about the benefits of breastfeeding; recommended standards for prenatal care; identified successful strategies for the prevention of childhood injuries; and developed health safety standards for out-of-home child care facilities.

During the Senate's debate on the fiscal year 2009 budget resolution, Senator Chris Dodd introduced a bi-partisan amendment co-sponsored by Senator Orin Hatch that called for full funding of the MCH Block Grant. Upon introducing the amendment, Senator Dodd stated:

The MCH program is critical to the health and well-being of millions of families across this country, including some of the most vulnerable members of our society. Years of funding cuts and level funding have stretched maternal and child health programs to their limits . . . The MCH block grant is a proven success for helping ensure a healthy future for our Nation's children [and] I urge my colleagues to support my amendment to increase MCH block grant funding to \$850 million in this year's budget resolution.

This amendment passed the Senate by unanimous consent, and over 30 national organizations have joined in support of full funding (see attached letter).

AMCHP urges the Senate to recognize the need for additional resources for States and their partners to continue this vital work. We request your support and leadership to fully fund the Title V Maternal and Child Health Services Block Grant at \$850 million for fiscal year 2009. Full funding for the MCH Block Grant is an effective and efficient investment in our Nation's women, children, and families.

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#### PREPARED STATEMENT OF THE ASSOCIATION FOR PSYCHOLOGICAL SCIENCE

##### SUMMARY OF RECOMMENDATIONS

- As a member of the Ad Hoc Group for Medical Research Funding, APS recommends \$31.1 billion for NIH in fiscal year 2009.
- APS requests committee support for behavioral and social science research and training as a core priority at NIH in order to: better meet the Nation's health needs, many of which are behavioral in nature; realize the exciting scientific opportunities in behavioral and social science research, and; accommodate the changing nature of science, in which new fields and new frontiers of inquiry are rapidly emerging.
- Given the critical role of basic behavioral science research and training in addressing many of the Nation's most pressing public health needs, we ask the committee to ensure that the National Institute of Mental Health coordinates with other NIH Institutes to provide support for basic behavioral science research.
- APS encourages the committee to review behavioral science activities at individual institutes. Examples are provided in this testimony to illustrate the exciting and important behavioral and social science work being supported at NIH.

Mr. Chairman, members of the committee: As our organization's name indicates, APS is dedicated to all areas of scientific psychology, in research, application, teaching, and the improvement of human welfare. Our 20,000 members are scientists and educators at the Nation's universities and colleges, conducting NIH-supported basic and applied, theoretical and clinical research. They look at such things as: the connections between emotion, stress, and biology and the impact of stress on health; they look at how children grow, learn, and develop; they use brain imaging to explore thinking and memory and other aspects of cognition; they develop ways to manage debilitating chronic conditions such as diabetes and arthritis as well as depression and other mental disorders; they look at how genes and the environment influence behavioral traits such as aggression and anxiety; and they address the behavioral aspects of smoking and drug and alcohol abuse.

As a member of the Ad Hoc Group for Medical Research Funding, APS recommends \$31.1 billion for NIH in fiscal year 2009, an increase of 6.5 percent over the fiscal year 2008 appropriations level. This increase would halt the erosion of the Nation's public health research enterprise, and help restore momentum to our efforts to improve the health and quality of life of all Americans.

Within the NIH budget, APS is particularly focused on behavioral and social science research and the central role of behavior in health. The remainder of this testimony concerns the status of those areas of research at NIH.

Behavior is a central part of health. Many leading health conditions—such as heart disease; stroke; lung disease and certain cancers; obesity; AIDS; suicide; teen pregnancy; drug abuse and addiction; depression and other mental illnesses; neurological disorders; alcoholism; violence; injuries and accidents—originate in behavior and can be prevented or controlled through behavior.

As just one example: stress is something we all feel in our daily lives, and we now have a growing body of research that illustrates the direct link between stress and health problems: chronic stress accelerates not only the size but also the strength of cancer tumors; mounting evidence indicates that chronic stressors weaken the immune system to the point where the heart is damaged, paving the way for cardiac disease; children who are genetically vulnerable to anxiety and who are raised by stressed parents are more likely to experience greater levels of anxiety and stress later in life; animal research has shown that stress interferes with working memory; and stressful interactions may contribute to systemic inflammation in older adults, which in turn extends negative emotion and pain over time.

None of the conditions or diseases described above can be fully understood without an awareness of the behavioral and psychological factors involved in causing, treating, and preventing them. Just as there exists a layered understanding, from basic to applied, of how molecules affect brain cancer, there is a similar spectrum for behavioral research. For example, before you address how to change attitudes and behaviors around AIDS, you need to know how attitudes develop and change in the first place. Or, to design targeted therapies for bipolar disorder, you need to know how to understand how circadian rhythms work as disruptions in sleeping patterns have been shown to worsen symptoms in bipolar patients.

#### *Prevention and Health: Changing Behavior*

Earlier this year in Labor HHS Subcommittee hearings, your colleagues in the House asked health experts why Americans, who know they need to stop smoking, eat better and exercise to be healthy, continue to engage in these detrimental behaviors. As the Partnership to Fight Chronic Disease has said, it all boils down to changing behavior. In this era of flat funding for NIH and a severely restricted discretionary budget, preventive health care that has real cost offsets have received a great deal of attention. The Centers for Disease Control and Prevention has said that “the United States cannot effectively address escalating health care costs without addressing the problem of chronic diseases,” and the Milken Institute estimates the annual economic impact of preventable chronic diseases on the U.S. economy to be more than \$1 trillion. Fully 75 percent of our current healthcare spending goes towards chronic diseases, the vast majority of which could be better prevented or managed.

Only a tiny fraction of health-care spending is devoted to the promotion of healthier behavior, even though health care experts agree that moderate improvements in prevention would result in enormous savings to the economy. The Milken Institute’s major policy recommendations include promoting healthy lifestyles and disease prevention. If we can reduce obesity and smoking in this country, we’d save \$60 billion over the next 15 years. The Partnership to Fight Chronic Disease agrees that behavioral factors play a critical role in this surging trend, and that prevention focusing on these factors should be the starting point of any campaign to reduce the incidence of these debilitating conditions.

Let me illustrate how critical behavioral research is to prevention: Basic decision science research elucidates the cognitive, emotional, and social factors that influence judgment and choice, and how judgment and decision-making can be predicted and improved. This research plays a central role in health education by identifying the most effective ways to frame messages that will encourage behavior change. For example, fundamental cognitive research has shown that for certain kinds of prevention efforts, public health information is best conveyed in a “gain-framed” message (e.g., “if you regularly apply sunscreen you’ll help prevent skin cancer,” versus “if you don’t apply sunscreen, you increase your risk for skin cancer”), whereas early detection strategies should be conveyed in a “loss-framed” way (e.g., “if you don’t get a mammogram, tumors can’t be detected early, and the later the detection of cancer, the fewer the treatment options.”). Additional research has shown that the influence of message framing on health behavior is also related to the type of behavior being promoted: People are risk-seeking when they consider losses and risk-averse when they consider gains, which is directly applicable to decision making related to health. This finding has been the basis for a new generation of tailored

health-related public service messages that advance the goal of encouraging people to protect their health.

While “prevention” has been the buzzword in Congress and health advocacy circles, and there are well-intended programs aimed at reducing health problems, we need to ensure that health promotion strategies are grounded in scientific understanding of how people process information and make decisions.

*Basic Behavioral Science Research Needs A Stable Infrastructure*

Broadly defined, behavioral research explores and explains the psychological, physiological, and environmental mechanisms involved in functions such as memory, learning, emotion, language, perception, personality, motivation, social attachments, and attitudes. Within this, basic behavioral research aims to understand the fundamental nature of these processes in their own right, which provides the foundation for applied behavioral research that connects this knowledge to real-world concerns such as disease, health, and life stages. Basic behavioral research continues to fare poorly at NIH, a circumstance that jeopardizes the success of the entire behavioral research enterprise. Let us remind you of the current situation:

Traditionally, the National Institute of Mental Health (NIMH) has been the home for far more basic behavioral science than any other institute. Many basic behavioral and social questions were being supported by NIMH, even if their answers could also be applied to other institutes. In recent years, NIMH has begun to aggressively reduce its support for many areas of the most basic behavioral research, in favor of translational and clinical research. This means that previously funded areas now are not being supported.

NIMH's abrupt decision to narrow its portfolio came without adequate planning and is happening at the expense of critical basic behavioral research. We favor a broader spectrum of support for basic behavioral science across NIH as appropriate and necessary for a vital research enterprise. But until other Institutes have the capacity to support more basic behavioral science research connected to their missions, programs of research in fundamental behavioral phenomena such as cognition, emotion, psychopathology, perception, and development, will continue to languish. The existing conditions for basic behavioral science research undermine the scientific community's efforts to address many of the Nation's most pressing public health needs. We ask the committee to ensure that NIMH coordinates with other NIH Institutes to support basic behavioral research and training at NIH.

Despite the clear central role of behavior in health, behavioral research has not received the recognition or support needed to prevent, or reverse the effects of, behavior-based health problems in this Nation. APS asks that you continue to help make behavioral research more of a priority at NIH, both by providing maximum funding for those institutes where behavioral science is a core activity, by encouraging NIH to advance a model of health that includes behavior in its scientific priorities, and by encouraging stable support for basic behavioral science research at NIH.

BEHAVIORAL SCIENCE AT KEY INSTITUTES

In the remainder of this testimony, we highlight examples of cutting-edge behavioral science research being supported by individual institutes.

*National Cancer Institute (NCI).*—NCI's Behavioral Research Program continues to make excellent progress, supporting basic behavioral research as well as translational research on the development and dissemination of interventions in areas such as tobacco use, dietary behavior, sun protection, and decision-making. With current focus on prevention in health care, NCI's ongoing program in decision-making exemplifies the relationship between basic and applied behavioral research. One study this program funds is testing health behavior interventions that can be broadly applied across sociodemographic populations. Researchers are experimenting with methods of communicating risk and statistics information to women at high risk for breast cancer. These messages draw from a foundation of basic behavioral and social science research into such issues as how people learn and remember health information, how they perceive health risks, and how they are persuaded to adopt healthy behaviors. APS asks Congress to support NCI's behavioral science research and training initiatives and to encourage other Institutes to use these programs as models.

*National Institute on Aging (NIA).*—One of NIA's major initiatives is the ACTIVE (Advanced Cognitive Training for Independent and Vital Elderly) trial, which aims to halt the decline of cognitive functioning in older adults. Without good mental capabilities, this population will lose its ability to live independently, which in turn places an enormous burden on an already stressed healthcare system. This landmark study showed that brief mental exercises produced long-lasting improvements



years later, which has profound implications for intervention design. These results show that basic behavioral and cognitive science, when it underlies sound interventions that help people in real time, has a very real impact. APS asks the committee to support NIA's behavioral science research efforts and to increase NIA's budget in proportion to the overall increase at NIH in order to continue its high quality research to improve the health and wellbeing of older Americans.

*National Institute on Drug Abuse (NIDA).*—By supporting a comprehensive research portfolio that stretches across basic neuroscience, behavior, and genetics, NIDA is leading the Nation to a better understanding and treatment of drug abuse. We still know very little about the ways in which social influences interact with the unique adolescent brain to increase vulnerability to drug abuse. New research supported by NIDA is examining events in brain development that change with exposure to drugs as well as to risky behavior. Researchers are asking how these behavioral and neurobiological changes during this stage of development may be uniquely sensitive to the problems of drug abuse behavior. If we can better understand the effects structural brain changes have on functions like thinking, decision-making, sensation and perception we will be able to better develop targeted and more likely effective prevention strategies from the brain development perspective. APS asks this committee to support this and other critical behavioral science research at NIDA, and to increase NIDA's budget in proportion to the overall increase at NIH in order to reduce the health, social and economic burden resulting from drug abuse and addiction in this Nation.

*National Institute of Dental and Craniofacial Research (NIDCR).*—Several Institutes are increasingly recognizing the value and relevance of basic behavioral research to their mission. NIDCR is to be particularly commended for their support of behavior and oral health research. As we've made explicit throughout this testimony, behavior impacts every aspect of health, and oral health is no exception—to that end, NIDCR is funding basic research on theoretical models that get beyond simple cause-and-effect relationships in behavior. By identifying new ways to conceptualize behavioral and social contributors to oral health, researchers can better identify potential targets for more efficient interventions to help Americans maintain good oral health. APS asks Congress to support NIDCR's emerging behavioral science research portfolio and to encourage other Institutes to use this program as a model for how basic behavioral research can greatly facilitate achieving their research goals.

It's not possible to highlight all of the worthy behavioral science research programs at NIH. In addition to those reviewed in this statement, many other institutes play a key role in the NIH behavioral science research enterprise. These include the National Institute for Child Health and Human Development, the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, the National Heart, Lung, and Blood Institute, and the National Institute of Diabetes and Digestive and Kidney Diseases. Behavioral science is a central part of the mission of these institutes, and their behavioral science programs deserve the committee's strongest possible support.

This concludes our testimony. Again, thank you for the opportunity to discuss NIH appropriations for fiscal year 2009 and specifically, the importance of behavioral science research in addressing the Nation's public health concerns. I would be pleased to answer any questions.

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PREPARED STATEMENT OF THE ASSOCIATION FOR RESEARCH IN VISION AND  
OPHTHALMOLOGY (ARVO)

ABOUT ARVO

ARVO, the world's largest association of physicians and scientists who study diseases and disorders affecting vision and the eye, has more than 12,300 members from the United States and 73 countries. As some 80 percent of the 7,000 United States members have or are affiliated with NIH grants, ARVO submits these comments supporting increased fiscal year 2009 NIH and NEI funding.

ARVO REQUESTS FISCAL YEAR 2009 NIH FUNDING AT \$31 BILLION, OR A 6.6 PERCENT INCREASE OVER FISCAL YEAR 2008, TO MATCH INFLATION/RESTORE PURCHASING POWER AND FUND YOUNG INVESTIGATORS/CLINICIAN SCIENTISTS

NIH is a world-leading institution and must be adequately funded so that its research can reduce healthcare costs, increase productivity, improve quality of life, and ensure our Nation's global competitiveness. Although ARVO commends the Congressional leadership's actions to significantly increase NIH funding above the

Administration's budget request in fiscal year 2008 appropriations, the net 0.46 percent increase meant a net loss in NIH purchasing power. For 5 consecutive years, NIH funding has failed to keep pace with the biomedical inflation rate and NIH has lost more than 10 percent of its purchasing power. The administration's fiscal year 2009 budget, which proposes to freeze the NIH budget at the fiscal year 2008 level, threatens to further hinder the momentum of discovery leading to treatments that are saving lives—as well as restoring the quality of life—and maintaining the Nation's competitive edge in medical research.

Adequate NIH funding is also essential to a strong and vibrant research community, which risks losing established investigators and failing to attract young scientists. The NIH funding situation threatens to affect an entire generation of young researchers. As noted in the March 2008 report entitled *A Broken Pipeline? Flat Funding of the NIH Puts a Generation of Science at Risk* and in March 13, 2008, House LHHAS Appropriations Subcommittee Citizen Witness hearing testimony presented by the Federation of American Societies for Experimental Biology (FASEB), the 60,000 postdoctoral researchers who represent America's scientific future and are on the path to a lifelong career in research are being negatively affected by the decline in NIH's budget. This impact includes:

- Fewer hires, lower salaries, and increased layoffs in the research community
- Young scientists seeing their mentors struggle to maintain grant funding
- Students seeking job opportunities outside of research or in other countries
- An appreciable drop in applications in 2007 from 2006—by nearly 600—of R01 grant applications by previously unfunded researchers (“new investigators”)
- An increase in the average age from 34.2 to 41.7 years for investigators who receive their first research project grant award

These concerns are especially acute for the eye and vision research community, especially for its clinician scientists, who have been so instrumental to the NEI's impressive track record of the translation of basic research into clinical applications that directly benefit patient care.

ARVO REQUESTS FISCAL YEAR 2009 NEI FUNDING AT \$711 MILLION, OR A 6.6 PERCENT INCREASE OVER FISCAL YEAR 2008, TO ENSURE ALL AMERICANS' VISION HEALTH

The NEI was flat funded in fiscal year 2008, meaning that over the past five funding cycles it has lost 18 percent of its purchasing power, reducing the number of grants by 160, which threatens its impressive record of breakthroughs in basic and clinical research that have resulted in treatments and therapies to save and restore vision, as well as to prevent eye disease. Vision impairment/eye disease is a growing, major public health problem that disproportionately affects the aging and minority populations, costing the United States \$68 billion annually in direct and societal costs, let alone reduced independence and quality of life. Adequately funding the NEI is a cost-effective investment in our Nation's health, as it can delay, save, and prevent expenditures.

FISCAL YEAR 2009 NEI FUNDING AT \$711 MILLION ENABLES IT TO LEAD COLLABORATIVE RESEARCH REFLECTING THE NEW PARADIGM OF 21ST CENTURY HEALTHCARE THAT IS PREDICTIVE, PREEMPTIVE, PERSONALIZED, AND PARTICIPATORY

NEI research addresses the NIH's overall major health challenges as set forth by NIH Director Elias Zerhouni, M.D.: an aging population; health disparities; the shift from acute to chronic diseases; and the co-morbid conditions associated with chronic diseases (e.g., diabetic retinopathy as a result of the epidemic of diabetes). NEI research responds to Dr. Zerhouni's vision for NIH research that is collaborative and cost-effective and meets the 21st century “P4Medicine” paradigm of predictive, preemptive, personalized, and participatory research and clinical practice. For example:

- One-quarter of all genes identified to date through NEI's collaboration with the Human Genome Project is associated with eye disease, such as age-related macular degeneration (AMD), retinitis pigmentosa (RP), and glaucoma. NEI-funded researchers have discovered gene variants strongly associated with an individual's risk of developing AMD, the leading cause of blindness in older Americans. These variants, responsible for about 60 percent of the cases of AMD, are associated with the body's inflammatory response and may relate to other inflammation-associated diseases, such as Alzheimer's and Parkinson's.
- NEI is currently conducting the second phase of its Age-Related Eye Disease Study (AREDS), which follows up on initial findings that high levels of dietary zinc and antioxidant vitamins (Vitamins C, E and beta-carotene) are effective in reducing vision loss in people at high risk for developing advanced AMD—by a magnitude of 25 percent. NEI estimates that 1.3 million Americans would develop advanced AMD if no treatment was given, and if all individuals at risk

engaged in the AREDS supplement regimen, more than 300,000 of them would avoid advanced AMD and any associated vision loss during the next 5 years.

- NEI's collaborative research into factors that promote or inhibit new blood vessel growth has resulted in the first generation of ophthalmic drugs approved by the Food and Drug Administration (FDA) to inhibit abnormal blood vessel growth in "wet" AMD, thereby stabilizing and restoring vision, and NEI's Diabetic Retinopathy Clinical Research (DRCR) Network is further evaluating these drugs for treatment of macular edema associated with diabetic retinopathy (DR).

These examples primarily reflect NEI's trans-Institute research within NIH. The NEI has also collaborated with other Department of Health and Human Services (DHHS) agencies, specifically to share the results of its basic and clinical research which may impact the product approval and reimbursement processes. For example:

- In a March 2008 meeting, NEI collaborated with FDA's drug and device Centers to consider the appropriateness of new clinical endpoints in glaucoma clinical trials. Advances in visual imaging technologies—many of which emerged from collaborative research between the NEI and the National Institute of Biomedical Imaging and Bioengineering (NIBIB)—have enabled researchers to better detect structural changes in the nerve fiber layer of the retina and contours of the optic nerve head. These structural changes could potentially be used as a direct endpoint in a clinical trial, rather than a surrogate endpoint such as elevated intra-ocular pressure, when appropriately correlated to functional changes in vision to assure clinical significance of a new therapy. This meeting, which followed a November 2006 joint NEI-FDA meeting on clinical endpoints in AMD and DR clinical trials, represents the cost-effectiveness of NEI funding, as its research results may ultimately shorten the time and cost associated with clinical trials and facilitate approval of new diagnostics/therapies.
- In collaboration with the Centers for Medicare and Medicaid Services (CMS), NEI has launched the Comparison of AMD Treatments Trial (CATT), a comparative effectiveness study of the two drugs used to block growth of abnormal blood vessels in patients with the "wet" form of AMD. NEI's collaboration with CMS could guide clinical practice and reduce costs to the Medicare program.

#### THE NEI'S DIMINISHED PURCHASING POWER JEOPARDIZES ITS ABILITY TO FOLLOW UP ON RESEARCH BREAKTHROUGHS FROM PAST INVESTMENT

Congress must adequately fund NEI so it can initiate promising new research, pursue results that have emerged from previous breakthroughs, and offer up its "fair share" of funding in its extensive collaborations. The number of NEI grants has declined by 160 over the past five years, from 1,214 in fiscal year 2004 to 1,054 in fiscal year 2008, representing myriad "lost opportunities"—any one of which could have been the key to curing eye disease or restoring vision. Examples of such lost opportunities include:

- Ocular gene therapy holds great promise for retinal degenerative diseases, in which nearly 200 gene defects have been implicated. Investigators supported by NEI and private-funding organization Foundation Fighting Blindness (FFB) have begun human clinical trials of a gene therapy to treat Leber Congenital Amaurosis (LCA), a rapid retinal degeneration that blinds infants in the first year of life. Previous research has restored vision in dogs with LCA, and the results of the human clinical trials are forthcoming. Although the NEI could expand this program to target more diseases, current budget realities limit further research.
- Promising protocols proposed within the Diabetic Retinopathy Clinical Research Network will not be funded. The DRCR Network is a large, multi-center study that engages ophthalmologists and optometrists, many in community health centers, in basic and clinical research. Past NEI diabetes networks developed laser treatments for DR that save \$1.6 billion annually in Federal disability payments.
- NEI funding for epidemiological studies is already limited, which jeopardizes future research into the basis/progression of eye disease in additional ethnic populations, such as Asian and Native Americans. Past NEI studies identified a three-fold greater risk of glaucoma in African Americans and glaucoma as the leading cause of irreversible vision loss in African Americans and Hispanics.
- NEI will not be able to fund proposed new Clinical Research Networks for AMD and for neuro-ophthalmic disorders. The latter could assist in understanding visual disorders associated with Traumatic Brain Injuries (TBI), especially those currently being incurred in record numbers by soldiers in Iraq and Afghanistan.

NEI research into other significant eye disease programs such as cataract will be threatened, along with quality of life research programs into low vision and chronic dry eye. This occurs at a time when the U.S. Census cites significant demographic trends that will increase the public health problem of vision impairment and eye disease, such as the first wave of 78 million Baby Boomers celebrating their 65th birthday in 2010, with about 10,000 Americans turning 65 each day for 18 years afterward.

EYE DISEASE IS A MAJOR PUBLIC HEALTH PROBLEM INCREASING HEALTH COSTS,  
REDUCING PRODUCTIVITY, AND DIMINISHING QUALITY OF LIFE

The 2000 U.S. Census reported that more than 119 million people in the United States were age 40 or older—the population most at risk for an age-related eye disease. The NEI estimates that more than 38 million Americans age 40 and older currently 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. Although the current annual cost of vision impairment and eye disease to the United States is \$68 billion, it does not fully quantify the impact of direct healthcare costs, lost productivity, reduced independence, diminished quality of life, increased depression, and accelerated mortality. This presents a major public health problem and financial challenge to the public and private sectors.

In public opinion polls over the past 40 years, Americans have consistently identified fear of vision loss as second only to fear of cancer. As recently as March 2008, the NEI's Survey of Public Knowledge, Attitudes, and Practices Related to Eye Health and Disease reported that 71 percent of respondents indicated that a loss of their eyesight would rate as a "10" on a scale of 1 to 10, meaning that it would have the greatest impact on their day-to-day life. As a result, Federal funding for the NEI is a vital and cost-effective investment in the health, and vision health, of our Nation as the treatments and therapies emerging from research can preserve and restore vision.

ARVO urges fiscal year 2009 NIH and NEI funding at \$31 billion and \$711 million, respectively.

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PREPARED STATEMENT OF THE ASSOCIATION FOR SUPERVISION AND CURRICULUM  
DEVELOPMENT (ASCD)

Chairman Harkin, ranking member Specter, and honorable members of the subcommittee: Thank you for the opportunity to share ASCD's priorities for Federal funding. My name is Dr. Gene Carter, and I am Executive Director and CEO of the Association for Supervision and Curriculum Development (ASCD).

ASCD is a nonprofit, nonpartisan organization representing 175,000 educators. ASCD members are found in schools throughout this country. They are superintendents, deputy superintendents, principals, teachers, professors of education, and school board members. With the exception of teacher unions, we represent more principals, superintendents, and educational leaders than any singular principal association or school administrator association. Formed in 1943, ASCD advocates for educational excellence and equity. As ASCD has grown in membership, our mission has evolved and expanded to address all aspects of effective teaching and learning—including professional development, educational leadership, capacity building, and effective pedagogy. ASCD membership is driven by best practices in the classroom to provide our children with the skills necessary to compete in the 21st century. We want the best policies to develop and educate the whole child.

ASCD believes that through effective program changes and increased flexibility education can thrive in this country. We also believe that accountability is as critical to education as textbooks. Although the proper accountability framework is a subject of debate, ASCD firmly believes in high standards and effective indicators that demonstrate progress towards those standards. Furthermore, ASCD is unique in that we have not previously submitted testimony to this committee asking for more resources. We have cautioned our membership against simply requesting more money when speaking with their Members of Congress. We do not believe money alone will solve the problems facing education. However, we do believe that a lack of money exacerbates the difficulties schools face when preparing our children to succeed in this global economy. We offer the following recommendations for your consideration:

## FUNDING GAPS: AUTHORIZATION VERSUS APPROPRIATIONS

Many in Congress believe legislative authorizations are a guardrail to restrain spending for Federal programs. Given the tremendous gap between authorized amounts and the appropriated amounts, especially in Title I and IDEA, the need for such a “guardrail” is not readily apparent. ASCD appreciates that several members of this subcommittee and the full committee decried the inadequate funding and put forth tremendous efforts to provide significant education increases for both NCLB and IDEA. Unfortunately, the gap persists, and educators across this country—those charged with implementing and complying with the requirements of NCLB and IDEA—are finding their work seriously impacted by the lack of Federal funds.

Looking at three significant and important programs—Title I, Title II, and IDEA—there is a Federal funding difference of \$19.6 billion between the authorized and appropriated amounts. This gap is exacerbated when combined with an inflation rate of 4.3 percent. In addition, student enrollment is expected to grow by almost 5 percent through 2014, the time frame included in the NCLB legislation. This gap requires schools to find crucial resources through State or local tax increases. Adding further pressure to this situation is the dismal fiscal outlook among the States for the next 2 years. Eighteen States are projecting budgetary shortfalls totaling \$14 billion for fiscal year 2008, and 17 States are projecting shortfalls of \$31 billion for fiscal year 2009—leading to either greater pressure on local taxpayers or drastic reductions in services to children.

We believe that the Federal Government has an obligation to support our schools and to pay for a larger share of the requirements associated with compliance of Federal programs. Although we do not expect to see an increase of \$19.6 billion, this funding gap illustrates a fundamental obstacle in the education of children. We urge the members of this committee to consider this situation when developing the funding legislation. We are hopeful this subcommittee will continue the promising support expressed by the Senate Budget Resolution, which contained an \$8.8 billion increase over the President’s fiscal year 2009 discretionary funding request for education, training, and social services programs.

## LOOKING AHEAD TO FISCAL YEAR 2009

ASCD urges you to provide the funding levels necessary to educate the whole child. Listed below are several programs we believe will make a substantial difference in helping schools, communities, educators, and policymakers to provide the necessary support and resources to ensure all children are healthy, safe, engaged, supported, and challenged.

## TITLE I

Title I enables schools to better serve the neediest student populations. This program provides critical funds and learning resources to help compensate for the difficulties faced by disadvantaged children. Additional programs and learning materials help students, and schools continue to narrow the achievement gap. However, given increasing costs and growing student populations, funding for Title I has been inadequate. We know that schools are capable of doing much more, but we recognize that they are presently bound by their lack of resources. A significant increase in Title I funding will provide schools the flexibility to use the resources for assisting targeted student populations.

## TITLE II

The correlation between teacher and school leader quality and student success is well documented. ASCD believes funding for Title II Teacher Quality Grants should be significantly higher than in previous years. It is time we begin to provide incentives, including salaries and professional development opportunities that better reflect the importance of teachers and educational leaders. We applaud past efforts by this committee to provide increased funds for Title II. However, to ensure that our teachers are well prepared to meet growing demands, we must provide the programs and opportunities that enable more professional development opportunities. We also believe effective programs like the Teacher Incentive Fund and other grant programs—enabling schools to offer financial and professional incentives for high-quality educators to serve in high-need areas—is a critically important role that should receive increased funding.

## HIGH SCHOOL REDESIGN

Our high schools are in crisis. We lose over 1 million students every year. One student drops out every 30 seconds. Beginning in the middle grades, the signs are clear as to which students are prone to dropping out. Students with low attendance, increasing academic difficulty or a failing grade, and decreasing or minimal engagement with educators all signify a danger of dropping out. Academic difficulty is not the only reason kids drop out; many students leave because they are not challenged or engaged by educators.

Yet, the answers exist. Pockets of successful schools graduate students and prepare them for high achievement in the real world or at advanced educational institutions. These solutions are not cheap. Effective high schools include personalized learning and mentoring to engage students. They have rich and relevant curricula that challenge students. The educators in these schools receive extensive professional development that is innovative and flexible. These high schools are also free to develop alternative scheduling options for fulfilling the Carnegie unit, including the length of the school day and school year. Yet additional resources are needed for many schools to develop and effectively implement these approaches.

Although there may be some hesitancy to invest significant resources now, given the difficult financial situation we face, consider numerous studies that demonstrate the hundreds of billions in dollars lost in productivity, taxes, and wages of high school dropouts. From a societal standpoint, dropouts are also associated with drastically higher medical and health care costs. High school dropouts also have higher incarceration rates. I am happy to share the extensive research on this topic. This committee faces a fundamental question: Do we spend this money now and invest in the future? Or does the country pay for our lack of funding in the future? Fortunately, a dedicated fund for secondary school improvement sponsored by Senators Pryor and Kennedy was unanimously approved as part of the Senate's 2009 Budget Resolution, signaling broad support for this investment. We are hopeful that this amendment remains as part of the final 2009 Budget Resolution. As such, it is our hope that this subcommittee will take the next step by including funding for high school redesign in the legislation.

## COMMUNITY SCHOOLS

One of the most cost-effective and innovative approaches to addressing not only educational needs but also the needs of local communities is full-service community schools. Full-service community schools facilitate collaboration among public schools, community-based organizations, and public and private partnerships, resulting in comprehensive educational, social, and health services provided to children and families. This approach does not saddle schools with the financial or service requirements of other agencies; instead these agencies use the school as the site or location to provide the relevant services. Full-service community schools create the school as the hub of the community and the centralized location to provide a multitude of services by relevant professionals. These schools not only address the health and social needs of many students, but also they provide extensive resources for other community members that achieve broader societal goals, including job training, career counseling, medical assistance, and linkage with social service programs. We request the subcommittee do its part in providing more resources to support these schools and the related services provided.

## CHILDREN'S HEALTH AND LEARNING

Among the many important choices facing the subcommittee, we encourage you to support those programs like Head Start that provide early childhood access to health services and pre-kindergarten education. Like high schools, the studies are numerous and overwhelming that children's health is an important factor in high academic achievement. The same is true of effective pre-kindergarten programs. If we truly want to close the achievement gap and prepare our children for success in the 21st century, we must provide these critical services.

## CONCLUSION

We recognize that the nation's economy is currently under tremendous strain, and we fully comprehend the need to be fiscally responsible in a time of growing budget deficits and economic downturns. However, ASCD believes important domestic priorities like education are not an expense, but an investment. Our children's education, health, and our teachers' professional development are three of the most proven methods of maintaining our strength and competitiveness in a global economy. It is apparent now more than ever that our funding choices today will lay the

foundation for our country's success tomorrow. To ensure that we educate our children and prepare them to be tomorrow's leaders; we need to make the investment in our children and students today.

Thank you again for the opportunity to share ASCD's positions. We look forward to working with you in the coming days to craft sound public policy for the good of our children and our future. Please contact me at 1-703-575-5494 with any questions or concerns. Thank you for your consideration.

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PREPARED STATEMENT OF THE ASSOCIATION OF UNIVERSITY PROGRAMS IN  
OCCUPATIONAL HEALTH AND SAFETY

Thank you for the opportunity to submit testimony to the subcommittee in support of funding for the National Institute for Occupational Safety and Health (NIOSH) and for the NIOSH-funded Education and Research Centers (ERCs). My name is Dr. Kent Oestenstad. I am the director of the Deep South Center for Occupational Health and Safety located at the University of Alabama at Birmingham.

I am testifying on behalf of the Association of University Programs in Occupational Health and Safety (AUPOHS), an organization that represents 17 multi-disciplinary, university-based Education and Research Centers (ERCs) which are funded by NIOSH, the Federal agency responsible for providing education and training for the prevention of work-related injuries and illnesses. The ERCs are regional resources for all parties involved with occupational health and safety—industry, labor, government, academia, and the general public. ERCs play the following roles in helping the Nation reduce losses associated with work-related illnesses and injuries:

- Prevention Research: Developing the basic knowledge and associated technologies to prevent work-related illnesses and injuries.
- Professional Training: Graduate degree programs in Occupational Medicine, Occupational Health Nursing, Safety Engineering, Industrial Hygiene, and other related fields to provide qualified professionals in essential disciplines.
- Research Training: Preparing doctoral-trained scientists who will respond to future research challenges and who will prepare the next generation of occupational health and safety professionals.
- Continuing Education: Short courses designed to enhance professional skills and maintain professional certification for those who are currently practicing in occupational health and safety disciplines. These courses are delivered throughout the regions of the 17 ERCs as well as through distance learning technologies.
- Regional Outreach: Responding to specific requests from local employers and workers on issues related to occupational health and safety.

THE SCOPE OF THE PROBLEM OF OCCUPATIONAL INJURY AND ILLNESSES

The many causes of occupational injury and illness represent a striking burden on America's health and well-being. Yet, despite significant improvements in workplace safety and health over the last several decades:

- Each day, an average of 9,000 U.S. workers sustain disabling injuries on the job, 16 workers die from an injury suffered at work, and 137 workers die from work-related diseases.
- In 2005, more than 4.2 million workers sustained work-related injuries and illnesses in the private sector alone.
- The Liberty Mutual 2005 Workplace Safety Index estimates that employers spent \$50.8 billion in 2003 on wage payments and medical care for workers hurt on the job; the indirect costs exceeded \$200 billion.

This is an especially tragic situation because most work-related fatalities, injuries and illnesses are preventable with effective, professionally directed, health and safety programs.

Here are some of the important issues that NIOSH deals with:

- When the Senate office buildings were attacked with anthrax, NIOSH and ERC professionals responded.
- NIOSH, helped by ERCs, took a lead role in protecting the safety of 9/11 emergency responders in New York City and Virginia.
- We are now seeing serious health problems in the workers who were at Ground Zero. NIOSH and the New York-New Jersey ERC are playing the major lead in their medical follow-up.
- NIOSH is the leading Federal agency conducting research and providing guidance on the worker health implications in the emerging field of nanotechnology.

We need manpower to address the sorts of issues mentioned above and it is the NIOSH ERCs that produce the graduates who fill key positions in health and safety

programs, regionally and around the Nation. And because ERCs provide training that is multi-disciplinary, ERC graduates protect workers in virtually every walk of life. Despite the recognized success of the ERCs in training such qualified professionals, the country continues to have ongoing shortages.

Furthermore, we do not live in a static environment. The rapidly changing workplace continues to present new health risks to American workers that need to be addressed through occupational safety and health research. For example, between 2000 and 2015, the number of workers 55 years and older will increase 72 percent to over 31 million. Work related injury and fatality rates begin increasing at age 45, with rates for workers 65 years and older nearly three times as high as the average for all workers.

In addition to factors that increasingly affect the vulnerability of our workers, we constantly face new threats to worker health. As an example, one of the greatest concerns regarding a potential outbreak of avian influenza is the drastic effect it may have on our workforce. The protection of health care workers in particular will become a major priority if we are to protect our population.

Despite being the primary Federal agency for occupational disease and injury prevention in the Nation, NIOSH receives only about \$1 per worker per year for its mission of research, professional education, and outreach.

#### HOMELAND SECURITY

The heightened awareness of terrorist threats, and the increased responsibilities of first responders and other homeland security professionals, illustrates the need for strengthened workplace health and safety in the ongoing war on terror. The NIOSH ERCs play a crucial role in preparing occupational safety and health professionals to identify and ameliorate vulnerabilities to terrorist attacks and other workplace hazards and increase readiness to respond to biological, chemical, or radiological attacks.

Thanks to the subcommittee's support for occupational health and safety research, NIOSH developed more effective methods to test for anthrax contamination in congressional offices. These procedures were quickly adopted by the Coast Guard, the FBI, and government building contractors. More recently, in response to ongoing safety concerns regarding the tunnels under the U.S. Capitol Complex, NIOSH was asked to evaluate health hazards in the tunnels for workers who maintain the plumbing that provides steam and chilled water to Congress, the Library of Congress, the Supreme Court and other Federal buildings.

In addition, occupational health and safety professionals have worked for several years with emergency response teams to minimize losses in the event of a disaster. NIOSH took a lead role in protecting the safety of 9/11 emergency responders in New York City and Virginia, with ERC-trained professionals applying their technical expertise to meet immediate protective needs and conducting ongoing activities to safeguard the health of clean-up workers. Additionally, NIOSH is now administering \$81 million in grants to provide health screening of World Trade Center responders. Included in the grantees is the New York-New Jersey ERC.

In the face of the growing concerns surrounding homeland security, ERCs have rapidly upgraded research coordination and expanded training opportunities, including sponsoring national and regional forums on response to bioterrorism and other disasters.

#### THE NEED FOR OCCUPATIONAL SAFETY AND HEALTH MANPOWER

The NIOSH ERCs were reviewed by the DHHS Office of the Inspector General in 1995. The resulting report affirmed the efficacy of the ERCs in producing graduates who pursue careers in occupational safety and health. Since the ERCs are regional, they are ready to respond to various trends in industries throughout the country. In the southeast, for example, automobile manufacturing has been the major growth industry since 2000. Alabama now has major facilities for Mercedes, Honda and Hyundai that employ thousands of workers. Graduates from the Deep South Education and Research Center (University of Alabama at Birmingham and Auburn University) fill key positions in the safety, health and environmental programs at all of these facilities. And because they provide training that is multi-disciplinary, ERCs graduate professionals can protect workers in virtually every walk of life. Despite the recognized success of the ERCs in training qualified occupational health and safety professionals, the country continues to have ongoing shortages. The manpower needs are especially acute for doctoral-level trained professionals who can conduct research and help in implementing the National Occupational Research Agenda (NORA).



In May 2000, the Institute of Medicine issued its final report on the education and training needs for occupational safety and health professionals in the United States. This report concluded that “the continuing burden of largely preventable occupational diseases and injuries and the lack of adequate occupational safety and health services in most small and many larger workplaces indicate a clear need for more occupational safety and health professionals at all levels.” Specific needs identified by the IOM report include:

- An insufficient number of doctoral-level graduates in occupational safety, thus limiting the Nation’s capacity to perform essential research and training in traumatic injury prevention.
- An inability to attract physicians and nurses into formal occupational safety and health academic training programs, thus limiting the resources needed to deliver occupational health services.

ERCs are accomplishing the critical mission of filling these gaps by preparing expert researchers and practitioners in occupational safety and health.

#### RECOMMENDATION FOR FISCAL YEAR 2009

In fiscal year 2009 AUPOHS requests a \$50 million increase for NIOSH over the fiscal year 2008 appropriated level, and within that increase, not less than a \$5 million increase for Education and Research Centers (ERCs).

A \$50 million increase would enable NIOSH to keep pace with the changing nature of work and ensure that research and education to prevent work-related disease and injuries remain a high priority. Given that much of NIOSH’s extramural research program is carried out by the Education and Research Centers (ERCs), sustaining the academic infrastructure provided by the ERCs is essential. Our recommendation would ensure that our Nation’s universities have the capacity and manpower to implement these initiatives and expand training programs to improve the health and productivity of American workers.

The ERCs play an essential role in preventive health research and the training of occupational safety and health professionals, many of which are in short supply. The 17 ERCs are distributed throughout the United States and have a critical community outreach function, as well as serve as local resources of occupational safety and health expertise. A \$5 million increase will bring the total budget for the 17 ERCs to \$26.4 million and promote achievement of the NIOSH strategic goal to increase the technical proficiency of the occupational safety and health professionals who lead occupational safety and health practice in both the private and public sectors.

Thank you for the opportunity to report the great need for research and training in occupational safety and health.

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#### PREPARED STATEMENT OF THE ASSOCIATION OF WOMEN’S HEALTH, OBSTETRIC AND NEONATAL NURSES

The Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN) appreciates this opportunity to provide testimony on the fiscal year 2009 appropriations for the Department of Health and Human Services (HHS).

AWHONN is a specialty nursing organizations with nearly 23,000 nurses dedicated to the mission of advancing the health and well-being of women and newborns. AWHONN members are registered nurses, nurse practitioners, and certified nurse-midwives, who are clinicians, executives, managers and educators serving in hospitals and health systems, independent practices, universities, and community clinics throughout the United States.

Nurses are typically the first and most consistent point of contact in the health care setting. Evidence suggests that they spend more time with patients—up to four times on average—than any other health care provider. As such, nurses have a unique perspective on the health care system and the public health programs and agencies funded under HHS.

We appreciate the leadership of the Subcommittee in providing generous funding in past years to the important public health and biomedical research programs within its jurisdiction. We recognize the challenges the Subcommittee will face in fiscal year 2009 in reconciling various expenditures in the face of overall budget deficits, but have faith that you will not sacrifice the Nation’s health needs in making these determinations.

AWHONN members know first hand the significant health returns our Nation has achieved based on the investments made in the various programs discussed below. We urge your continuing support of them at levels that serve the Nation adequately. We emphasize the term “adequately,” as we and the large coalition of orga-

nizations that stand behind these recommendations believe the proposed funding levels are truly necessary just to maintain current progress in fiscal year 2009 and do not represent “stretch” spending at this time of necessary trade-offs.

#### HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

##### *AWHONN recommends \$7.9 billion for HRSA in fiscal year 2009*

HRSA is responsible for a variety of programs ranging from support for health professions education to the care of underserved populations to the special needs of mothers and children. The funding for these programs has not kept pace with need and we cannot afford to lose further ground if the Nation’s safety net. Our health system’s infrastructure is to be preserved in ways that ensure quality care in the United States.

##### *Title VIII—Nursing Workforce Development Programs*

*AWHONN recommends \$200 million for Title VIII programs in fiscal year 2009.*—Title VIII programs help to address the Nation’s continuing nursing and nurse faculty shortage via scholarships, grants and loan repayments to nursing students, recent nursing graduates and nursing school faculty. Title VIII also provides grants to schools of nursing and health centers to foster greater diversity and improved retention rates in the nursing workforce.

##### *The Nursing Shortage*

Nursing is the Nation’s largest health care profession with nearly 2.5 million jobs. However, the United States is experiencing a shortage of nurses, which is expected to intensify as the baby-boomer population ages and the need for healthcare services and providers grows. Today, less than 9 percent of all nurses are under the age of 30. With the average age of nurses standing at 46.8 years old, a wave of retirements is expected in the near future.

According to projections from the U.S. Bureau of Labor Statistics, more than 1.2 million new and replacement nurses will be needed by 2014. Unless we act now, this shortage may jeopardize access to quality patient care.

##### *The Nurse Faculty Shortage*

In addition to a shortage of nurses at the bedside, the United State is also facing a shortage of nursing school faculty members. From 2002 to 2006 almost 129,000 qualified candidates were turned away from entry-level baccalaureate nursing programs. Almost 75 percent of nursing schools cited faculty shortages as a primary reason for not accepting all qualified applicants into nursing programs.

The average age of nurse faculty is 55 years old. Much like nurses at the bedside, a wave of retirements is expected in the coming years. However, according to an April 2006 report, HRSA projects that nursing schools must increase the number of graduates by 90 percent in order to adequately address the nursing shortage.

Without an adequate number of faculty members to prepare the next generation of nurses, the shortage is expected to intensify even further.

##### *Title VIII Programs are Effective in Addressing the Shortages*

Ongoing attrition among practicing nurses and faculty nurses due to retirement and the growing demand for health services have left the Nation with a severe shortage of nurses.

Significant near- and long-term gains can be made in addressing the nursing shortage if Title VIII Nursing Workforce Development Programs are adequately funded. AWHONN joins the larger nursing community and 52 Senators in requesting a funding level of \$200 million for fiscal year 2009. This figure was determined based on an a serious calculation of what will be required to sustain current progress toward reversing the nursing shortages and averting a reversal of the positive momentum that has been achieved toward achieving needed workforce levels.

##### *7Title V—Maternal and Child Health Block Grant (MCHB)*

*AWHONN recommends \$850 million for Title V in fiscal year 2009.*—MCHB programs provide prenatal health services to two million women, and primary and preventive health care to more than 17 million children, including almost one million children with special health needs. Title V special projects target underserved urban and rural areas with efforts at the community level to promote collaboration between public and private sector leaders, and health care providers. Title V programs also underwrite public education campaigns addressing critical issues such as immunizations, prenatal care and healthy weight. In addition to targeting primary care to the underserved, Title V programs are essential to helping people to help themselves and avert costly health care services.

*National Health Service Corps (NHSC)*

*AWHONN recommends 200 million for NHSC in fiscal year 2009.*—The National Health Service Corps (NHSC) provides health care services to communities in serious need of qualified health professionals. The program enables clinicians, including nurses, to acquire scholarships or loan repayments for practicing in a designated Health Professional Shortage Area (HPSA) for a minimum of 2 years. Since 1972, more than 28,000 physicians, nurses, dentists, and mental health professionals have provided critical primary care services to the underserved through NHSC.

Currently, NHSC supports the important work of approximately 4,000 providers nationally, with a significant backlog of eligible candidates to meet needs estimated to require nearly 30,000 health care professionals nationwide. NHSC providers are a critically important element in our Nation's health safety net and a means of supporting the education and practice of providers who are in categories of health professionals in undersupply across the country. The administration's proposed fiscal year 2009 cuts to this program would prove devastating to the Corps' ability to recruit and provide awards. We urge your leadership in averting this catastrophe at the reasonable funding level of 200 million that would be applied to both NHSC lines: the recruitment line, which provides the scholarship and loan repayments, and the field line which includes Ready Responders, SEARCH, and the Ambassador Programs.

NATIONAL INSTITUTES OF HEALTH (NIH)

*AWHONN recommends a \$1.9 billion increase for NIH funding, totaling \$31.1 billion for fiscal year 2009.*

NIH is the world's leading medical research enterprise. Thanks to a doubling of the NIH budget in the 1990s, the U.S. has amassed a wealth of knowledge that continues to provide the science behind new discoveries and possible treatments for life's most devastating diseases. Research done at the NIH is leading to better patient care. Further, its outcomes are returning financially to the government via novel licensing agreements and patents; and to the overall U.S. economy through job creation in university labs, as well as private pharmaceutical and device companies.

The proposed increase in NIH funding for fiscal year 2009 accounts for general inflation, as well as biomedical inflation, so that NIH can maintain its current purchasing power and continue to pursue groundbreaking research and life saving discoveries. While AWHONN supports the NIH in its entirety, several institutes are especially important to the advancement of nursing and the health and well-being of women and newborns.

*National Institute of Nursing Research (NINR)*

*AWHONN recommends \$150 million for NINR in fiscal year 2009.*—NINR supports nurse-led research that contributes to advancing high quality, evidence based care across the lifespan. Research at NINR has targeted, among other topics, health disparities, risk reduction, chronic illnesses and care for rural and underserved populations. NINR promotes a uniquely important nursing perspective, as there is no caregiver that interacts with patients more or is more trusted by patients than nursing professionals. There is no other body that funds important nursing research similarly in this country, and NINR research has contributed measurably to more efficient and effective health care as our Nation struggles to fill continuing staffing shortages and gaps in health care services.

*National Institute of Child Health and Human Development (NICHD)*

*AWHONN recommends \$1.34 billion for NICHD in fiscal year 2009.*—NICHD is tasked with understanding human development, from pre-conception to adulthood. The Institute has many opportunities to research and correct some of the Nation's leading health problems among our most vulnerable populations. Its legacy of contributions to the scientific literature and to diagnostics and treatments now in use is a testament to the value of past Congressional investment. There is no other Institute that devotes itself more to ensuring the quality of life and health care for women of childbearing age, and the potential for successful beginnings of life for their offspring.

*National Institute of Mental Health (NIMH)*

*AWHONN recommends \$1.5 billion in for NIMH in fiscal year 2009.*—NIMH aims to reduce the burden of mental illness and behavioral disorders through research on mind, brain and behavior. Tasked with researching some of our Nation's most devastating mental and behavioral disorders, such as autism, bipolar disorder, and, in the instance of women of childbearing age, perinatal mood and anxiety disorders

such as postpartum depression, NIMH has the potential by some estimates to improve the lives of one-third of all Americans who suffer some level of mental impairment.

*National Institute of Environmental Health Sciences (NIEHS)*

AWHONN recommends \$684 million for NIEHS in fiscal year 2009. Research conducted by NIEHS plays a critical role in our understanding of environmental exposures and the health of Americans. Through their research, various types of cancer, birth defects, infertility and other chronic illnesses have been shown to be attributable in many instances to gene disruptions caused by exposure to environmental contaminants. These findings have tremendous potential to lead to means of averting or reversing the impacts of such disease triggers.

AWHONN thanks the committee for your consideration and greatly appreciates this opportunity to submit testimony on these critical funding areas.

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PREPARED STATEMENT OF THE BRAIN INJURY ASSOCIATION OF AMERICA

Chairman Harkin and ranking member Specter: Thank you for the opportunity to submit this written testimony with regard to the fiscal year 2009 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.

A traumatic brain injury (TBI) is a blow or a jolt to the head that temporarily or permanently disrupts brain function—i.e. who we are and how we think, act, and feel. In the civilian population alone every year, more than 1.5 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.

Now we are seeing an increasing number of servicemembers returning from the conflicts in Iraq and Afghanistan with TBI, which has been termed one of the signature injuries of the War. The Army's Traumatic Brain Injury Task Force, released this past January, reported estimates that up to 20 percent of Marines and soldiers returning from Afghanistan and Iraq might have experienced brain injuries. This means that possibly upwards of 150,000 American troops have been, or will be, impacted by TBI as a result of ongoing combat operations. Many of these returning servicemembers 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 11 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 was gravely disappointed that last year, even as Congress had the good judgment to add hundreds of millions dollars to the budgets of the Department of Defense and the Department of Veterans Affairs to help address the problem of TBI among returning servicemembers, funding for the HRSA Federal TBI Program was reduced from \$8.91 million to \$8.754 million.

If I may, I would like to provide you with an example of the disconnect which results as a consequence of these appropriations decisions. Last year's reduction in funding for the HRSA Federal TBI Program means that one of our State affiliates—the Brain Injury Association of New York (BIANYS)—whose work has been supported through the HRSA Federal TBI Program, now may face reduced funding to support its current efforts to develop relationships with the New York State Division of Veterans Affairs in order to assist returning servicemembers with TBI and their families through the provision of training, education, collaboration, and outreach services.

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:

- \$9 million for the Centers for Disease Control and Prevention TBI Registries and Surveillance, Prevention and National Public Education/Awareness;
- \$15 million for the Health Resources and Services Administration (HRSA) Federal TBI State Grant Program; and
- \$6 million for the HRSA Federal TBI Protection & Advocacy (P&A) Systems Grant Program.

In addition, BIAA urges you to provide sufficient funding in fiscal year 2009 to enable the National Institute on Disability and Rehabilitation Research (NIDRR) within the Department of Education to sustain and increase its medical rehabilitation research portfolio and to continue its annual allocation of at least \$8.3 million to fund 16 TBI Model Systems research centers. The fiscal year 2008 Defense Authorization bill, which was recently signed into law, includes specific language directing new TBI research efforts within the Department of Veterans Affairs to collaborate with NIDRR TBI research programs, such as the TBI Model Systems of Care. The TBI Model Systems of Care program has established a vital national network of expertise and research in the field of TBI, and weakening this program would have deleterious effects on both military and civilian populations.

Last year, Congress provided \$900,000 in additional stopgap funding for the TBI Model Systems of Care program in order to maintain 16 valuable TBI research centers around the country, and to prevent the nation's valuable TBI research capacity from being diminished. It is essential that Congress maintain this investment.

Furthermore, BIAA urges increased support for medical rehabilitation research at NIDRR, which is the country's lead Federal agency on rehabilitation and disability research. In addition to the challenges of flat funding for NIDRR for at least the past five fiscal years, the agency has recently signaled an intent to narrow its focus to emphasize research of interest to its parent agency, the Office of Special Education and Rehabilitative Services (i.e., employment and vocational rehabilitation research) at the expense of research related to health and function, particularly medical rehabilitation research. NIDRR appears to be making a conscious effort to move away from a long-term, key aspect of the NIDRR research portfolio; improving the health and functioning of people with disabilities. Given the multi-dimensional character of the disability experience, NIDRR's scope needs to transcend the specific Federal department and agency in which it is currently located.

In the recent past, NIDRR has eliminated funding for:

- A rehabilitation research and training center (RTC) on neuromuscular disease, the only Federal source for rehabilitation research funding for persons with conditions such as ALS, muscular dystrophy, and peripheral nerve diseases;
- An RTC on arthritis and related musculoskeletal conditions;
- An RTC on health and wellness of people with spinal cord injuries; and
- An RTC on community integration of individuals with traumatic brain injury, one of the key aspects of functioning with a TBI over the long term.

Each of these grants were funded at \$800,000 per year for a five-year period. Each of these centers developed valuable insight and disseminated meaningful information that improved the lives of these disability groups during the course of these grants.

To make matters worse, NIDRR recently announced that grant announcements for four additional RTCs would be delayed and reformulated to focus attention on employment and vocational rehabilitation. These announcements may or may not be released over the remainder of this fiscal year. The four RTCs that have been delayed address the areas of Multiple Sclerosis, stroke, aging with a disability, and the psychiatric aspects of disability.

In order to preserve the valuable health and functioning research capacity developed by NIDRR over three decades, BIAA recommends that Congress increase the President's fiscal year 2009 request by \$3.2 million in new Federal dollars in order to reinstate the four RTCs that were eliminated over the course of the past six months, and explicitly direct that these funds be used for the purposes of continuing these RTCs through a competitive grant process.

As for the four delayed RTCs addressing Multiple Sclerosis, stroke, aging with a disability, and the psychiatric aspects of disability, BIAA requests that Congress impress upon NIDRR in fiscal year 2008 the importance of preserving the traditional focus of these research centers and direct NIDRR to expeditiously reissue competitive grant announcements for these critical research centers.

Thank you for this opportunity to testify. BIAA appreciates your leadership and looks forward to working with you in the months and years ahead to not only maintain, but enhance funding for Federal TBI programs.

## 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 health care. As the advocacy arm of AcademyHealth, the Coalition represents the interests of 3,500 researchers, scientists, and policy experts, as well as 130 organizations that produce and use health services research.

Health care in the United States has the potential to improve people's health dramatically, but often falls short and costs too much. Health services research is used to understand how to better finance the costs of care, measure and improve the quality of care, and improve coverage and access to affordable services. It provides patients, providers, payers, and policymakers with the necessary tools to make health care:

- Affordable, by decreasing cost growth to sustainable levels.
- Efficient, by decreasing waste and overpayment and monitoring cost effectiveness of care.
- Safe, by decreasing preventable medical errors, monitoring public health, and improving preparedness.
- Effective, by evaluating programs and outcomes and promoting evidence-based innovations.
- Equitable, by eliminating disparities in health and health care.
- Accessible, by connecting people with the health care they need when they need it.
- Patient-centered, by increasing patient engagement in, and satisfaction with, the care they receive.

Indeed, health services research is changing the face of American health care, uncovering critical challenges facing our Nation's health care system. For example, the 2000 Institute of Medicine (IOM) report *To Err is Human* found that up to 98,000 Americans die each year from medical errors in the hospital. Health services research also uncovered that disparities and lack of access to care in rural and inner cities result in poorer health outcomes. And, it found that obesity accounts for more than \$92 billion in medical expenditures each year and has worse effects on chronic conditions than smoking or problem drinking.

But health services research does not just lift the veil on problems plaguing American health care; it also seeks ways to address them. Health services research framed the debate over health care reform in Massachusetts—forming the basis for that state's 2006 health reform legislation—and continues to frame the debate on the national stage today. It offers guidance on implementing and making the best use of health information technology, and getting the best care at the best value across a menu of treatment options.

In fact, there are increasing examples that demonstrate how comparative effectiveness research—an emerging science in the broader field of health services research—provides the scientific basis needed to determine what treatments work best, for whom, and in what circumstances.

- The Agency for Healthcare Research and Quality (AHRQ) found that drugs can be as effective as surgery in management of gastroesophageal reflux disease (GERD)—where stomach acid enters the esophagus, causing heartburn and potential esophageal damage. GERD is one of the most common health conditions among older Americans and results in \$10 billion annually in direct health care costs. Knowing that, for the majority of patients, drugs can be as effective as surgery in relieving the symptoms could result in significant health care savings and improved quality of life.
- The National Institute of Mental Health (NIMH) found that, within a class of antipsychotic drugs, the older, less expensive drug (Perphenazine) was just as effective and caused no worse side effects than the three newer, more expensive drugs in treating patients with schizophrenia. One of the newer drugs (Zyprexa) was slightly more effective in controlling systems than the other drugs, but at the cost of serious side effects.<sup>1</sup> This study enables greater flexibility in care and informs patients and providers about costs and quality of care.

As these examples suggest, health services research can contribute greatly to better health care at better value. It is a true public good, providing a basis for improvements in our health care system that will benefit the general public. Americans overwhelmingly agree. According to a 2005 Research!America survey, roughly

<sup>1</sup>Lieberman, J.A., et. al. "Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia," *New England Journal of Medicine*, Vol. 353, No. 12, pp.1209–1223 (Sept. 22, 2005). Available on the Web at <http://content.nejm.org/cgi.content/abstract/353/12/1209>.

95 percent of Americans agree that it is important to support research that focuses on how well health care functions and how it can function better, and that health care delivery should be based on the best and most recent research available.<sup>2</sup> After all, the investment in basic research and the development of new medicines and equipment is wasted if the health system cannot safely and effectively deliver that care.

For the last 5 years, the Coalition has been collecting data to track the Federal Government's expenditures for health services research and health data. From information provided to us by these funders—including AHRQ, National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC)—funding for this field has remained constant since 2003 and has not kept pace with inflation.

In stark contrast, spending on health care overall has risen faster than the rate of inflation—from \$1.4 trillion in 2000 to nearly \$2 trillion in 2005.<sup>3</sup> The total Federal investment in health services research and data by our estimates approaches \$1.5 billion—representing just 0.075 percent of the \$2 trillion we spend on health care annually.<sup>4</sup> Health services research needs Federal support—now more than ever—to help us spend our health care dollars more wisely.

We recognize the support the subcommittee currently provides to Federal agencies that fund health services research and now ask that the subcommittee strengthen the capacity of the health services research field to address the pressing challenges America faces in providing access to high-quality, cost-effective care for all its citizens.

#### AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AHRQ is the lead Federal agency charged with supporting unbiased, scientific research to improve health care quality, reduce costs, advance patient safety, decrease medical errors, and broaden access to essential services. Yet chronic underfunding threatens the agency's ability to achieve this important mission—at a time when health care costs are at an all time high, and Americans' basic health status lags behind that of others around the world.

Before the targeted increase Congress provided last year to study the comparative effectiveness of health care interventions and Methicillin-resistant *Staphylococcus aureus* (MRSA), the agency's budget rose just 6.7 percent since fiscal year 2002. Even with last year's increase, the agency has lost \$19 million in purchasing power since fiscal year 2005 due to inflation and years of flat funding. And under the President's budget, the agency stands to lose an additional \$9 million.

This "no growth" budget has a significant impact on the field of health services research and its ability to respond to the needs of policymakers. For example, investigator-initiated research, such as that undertaken by Lucian Leape in discovering the prevalence of medical errors (which provided the basis for the IOM's *To Err is Human*), is now practically non-existent. Specifically, there has been a dramatic decline in the number of, and funding for, grants that support researcher innovation and career development; and based on the President's fiscal year 2009 budget, support for these awards will hit new lows. AHRQ needs funding for new and competing grants to rejuvenate the free marketplace of ideas, and for supporting the next generation of researchers to ensure the field's capacity to respond to the growing public and private sector demand for research.

We join the Friends of AHRQ—a coalition of more than 100 health professional, research, consumer, and employer organizations that support the agency—in recommending a fiscal year 2009 funding level of at least \$360 million, an increase of \$26 million over the fiscal year 2008 level. This investment will allow AHRQ to restore its critical health care safety, quality, and efficiency initiatives; strengthen the infrastructure of the research field; and reignite innovation and discovery.

#### CENTERS FOR DISEASE CONTROL AND PREVENTION

Housed within CDC, the National Center for Health Statistics (NCHS) is the Nation's principal health statistics agency, providing critical data on all aspects of our health care system. Thanks to NCHS, we know that too many Americans are overweight and obese, cancer deaths have decreased, average life expectancy has increased, and emergency rooms are over-crowded. We know how many people are un-

<sup>2</sup>Woolley, M. and S. Propst. "Public Attitudes and Perceptions about Health-Related Research." *Journal of the American Medical Association*, Vol. 294, No. 11, p. 1382 (Sept. 21, 2005).

<sup>3</sup>Catlin, A., et. al. "National Health Spending in 2005: The Slowdown Continues," *Health Affairs*, Vol. 26, No. 1, pp. 142–153 (Jan./Feb. 2007).

<sup>4</sup>*Federal Funding for Health Services Research*, Coalition for Health Services Research (Feb. 2008). Available on the Web at [www.chsr.org](http://www.chsr.org).

insured, how many children are immunized, how many Americans are living with HIV/AIDS, and how many teens give birth.

Before the small increase Congress provided last year, NCHS had lost \$13 million in purchasing power since fiscal year 2005 due to years of flat funding and inflation. These shortfalls forced the elimination of data collection and quality control efforts, threatened the collection of vital statistics, stymied the adoption of electronic systems, and limited the agency's ability to modernize surveys to reflect changes in demography, geography, and health delivery.

Even amid deep cuts to CDC and health programs broadly, the President recognized the value of NCHS and its data to the health infrastructure, providing the agency nearly \$125 million in his fiscal year 2009 budget request. This level of funding is critical for sustaining uninterrupted collection of vital statistics from states. Without sustained support for these critical data systems, we are at risk of becoming the first industrialized Nation unable to afford to continuously collect birth, death, and other vital health information. The Coalition joins the Friends of NCHS—a coalition of more than 100 health professional, research, consumer, industry, and employer organizations that support the agency—in supporting the President's funding request of \$125 million to ensure uninterrupted collection of vital statistics; restore other important data collection and analysis initiatives; and modernize its systems to increase efficiency, interoperability, and security.

While significant funding has been provided to improve the public health system's capacity to respond to a terrorist attack or a public health crisis such as pandemic flu, insufficient funding has been provided to support research that evaluates the effectiveness of our preparedness interventions and seeks to improve the delivery of public health services. For example, how cost effective are public health and prevention programs? How can the medical care and public health delivery systems be better linked?

This important Public Health Research program has been flat funded since fiscal year 2005 at a level of \$31 million, and the President's budget requests this same amount in fiscal year 2009. The Coalition requests at least \$35 million for this program in fiscal year 2009 to restore purchasing power to fiscal year 2005 dollars.

#### CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The President's budget request for the Office of Research, Development and Information is \$31 million—consistent the fiscal year 2008 level. This level—a decrease of \$26 million since fiscal year 2006—hinders CMS' ability to meet its statutory requirements and conduct new research into Medicare, Medicaid, and SCHIP, public programs which together provide coverage to nearly 100 million Americans and comprise 45 percent of America's total health expenditures.<sup>5</sup> At a time when these programs pose an ever increasing threat to the Nation's fiscal sustainability, it is critical that we adequately fund research to evaluate the programs' efficiency and effectiveness, and seek ways to curtail spending growth.

The Coalition supports a fiscal year 2009 funding level of \$45 million in discretionary research and development funding—in addition to funding for programmatic earmarks—as a critical down payment to help CMS recover lost resources and restore research to evaluate these programs, analyze pay for performance and other tools to update payment methodologies, and to further refine service delivery methods.

#### NATIONAL INSTITUTES OF HEALTH (NIH)

The NIH reported that it spent \$921 million on health services research in fiscal year 2007—roughly 3.3 percent of its entire budget—making it the largest Federal sponsor of health services research. Nevertheless, this represents a \$17 million decline over the previous fiscal year in the portion of NIH's total budget allocated to health services research.

For fiscal year 2009, the Coalition recommends a funding level of at least \$1 billion—3.3 percent of the nearly \$31 billion the broader health community is seeking for NIH. We recognize the support various institutes now provide to fund health services research, but this level of funding should be viewed as our minimum request. We encourage NIH to increase the proportion of their overall funding that goes to health services research from 3.3 to 5 percent to assure 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.

<sup>5</sup> Catlin, A, et. al. "National Health Spending in 2005: The Slowdown Continues," *Health Affairs*, Vol. 26, No. 1, pp. 142–153 (Jan./Feb. 2007).



In conclusion, the accomplishments of health services research would not be possible without the leadership and support of this subcommittee. As you know, the best health care decisions are based on relevant data and scientific evidence. Increased funding for health services research and health data will yield better information and lead to improved quality, accessibility, and affordability. We urge the subcommittee to accept our fiscal year 2009 funding recommendations for the Federal agencies funding health services research and health data.

If you have questions or comments about this testimony, please contact Emily Holubowich, Director of Government Relations at 202-292-6743 or e-mail at [emily.holubowich@academyhealth.org](mailto:emily.holubowich@academyhealth.org).

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#### PREPARED STATEMENT OF THE COALITION OF NORTHEASTERN GOVERNORS

The Coalition of Northeastern Governors thanks you for this opportunity to provide testimony for the record to the Senate Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies regarding fiscal year 2009 appropriations for the Low Income Home Energy Assistance Program (LIHEAP). The Governors appreciate the subcommittee's continued support for the LIHEAP program and recognize the considerable fiscal challenges facing the subcommittee this year. However, the skyrocketing cost of home energy has made this program more crucial than ever. The Governors request that regular fiscal year 2009 LIHEAP block grant funding be appropriated at the full \$5.1 billion level as authorized by the Energy Policy Act of 2005. The Governors also ask the Congress to appropriate additional contingency funds to address unforeseen energy emergency situations.

Funding the LIHEAP block grant at the \$5.1 billion level will help restore some of the purchasing power of the program, provide greater certainty for program planning, and enable States across the Nation to provide meaningful assistance to more citizens struggling to pay unaffordable home energy bills.

LIHEAP is a vital safety net for many of our Nation's most vulnerable citizens. The program has served as a foundation of other assistance programs provided by utilities and the private sector, such as shutoff moratoria and other direct assistance. The highest level of LIHEAP assistance is provided to households with the lowest incomes that pay a high proportion of their income for home energy. These low-income households spend an average of 14 percent of annual income on home energy, compared to 3.6 percent for all other households. In 2004, elderly households in receipt of Supplemental Security Income paid nearly 19 percent of their income for energy, leaving few remaining funds to pay for food, shelter or medication. LIHEAP provides vital assistance to elderly households struggling to survive on fixed incomes, as 41 percent of LIHEAP recipient households include at least one elderly member.

Adding to the economic stress on these low-income households are the rapidly escalating costs of heating fuels that have eroded the purchasing power of the LIHEAP dollar. According to the Energy Information Administration (EIA), the national average cost of heating a home has risen from \$704 during the winter of 2003-2004 to a projected \$981 this winter—a 39 percent increase. This increase has far outpaced the growth in income for this population. Faced with simply unaffordable energy bills, these households take drastic measures such as keeping their homes at unhealthy or unsafe temperatures, using unsafe alternative heating options, or accumulating high levels of home energy debt and the possibility of utility service shut-off.

At the same time that home energy prices are escalating, the average LIHEAP benefit has decreased and the number of households receiving assistance has declined since the peak of fiscal year 2006. Approximately 5.7 million households—less than 16 percent of those eligible—now receive LIHEAP assistance (down from 5.8 million in fiscal year 2006), and the average LIHEAP benefit has decreased from \$464 to \$378.

The recent price increases are especially troubling for households that rely on delivered fuels such as home heating oil and propane. According to the Department of Energy, roughly 69 percent of the Nation's 5.3 million households that use home heating oil are in the Northeast. EIA estimates that households heating primarily with home heating oil will pay \$1,990 this year, or 35.6 percent more than last year and a 66 percent increase over 3 years. Without an adequate benefit that can meet the minimum delivery requirement, these households face the prospect that a dealer will not make a delivery or will require a surcharge, further reducing the purchasing power of the LIHEAP benefit.

Households that use natural gas are also struggling with dramatically increasing home energy costs. While the cost has increased at a slower rate than home heating oil, households using natural gas are expected to pay 7.2 percent more than last year, and 32 percent more than during the winter of 2003–2004. The rising utility bills result in many of these households accumulating substantial arrearages and facing the prospect of shutoffs as the moratoria period in some States ends. A recent report by the American Gas Association found that the percentage of past due accounts rose from 16.5 percent in 2001 to 21 percent in 2006, and the total amount of uncollectible expenses rose 39 percent between 2003 and 2006. LIHEAP funds can be instrumental in helping these households stay out of debt or get their utilities reconnected.

If Federal resources remain level or decline as home energy prices continue to rise, States face the difficult decision of serving fewer households in order to maintain some of the purchasing power of the LIHEAP grant for the program's poorest families, or reducing the level of benefits to recipients. To deliver maximum program dollars to households in need, States in the Northeast have incorporated various strategies to minimize the program's administrative costs including using uniform application forms to determine program eligibility, establishing a one-stop shopping approach for the delivery of LIHEAP and related programs, sharing administrative costs with other programs, and using mail recertification. However, opportunities to further reduce LIHEAP administrative costs are limited, since they are already among the lowest of the human service programs. In spite of these State efforts to stretch Federal and State LIHEAP dollars, the need for the program is far too great. Increased, predictable and timely Federal funding is vital for LIHEAP to assist the Nation's vulnerable, low-income households faced with exorbitant home energy bills.

An increase in the regular LIHEAP appropriation to the \$5.1 billion level for fiscal year 2009 as well as the appropriation of additional contingency funds will enable States across the Nation to help mitigate the potential life-threatening emergencies and economic hardship that confront the Nation's most vulnerable citizens. With these additional funds, States can provide assistance to more households in need, offer benefit levels that provide meaningful assistance, lessen the need for emergency crisis relief, plan and operate a more efficient program, and again make optimal use of leveraging and other cost-effective programs.

We thank the subcommittee for this opportunity to share the views of the Coalition of Northeastern Governors, and we stand ready to provide you with any additional information on the importance of the Low Income Home Energy Assistance Program to the Northeast and the Nation.

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PREPARED STATEMENT OF THE COMMISSIONED OFFICERS ASSOCIATION OF THE U.S.  
PUBLIC HEALTH SERVICE

I write to ask the subcommittee to approve \$50 million to support transformation of the U.S. Public Health Service's Commissioned Corps, including a new emergency preparedness activity within the Corps.

Secretary Michael O. Leavitt's proposed development of Health and Medical Response (HAMR) teams is a new initiative resulting from recommendations to improve public health preparedness and response following the devastating hurricanes of 2005. The requested funds would be used to organize, train, equip, and roster medical and public health professionals in pre-configured and deployable teams.

In the event of a terrorist attack or natural disaster, these HAMR teams would be the Secretary's first asset in addressing deployment needs.

All HAMR Team members would be USPHS officers and full-time employees of the Office of the U.S. Surgeon General. This would guarantee a dedicated, immediately deployable force. HAMR team members would maintain a state of readiness through continuous training or actual deployment, including disaster response assistance to State and local health departments.

All HAMR team members would receive advanced training in trauma life support and the emergency medical management of casualties due to chemical or biological agents or ionizing radiation. HAMR teams would address not only clinical tasks but the full range of public health concerns in a major crisis.

Creation of this new emergency response capability was among Secretary Leavitt's top priorities for fiscal year 2008. The administration's budget request contained \$38 million for this purpose. Unfortunately, however, the HAMR teams were not funded. They are once again among the Secretary's top priorities for fiscal year 2009.

The HAMR team proposal grows out of recommendations contained in the White House report on “lessons learned” from the response to the 2005 hurricanes. The performance of the 2,500 USPHS officers in that crisis was one of the few aspects of the Federal response to draw widespread praise.

For as long as our Nation remains at risk of terrorist attack, the Department of Health and Human Services will remain responsible for detecting and preventing attacks and for responding to mass casualty events. Because the training of emergency medical teams is essential to that mission, funding to support the effort should be approved.

On behalf of the Commissioned Officers Association (COA) and the 7,500 active-duty and retired USPHS officers who are its members, I thank you for your consideration of this request.

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PREPARED STATEMENT OF THE COOLEY’S ANEMIA FOUNDATION

Mr. Chairman and members of the subcommittee: Thank you for the opportunity to present this testimony to the subcommittee today. My name is Frank Somma. I live in Holmdel, New Jersey and I am honored to serve as the National President of the Cooley’s Anemia Foundation. As many members of this subcommittee know, Cooley’s anemia, or thalassemia, is an incurable, fatal genetic blood disorder.

Over the years, this subcommittee has been a consistent supporter of the programs that exist to improve the lives of our children—children who suffer from thalassemia. We are very grateful for all that you have done to help over the years and again, we are asking that you continue to support the research and the programs that will help lead to a cure for this dreaded disease.

I could bog you down in a detailed scientific explanation of what happens physiologically when the human body cannot produce red blood cells in adequate numbers and of adequate quality to sustain life or the danger and pain of bi-weekly blood transfusions I am not going to do that. The important thing for members of this subcommittee to remember about Cooley’s anemia is that it is an incurable, fatal genetic blood disorder. Period.

In my testimony, I am going to address the following three issues in what I hope is a clear and succinct manner.

- The first is the immediate need to provide a 5 percent increase to the CDC’s Division of Blood Disorders to fund the thalassemia blood safety surveillance network. This program works for thalassemia patients, and for all Americans, by providing a mechanism to take immediate actions to keep the blood supply safe when a threat emerges. The President’s budget recommends \$1.85 million; we are requesting \$1.95 million.
- The second issue is the equally critical need for this subcommittee to commit our government through the NIH—and more specifically through NHLBI—to the development of a vigorous, ethical, progressive and focused gene therapy program that is designed to cure single-gene disorders in the shortest possible time.
- The third issue is the urgent need to increase funding for the NIH by a minimum of 6.5 percent this year and to assure the continuation of desperately needed research through the Thalassemia Clinical Research Network, which is based at NHLBI.

BLOOD SAFETY SURVEILLANCE

Mr. Chairman, when a baby is diagnosed with Cooley’s anemia, or thalassemia major, the standard of treatment is to begin that child on blood transfusions. I want to be very clear here that the treatment is not to give the child a blood transfusion; it is to begin a lifetime treatment regimen of this most invasive and dangerous intervention. Once diagnosed, our children receive a blood transfusion every two weeks for the rest of their lives.

Because Cooley’s anemia patients are transfused so regularly and so often, they represent an “early warning system” for problems in the blood supply. If there is an emerging infection or other problem with the blood supply, it is our patients that will get it first and, because of their fragile health, will likely suffer more critically from secondary complications.

Please understand, for example, that nearly every patient over the age of 18 today who has thalassemia major also has HIV or hepatitis C, or both, as a result of their transfusions—or did have it before the combination of the infectious disease and their underlying genetic disease killed them.

Blood safety is a major national issue. Surgical and trauma patients often have no choice but to be transfused. And, it is done on an emergency basis everyday in

hospitals in your states and districts. Nothing is more important to the patient at the time of transfusion than that they can be confident that the blood being pumped into their veins is free from infectious agents—HIV, HCV, or something that none of us have yet heard and doctors have yet to identify.

The blood safety surveillance program is currently operating very effectively through the Division of Blood Disorders in the National Center for Birth Defects and Developmental Disability (NCBDDD) with about \$1.86 million in funding. We are pleased that the President's budget recommends continuing it, although at a \$1.85 million level.

We are respectfully urging that the subcommittee increase this funding to \$1.95 million to reflect inflationary pressures in order to continue to protect Americans from unnecessary infections and diseases that may occur in the blood supply. Also, we are requesting that the subcommittee and its staff remain vigilant in protecting this program from unjustified and unjustifiable assaults as we saw after the passage of the fiscal year 2007 Continuing Resolution.

#### GENE THERAPY

Mr. Chairman, as you know, in the last year or two we have begun to see evidence of some very good news about gene therapy. After decades of overblown promises and false starts, we can now see a pathway for scientists to follow to help make the promise of gene therapy become the reality of cures. The problem to this point in the long saga that is gene therapy has not been one of science; it has been one of expectations. As a society, we all forgot that science requires trial and error and that experiments are just that—experiments. Sometimes they succeed, but often they fail. And, when they fail, we need to analyze what happened and identify how to correct it and then try again.

Today, gene therapy is advancing at a rapid pace in the rest of the world. Exciting work is being undertaken in Japan and China, in the UK and in France. Unfortunately, it is showing less progress the United States of America and that is not right. We are the international leaders in scientific research and, in a field like this—fraught with financial, scientific and ethical minefields—it is essential that America demonstrate its continued leadership to the world. We set the highest ethical and moral standards on every one of these issues. We protect human subjects best. The future of gene therapy as a means of curing disease is simply too important to leave it to anyone else.

For persons with a single cell mutation disorder like thalassemia or sickle cell disease or “boy in the bubble” disease (SCID), gene therapy holds tremendous promise for a cure. We are now learning so much about how to deliver healthy genes to unhealthy cells that we cannot turn back—nor can we as a nation afford to let down the scientists in this country who have such a depth of knowledge and experience. Our friends in Europe and Asia are leaping ahead of us in this critical area of biomedical research and gene therapy.

We hope that this Congress—speaking through this subcommittee—will do what we have done and dare the NIH and its grantees to “cure something.” You are investing nearly \$29 billion of taxpayer money in this agency that houses the “best and the brightest” in Bethesda and that funds “the best and the brightest” throughout the nation. We as Americans must never stop striving to reach previously unimaginable heights. If that means that we have to shake up the status quo and create a new funding mechanism, let's do it. But let's not continue to follow the slow going incremental, some might say “glacial,” path of the past.

We need to spend our tax dollars in a coordinated and focused manner that will maximize the chances that science will unlock the secrets of how to correct single gene defects. We are gaining direct knowledge of how to safely proceed, with an experiment currently being conducted—in France—that may be a breakthrough. It is time for the United States to step up and lead the world in this life-saving area of research. We are counting on our representatives in Congress to lead the way. As I said, this research is being done in other places around the world. In the United States I have detected a reticence to proceed because of safety concerns which made news years ago. If we are truly concerned with safety, doesn't it make sense to embark on gene therapy here where we know the IRB's will ensure that patients come first?

#### NIH AND THE THALASSEMIA CLINICAL RESEARCH NETWORK

Mr. Chairman, 8 years ago, working closely with members of this subcommittee from both sides of the aisle, the CAF convinced the NHLBI of the need to create a Thalassemia Clinical Research Network. The purpose of the Network is to create an infrastructure that would enable the top researchers in the field to collaborate

on desperately needed research projects using common protocols. Today, the Network is up and running and is the focal point for thalassemia research, most of which takes place in academic medical centers, literally spread from coast to coast.

However, there remains a cloud hanging over this, and all other, research at NIH. As the Biomedical Research and Development Price Index continues to escalate, the buying power of an NIH that has been flat-funded for 5 years continues to decrease. There would be nothing wrong with this if we had cured thalassemia, hemophilia, cystic fibrosis, and all other genetic and non-genetic diseases. But that is not the case.

There is an enormous amount of work to be done, treatments to be developed and cures to be found. And there is no one else to do it but our National Institutes of Health, with the support of our Congress and President.

I urge the subcommittee to make a commitment this year in this bill to at the very least a 6.5 percent increase for the National Institutes of Health. This level of funding will help to restore some of the purchasing power that has been lost since the end of the 5 year doubling. It is time to commit to undo the damage that has been done in the last 5 years. I also urge the committee to assure that NIH shows no diminution of support the Thalassemia Clinical Research Network.

#### CONCLUSION

As I indicated at the outset, Mr. Chairman, the Cooley's Anemia Foundation has three priorities this year:

- Funding the blood safety surveillance program at CDC at \$1.95 million;
- An enhanced focus on gene therapy designed to cure something; and,
- At least a 6.5 percent increase in NIH funding and the continuation of the Thalassemia Clinical Research Network.

Mr. Chairman, every night when I watch my beautiful, smart, talented 23 year old daughter Alicia suffer from the complications of thalassemia such as osteoporosis and as I watch her endure daily 8–10 hours of painful drug infusions to remove the excess iron in her system from her bi-weekly blood transfusions, I know we can do better than what we are doing now.

Please excuse my passion, but this is the United States of America. I know we can prevent this disease from happening in newborns. I know we can improve the lives of those who currently have it. And, most importantly, I know that we can cure it once and for all.

It is long past time to demand the very best from the very best—our scientists, our government, and ourselves.

Thank you for your very kind attention and for all the support this committee has shown to our patients and their families over the years.

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#### PREPARED STATEMENT OF THE COUNCIL FOR OPPORTUNITY IN EDUCATION

The Council for Opportunity in Education advocates on behalf of the Federal TRIO programs, which are intended to promote equal access to higher education for low-income, first-generation, and disabled students. For more than 40 years, the Federal TRIO programs—Talent Search, Upward Bound, Upward Bound Math/Science, Veterans Upward Bound, Student Support Services, Equal Opportunity Centers, and the Ronald E. McNair Postbaccalaureate Achievement Programs—have provided the academic tutoring, personal counseling, mentoring, and other vital support services that disadvantaged students need to overcome both the economic and social barriers they face in their pursuit of higher education.

Currently, TRIO programs serve more than 840,000 students across the nation, including several U.S. territories. Over the last several years, program costs and student needs have grown. Yet, because the programs have not received an increase in funding since fiscal year 2005, TRIO can serve only about 7 percent of the eligible population. As the United States now ranks 10th among developed nations in the percentage of 24 to 35 year olds who have completed college, the time is ripe to make a substantial investment in higher education opportunities for American students. By providing a \$120 million increase in TRIO funding in fiscal year 2009, Congress can renew its commitment to serving its most needy and deserving students while also strengthening the United States' competitiveness in this global, knowledge-based economy. More specifically, a \$120 million increase for TRIO in fiscal year 2009 would:

- Improve the capacity of TRIO's pre-college access and college-based retention programs to support students in math and science, a vital component in the nation's ability to increase global competitiveness. (\$57 million)

For example, TRIO programs would be eligible to receive funding from this additional money if they commit to undertake activities such as the following:

1. Talent Search Programs (currently serving nearly 400,000 students) will use the supplementary funding to strengthen pre-algebra and algebra preparation so that students can succeed in higher level mathematics;
2. Upward Bound (more than 960 projects) will enhance mathematics and science curricula to encourage greater numbers to pursue STEM studies in college;
3. EOCs (currently serving 206,000 individuals, mostly displaced or under-employed workers) will use the funding to strengthen math refresher tutoring services;
4. Student Support Services Programs (currently serving about 201,000 students) will provide supplementary funding to enhance tutoring and other academic support for developmental mathematics and calculus gateway courses;
5. Ronald E. McNair Post-Baccalaureate Achievement Programs (serving nearly 4,200 undergraduates contemplating graduate degrees) will increase undergraduate research opportunities for students intending to pursue graduate education in the STEM fields.

—Increase the number of SSS programs by 100 to serve an additional 20,000 disadvantaged college students. (\$28 million)

This is an SSS grant competition year and, therefore, the perfect moment to make a stronger federal investment in helping disadvantaged students earn college degrees. As last year's competitions demonstrated, there are many quality applications worthy of funding, and on their own, colleges and universities are not committing the resources necessary to ensure that students have the support they need to succeed in college.

—Increase overall TRIO appropriations by 4 percent. (\$35 million)

Funding for TRIO programs has not increased since fiscal year 2005. Projects are struggling to maintain critical core services for students, and this increase of \$35 million, equal to the current rate of inflation, would help projects sustain their efforts on behalf of low-income, first-generation students.

We thank the subcommittee for its ongoing commitment to the TRIO programs and the nation's low-income students. While we understand the need to balance priorities, we hope you will agree that the TRIO Programs are critical to the success of many of our Nation's students and will support these programs in the Labor, Health and Human Services, and Education Appropriations bill.

Thank you for the opportunity to submit these comments for the public record and we look forward to working with you to support TRIO programs and TRIO students everywhere.

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#### PREPARED STATEMENT OF THE COUNCIL ON SOCIAL WORK EDUCATION

On behalf of the Council on Social Work Education, I am pleased to offer this written testimony to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies for the official committee record. I will focus my testimony on issues pertaining to fostering a diverse social work workforce through training and accessibility to higher education. In particular, this statement will touch on the importance of funding the Substance Abuse and Mental Health Services Administration's (SAMHSA) Minority Fellowship Program at \$6 million for fiscal year 2009; the need to protect the National Institute of Mental Health (NIMH) minority training program which is also in jeopardy of cancellation; and the importance of sustaining funding for programs within the Department of Education that expand accessibility in higher education.

#### EDUCATING SOCIAL WORKERS TO HELP VULNERABLE POPULATIONS

The Council on Social Work Education (CSWE) is a nonprofit national association representing more than 3,000 individual members as well as over 650 graduate and undergraduate programs of professional social work education. The Council on Higher Education Accreditation (CHEA) authorizes CSWE to establish national educational standards while evaluating individual academic programs to determine if these standards are met for professional accreditation. The central components of these accreditation requirements include critical-thinking, evidence based practice, communication skills, human behavior theory and supervised experiential learning. 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.

In particular, social work education prepares students at the graduate and undergraduate levels for professional practice in the leadership and staffing of our nation's most vital social service programs. Social workers help vulnerable populations

in society—such as children and adults with physical or mental disabilities, trauma victims, individuals under stress or facing coping challenges both temporary and permanent, and segments of society needing assistance to adjust to changing circumstances or overcome injustices—be as healthy and productive as possible. Social work educational programs provide rigorous academic experiences in both classroom and field agency or organizational internship settings and professional social work graduates are employed in a wide array of settings such as public schools, veterans' hospitals and general as well as other special service health care facilities, substance abuse prevention and treatment programs, child protective services, family service settings, and gerontological long-term care facilities. CSWE recognizes that fostering a diverse workforce is key to providing the best possible service to populations in need.

FOSTERING A DIVERSE SOCIAL WORK WORKFORCE THROUGH TRAINING AND  
ACCESSIBILITY

*Minority Fellowship & Training Programs, Department of Health and Human Services*

In 1974, amidst concerns about the limited number of minority scholars able to do indigenous research to improve services to minority communities, the National Institute of Mental Health (NIMH) within the National Institutes of Health (NIH) initiated a training program with the goal of increasing the number of minority doctoral students focusing their research in mental health. A few years later the Substance Abuse and Mental Health Services Administration (SAMHSA) created its own program that strived to achieve greater numbers of minority doctoral students preparing for leadership roles in the mental health and substance abuse field. These two programs provide grants to professional organizations which in turn administer fellowship grants to pre- and post-doctoral students. CSWE is one of the administering organizations. Together these programs make up CSWE's Minority Fellowship Program (MFP).

The MFP has been instrumental in the recruitment and training of underrepresented groups (African-American, Asian-American, Latinos, American Indians), in the field of substance abuse and mental health. Through effective recruitment and selection, the MFP has facilitated minority students' retention and success in doctoral programs in mental health and substance abuse. The MFP fellows receive a unified program of assistance to include mentoring, research training, access to professional networks, and on-going guidance in cooperation with their department advisors, which supports success in all facets. CSWE has supported over 500 minority fellows since the program's inception and two-thirds of those students have gone on to receive their doctoral degrees. They are employed at universities and agencies throughout the United States.

The administration's fiscal year 2009 budget request proposes to eliminate funding for the SAMHSA program, which received \$3.8 million in fiscal year 2008 and \$4.2 million in fiscal year 2007. The Minority Fellowship Program directly contributes to reversing disparities in mental health services and the quality of those services to minority populations. For this reason, CSWE urges the subcommittee to restore this vital SAMHSA program for fiscal year 2009 and in addition provide much needed additional resources in the sum of \$6 million so that the program can continue to turnout minority mental health professionals equipped to provide culturally competent, accessible mental health and substance abuse services to diverse populations.

In addition to the SAMHSA MFP, the minority education program in NIH's mental health institute is also in jeopardy. The NIMH minority education program focuses on increasing the number of minority doctoral students conducting mental health research; it is the "research" side of mental health training while the SAMHSA program represents the "clinical" side.

NIMH Director Thomas Insel has expressed his intent to eliminate funding for this program upon the expiration of the sole remaining institutional training grant in 2010. As the subcommittee knows, new and young investigators continue to face an up-hill climb in terms of breaking into the NIH grant pool for the first time. NIH Director Elias Zerhouni has testified before your subcommittee several times about the need for "new talent" at NIH, stating as recently as last year that "One of NIH's highest priorities will be to preserve the ability of new and junior scientists with fresh ideas to enter the competitive world of NIH funding."

While we applaud NIH's efforts to diversify the NIH grant pool through the development of such programs as the "Pathway to Independence" program and others, at a time when NIH has pledged a commitment to growing "fresh talent," NIMH

is essentially abandoning a proven program that has educated and prepared hundreds of minority scholars for research and leadership in the mental health sciences.

While we understand that this issue cannot be fixed via the annual appropriations process, we urge the subcommittee to put pressure on NIH to reconsider its intent to cut off funding for this crucial training program beginning in 2010.

*Aid for Institutional Development, Department of Education*

Fostering a diverse workforce is central to ensuring that we are able to provide culturally competent services to minority populations. Social workers must be able to relate to the communities they serve. However, getting minority students into the workforce pipeline is often difficult due to the many barriers to higher education facing minority and lower-income populations.

The Department of Education supports several programs whose goal is to expand the accessibility of higher education to lower-income and minority populations. These programs provide financial assistance to minority-serving institutions to address needs in academic quality, student services, educational equipment acquisition, facility construction, and faculty and staff development. In turn, funds for these programs make these institutions more accessible while at the same time culturally relevant.

For fiscal year 2009, the administration has proposed to substantially cut funding for these very important programs. Specifically, cuts are proposed for programs geared toward strengthening Tribally Controlled Colleges and Universities; Alaska Native and Native Hawaiian-serving Institutions; Historically Black Colleges and Universities; Historically Black Graduate Institutions; Predominantly Black Institutions; Asian American and Native American Pacific Islander-serving, and Native American-serving nontribal institutions.

CSWE asks the subcommittee to reject the President's proposed cuts for fiscal year 2009 and provide these programs with at least the amount enacted for fiscal year 2008. Minority-serving institutions like these play a vital role in educating the diverse workforce that is the backbone of the social work profession, and since they do not have access to the same resources (large endowments, high tuition) as other institutions, they depend heavily on this modest Federal support to function. While the administration's rationale for these cuts is that the College Cost Reduction Act of last year provides additional mandatory funding for these institutions, we presume that Congress provided those funds so that minority-serving institutions could move forward, not remain stagnant.

Thank you for the opportunity to express these views on behalf of the Council on Social Work Education. We hope the subcommittee will take these points into consideration as you move forward in the fiscal year 2009 appropriations process. Please do not hesitate to contact me with any questions.

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PREPARED STATEMENT OF THE CYSTIC FIBROSIS FOUNDATION

On behalf of the Cystic Fibrosis Foundation, and the 30,000 people with cystic fibrosis (CF), we are pleased to submit the following testimony regarding fiscal year 2009 appropriations for cystic fibrosis-related research at the National Institutes of Health (NIH) and other agencies.

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, which clogs the lungs and results in fatal lung infections. The thick mucus in those with CF also obstructs the pancreas, causing patients difficulty in absorbing nutrients from food.

Since its founding, the Cystic Fibrosis Foundation has maintained its focus on promoting research and improving treatments for CF. CF has been significantly transformed from a childhood death sentence into a chronic disease, which requires a rigorous daily regimen of therapy.

It is a promising time for CF research. More than thirty drugs are now in development to treat CF, some which treat the basic defect of the disease, while others target its symptoms. Through the research leadership of the Cystic Fibrosis Foundation, the life expectancy of individuals with CF has been boosted from less than six years in 1955 to nearly 37 years in 2007. Today, almost 45 percent of people with CF are 18 or older. This improvement in the life expectancy for those with CF can be attributed to research advances, which this testimony will discuss in some detail later, and to the teams of CF caregivers who offer specialized care of the highest



quality. Although life expectancy has improved dramatically, we continue to lose young lives to this disease. Our progress is not sufficient for those affected by CF.

The promise for people with CF is in research. In the past five years, the Cystic Fibrosis Foundation has invested over \$660 million 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. This testimony focuses on the investment that will be required to discover and develop new CF treatments rapidly and efficiently and to encourage research for a cure.

#### SUSTAINING THE FEDERAL INVESTMENT IN BIOMEDICAL RESEARCH

This subcommittee and Congress are to be commended for their steadfast support for biomedical research, and their commitment to the National Institutes of Health (NIH), including the effort to double the NIH budget between fiscal year 1999 and fiscal year 2003. This impressive increase in funding resulted in a revolution in medical research, fueling discoveries that benefit all Americans.

If we fail to adequately fund the NIH so that it can capitalize on scientific advances, we risk losing the momentum that the doubling generated. The flat-funding of the NIH has already led to a decrease in purchasing power, limiting the research that could have been conducted. The Cystic Fibrosis Foundation joins the Ad Hoc Group for Medical Research to recommend increasing the NIH budget by at least 6.5 percent in fiscal year 2009, or \$1.9 billion over fiscal year 2008. This increased investment will help maintain the NIH's ability to fund essential biomedical research today that will provide tomorrow's care and cures.

#### STRENGTHENING OUR NATION'S RESEARCH INFRASTRUCTURE

We urge the NIH to pay special attention to advances in treatment methods and mechanisms for translating basic research into therapies that can benefit patients. The Cystic Fibrosis Foundation has been recognized for its own research approach that encompasses basic research through Phase III clinical trials, 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 thirty potential therapies that are being examined to treat people with CF. These therapies aim to treat CF on multiple fronts, an important consideration for a disease that affects the body in multiple ways.

Because CF is a disease which impacts several systems in the body, different institutes at NIH share responsibility for CF research. Having multiple responsible institutes presents roadblocks to CF research in that there can be imperfect communication among the institutes regarding research in the field. This can limit our ability to capitalize on all research opportunities. Moreover, multidisciplinary research approaches of the sort we believe are most promising in CF, may be disadvantaged in the NIH system of review and funding.

#### *The Clinical and Translational Science Awards (CTSA)*

The Clinical and Translational Science Awards (CTSA) program was a key component of the NIH's Roadmap initiative. The program is designed to transform how clinical and translational research is conducted, ultimately enabling researchers to provide new treatments more efficiently and quickly to patients. There have been significant cuts to the program since its launch in 2006. Tremendous effort brought institutions together to rally around this program, yet current funding levels make it difficult for the current 24 programs (out of a planned 60) to succeed.

This program is largely funded and managed by the National Center for Research Resources (NCRR). Key to the success of the CTSAs is the development of cost sharing for use of infrastructure services, such as the General Clinical Research Centers (GCRC). In the past, all services within the NIH's GCRC were provided at no cost to investigators. The other institutes expected that they could reduce their research budgets by having investigators use the GCRC where clinical care such as inpatient stays, lab tests, nursing staff, was available at no additional cost. Today, individual investigators must provide funds for clinical care cost sharing from grants funded from other NIH institutes.

As research becomes more expensive, it becomes even more critical to ensure support for translational research, that is, research that moves a potential therapy from being developed in the lab into one that is delivered to the public. In order to maximize the success of the CTSA, multiple institutes within the NIH must be able to provide financial resources for the program. Stronger support for the CTSA is needed because the program is a critical mechanism for improving the translational re-

search activities necessary to develop treatments for common and rare diseases alike.

#### *Supporting Clinical Research*

A significant discrepancy still persists between the funding awarded to clinical and basic laboratory investigators for first awards and the discrepancy is even greater for second awards and prolonged funding of clinical investigators. The NIH must maintain the ability to support translational research and the investigators piloting those projects. Without this support, the NIH stands to lose an entire generation of clinically trained individuals committed to clinical research. The “generation gap” that would be created by the loss of a cache of clinical researchers would not only affect the ability of the NIH to continue to conduct world-class clinical investigation, but would also jeopardize the standing of the United States as the world’s premiere source for biomedical research.

#### FACILITATING CLINICAL RESEARCH AND DRUG DEVELOPMENT

The Cystic Fibrosis Foundation applauds the efforts of NIH to encourage greater efficiency in clinical research. The Foundation has been a leader in creating a clinical trials network to achieve greater efficiency in clinical investigation. Because the CF population is so small, a more significant portion 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. Research conducted by the Foundation is more efficient than ever before. The clinical trials network is a model for other disease groups.

We have a permanent network of clinical trial sites and have centralized and coordinated data management and analysis functions and data safety monitoring. Among the results of this outstanding network—called the Therapeutics Development Network—are the ability to achieve rapid accrual to trials and the capacity to conduct multiple trials simultaneously, even in a population of 30,000 CF patients. Since the TDN’s inception, it has conducted over 40 trials. Of course, the ultimate goal of a centralized clinical trials system is the acceleration of the therapeutic development process.

Although we have achieved significant efficiencies in our clinical trials system, we still encounter substantial slowdowns in the review of our multi-institutional trials by the institutional review boards (IRBs) at each of the institutions participating in the trials. We are pleased that the Department of Health and Human Services has encouraged the exploration of alternative models of IRBs, including central IRBs, by the CTSA, however we encourage Congress to urge the Department to demonstrate more aggressive leadership in persuading all academic institutions to accept review by a central IRB—without insisting on parallel and often duplicative review by their own IRB—at least in the case of multi-institutional trials in rare diseases. Such central oversight can help provide greater expertise to improve trial design and enable critical research to move forward in a timelier manner without undermining patient safety.

#### *Pursuing New Therapies: The Cystic Fibrosis Therapeutics Development Network*

The Cystic Fibrosis Foundation requests that the committee allocate \$1.5 million in Federal funding in fiscal year 2009 to support a much-needed expansion of our clinical research program, the Therapeutics Development Network (TDN), through the Coordinating Center at Children’s Hospital & Regional Medical Center in Seattle, Washington. This will provide a significant investment in the Cystic Fibrosis Foundation’s ongoing efforts to meet the demand for testing of all the promising new therapies for cystic fibrosis.

Designating Federal funding for the Cystic Fibrosis Therapeutics Development Network will accelerate testing of new therapies for CF. The TDN plays a pivotal role in accelerating the development of new treatments to improve the length and quality of life for cystic fibrosis patients. Lessons learned from centralization of data management and analysis and data safety monitoring in the TDN will be useful in designing clinical trial networks in other diseases. Again, we urge the committee to provide \$1.5 million to Children’s Hospital & Regional Medical Center in Seattle, Washington for this important work.

#### *Partnership with the National Center for Research Resources*

As mentioned previously, the Institutional CTSA program is an initiative of particular importance to CF. This NIH Roadmap program administered by the NCRR encourages novel approaches to clinical and translational research, enhances the utilization of informatics, and strengthens the training of young investigators. The Cystic Fibrosis Foundation has enjoyed a productive relationship with the NCRR to

support our vision for improving clinical trials capacity through its early financial support of the TDN. However, the CF Foundation urges NCRR to reverse its decision to reject funding for disease-specific networks in favor of those without a disease focus. As a result of this policy, some of the best clinical research consortia are prohibited from competing for NCRR grants, including but not limited to the CF TDN.

#### SUPPORTING DRUG DISCOVERY

While much of this testimony has focused on clinical research, new therapies rely on solid basic research. The CF Foundation's clinical research is fueled by a vigorous drug discovery effort; early stage translational research of promising strategies to find successful treatments for this disease. Several research projects at the NIH hold the promise of expanding our knowledge about the disease, which may lead to potential interventions to alter its course. We strongly support this important research, which fuels our efforts to find a cure.

##### *Protein Misfolding & Mistrafficking*

The Cystic Fibrosis Foundation urges the NIH to devote special attention to research in protein misfolding and mistrafficking, an area which may yield significant benefits for CF and other diseases where misfolding is an issue. We applaud the National Heart, Lung and Blood Institute (NHLBI), and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for their initiatives that target research on protein misfolding, and urge an aggressive commitment to facilitate continued exploration in this area to build upon promising discoveries. Additionally, we urge funding by the National Institute of General Medical Sciences (NIGMS) for the creation of tools and reagents and advances in techniques that will allow for precision monitoring of folding and trafficking events and for the sharing of resulting data that would complement the efforts of NIDDK—and NHLBI—funded investigations in this area.

##### *Opportunities In Animal Models*

In particular, the Cystic Fibrosis Foundation has been encouraged to see a substantial NIH investment in a research program through the University of Iowa to study the effects of CF in a pig model. The recent birth of a pig engineered to have a mutation in its CFTR gene is the first time a large animal model of a genetic disease has been created. The program, funded through research awards from both the Cystic Fibrosis Foundation and NHLBI, bears great promise to help make significant developments in the search for a cure. We encourage additional funding in this area to create a facility that would enable researchers beyond just those at the University of Iowa to conduct their research. Such a facility is needed as many institutions do not have the infrastructure needed to house and care for large animals.

##### *Small Business Innovation Research Program at NIH*

Small Business Innovation Research (SBIR) program grants through the NIH have helped many small biotechnology and pharmaceutical companies to develop vital treatments for a variety of diseases. Several companies developing CF treatments have used SBIR grants to help in their development process.

One company, PTC Therapeutics, previously received an SBIR grant while developing a drug. That minor infusion of money was enough to allow the company to take innovative risks in developing a second drug, PTC-124. PTC-124 proved to be so promising for multiple diseases, including CF, that the company was awarded \$15 million by the NIH to continue development. The initial support of the SBIR grant allowed for one innovation to follow another. By continuing to ensure that the NIH has adequate funding for small dollar-amount programs like SBIR, great things can emerge.

The SBIR program could provide further support by designating that a portion of all grants awarded must be used for rare disease research. With such a small portion of the population likely to purchase the drugs, research to produce drugs to treat rare diseases is often considered too large a financial risk to take on. It is important to note, however that there are over 25 million Americans with a rare disease. By directing even small dollar grants specifically to help develop drugs for these diseases, biotechnology and pharmaceutical companies can receive the financial spark that makes drug development for rare diseases less risky.

On behalf of the Cystic Fibrosis Foundation, we thank the committee for its consideration. Congress has reason to be proud of its role in supporting NIH as the world's leader in biomedical research. The NIH has spent decades on the basic research that made our discoveries possible and to let that information languish for lack of funding would be tragic indeed.

Dr. Zerhouni has wisely focused on translational research as a touchstone for ensuring the relevance of the NIH to the American public. The CF Foundation is the perfect example of this notion, having devoted our own resources to developing treatments through drug discovery, clinical development, and clinical care. Our patient registry allows us to track outcomes at the patient, center, and national level and learn more about the course of this disease and how to fight it. Our efforts are paying off. This spring we received news that one of the drugs in our pipeline showed remarkable promise in a clinical trial and we are increasingly more hopeful that this discovery will bring us even closer to a cure. Encouraged by our successes, we believe the experience of the CF Foundation in clinical research can serve as a model for research on other orphan diseases and we stand ready to work with NIH and Congressional leaders.

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#### PREPARED STATEMENT OF THE DYSTONIA MEDICAL RESEARCH FOUNDATION

##### SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2009

- A minimum 6.5 percent funding increase for the National Institutes of Health and its Institutes and Centers.
- Urge the National Institute on Neurological Disorders and Stroke, the National Institute on Deafness and Other Communication Disorders, and the National Eye Institute to expand their research portfolios on Dystonia.

Dystonia is a neurological movement disorder characterized by powerful and painful involuntary muscle spasms that cause the body to twist, repetitively jerk, and sustain postural deformities. There are several different variations of dystonia, including; focal dystonias, which affect specific parts of the body, and generalized dystonia, which affect many parts of the body at the same time. Some forms of dystonia are genetic and others are caused by injury or illness. Dystonia does not affect a person's consciousness or intellect, but is chronic and progressive. In North America alone, conservative estimates indicate that between 300,000 and 500,000 individuals suffer with dystonia. Currently, there is no known cure and treatment options remain limited.

While the underlying mechanisms of dystonia remain a mystery and the onset of symptoms can occur for a number of reasons, two therapies have emerged with proven health benefits to the dystonia patient community. Botulinum toxin injections and deep brain stimulation have shown varying degrees of success, depending on the individual, in alleviating a dystonia patient's symptoms. More research is needed to fully understand how to combat and cure dystonia, and in the mean time, maintaining patient access to life-improving therapies remains critical.

##### DEEP BRAIN STIMULATIONS (DBS)

Deep brain stimulation (DBS) is a surgical procedure that was originally developed to treat Parkinson's disease, but is now being applied to severe cases of dystonia. A neurostimulator, or brain pacemaker, is surgically implanted and delivers electrical stimulation to the areas of the brain that control movement. While the exact reasons for effectiveness are unknown, the electrical stimulation blocks abnormal nerve signals that cause abnormal muscle spasms and contractions.

Since DBS was approved for use by dystonia patients in 2003, it has drastically improved the lives of many individuals. Results have ranged from quickly regaining the ability to walk and speak, to regaining complete control over one's body and returning to an independent life as an able-bodied person. DBS is currently used to treat severe cases of generalized dystonia, but its promising role in treating focal dystonias is being explored and requires continuous support. Surgical interventions are a crucial and active area of dystonia research and may continue to lead to the development of promising treatment options.

##### BOTULINUM TOXIN INJECTIONS (BOTOX/MYOBLLOC)

The introduction of botulinum toxin as a therapeutic tool in the late 1980s revolutionized the treatment of dystonia by offering a new, localized method to significantly relieve symptoms for many people. Botulinum toxin, a biological product, is injected into specific muscles where it acts to relax the muscles and reduce excessive muscle contractions.

Botulinum toxin is derived from the bacterium *Clostridium botulinum*. It is a nerve "blocker" that binds to the nerves that lead to the muscle and prevents the release of acetylcholine, a neurotransmitter that activates muscle contractions. If the message is blocked, muscle spasms are significantly reduced or eliminated.

Injections of botulinum toxin should only be performed by a physician who is trained to administer this treatment. The physician needs to know the clinical features and study the involuntary movements of the person being treated. The physician doing the treatment may palpate (touch) the muscles carefully, trying to ascertain which muscles are over-contracting and which muscles may be compensating. In some instances, such as in the treatment of laryngeal dystonia, a team approach including other specialists may be required.

For selected areas of the body, and particularly when injecting muscles that are difficult or impossible to palpate, guidance using an electromyograph (EMG) may be necessary. For instance, when injecting the deep muscles of the jaw, neck, or vocal cords, an EMG-guided injection may improve precision since these muscles cannot be readily palpated. An EMG measures and records muscle activity and may help the physician locate overactive muscles.

Injections into the overactive muscle are done with a small needle, with one to three injections per muscle. Discomfort at the site of injections is usually temporary, and a local anesthetic is sometimes used to minimize any discomfort associated with the injection. Many dystonia patients frequently rely on botulinum toxins injections to maintain their improved standard of living due to the fact that the benefits of the treatment peak in approximately four weeks and lasts just 3 or 4 months. Currently, FDA approved forms of botulinum toxin include Botox and Myobloc.

#### DYSTONIA AND THE NATIONAL INSTITUTES OF HEALTH (NIH)

Currently, three Institutes at the National Institutes of Health (NIH) conduct medical research regarding dystonia. They are the National Institute of Neurological Disorder and Stroke (NINDS), the National Institute on Deafness and Other Communication Disorders (NIDCD), and the National Eye Institute (NEI).

NINDS has released important Program Announcements in recent years to study the causes and mechanisms of dystonia. These awards covered a wide range of research areas, which included gene discovery, the genetics and genomics of dystonia, the development of animal models of primary and secondary dystonia, molecular and cellular studies inherited forms of dystonia, epidemiology studies, and brain imaging. DMRF often works with NINDS to support as much critical research as possible and advance understating of dystonia.

NIDCD has funded many studies on brainstem systems and their role in spasmodic dysphonia. Spasmodic dysphonia is a form of focal dystonia, and involves involuntary spasms of the vocal cords causing interruptions of speech and affecting voice quality. Our understanding of spasmodic dysphonia has been greatly enhanced by research initiatives at NIDCD, like the brainstem systems studies.

NEI focuses some of its resources on the study of blepharospasm. Blepharospasm is an abnormal, involuntary blinking of the eyelids from an unknown cause that is associated with abnormal function of the basal ganglion. The condition can progress to the point where facial spasms develop. Presently, NEI is conducting a study entitled, Mexiletine for the Treatment of Focal Dystonia and a Doxil® Blepharospasm Treatment Trial, both of which have the potential to significantly improve treatment options for blepharospasm patients.

DMRF also supports many extramural researchers studying dystonia. Research includes: exploring improved clinical rating scales for dystonia, elevations of sensory motor training, utilizing Botox as a possible treatment for focal hand dystonia, characterization of abnormalities in sensory regions of the brain, treatments for spasmodic dysphonia, deep brain stimulation (the direct electrical stimulation of specific brain targets), non-invasive transcranial brain stimulation, anatomy imaging of the affect of dystonia on brain activity, and exploring the link between laryngitis and spasmodic dysphonia.

Recent years of near level-funding at NIH have negatively impacted the mission of its Institutes and Centers. For this reason, DMRF applauds efforts like Senators Tom Harkin (D-IA) and Arlen Specter's (R-PA) adopted amendment to the fiscal year 2009 Senate Budget Resolutions which calls on appropriators to provide NIH with a 10.3 percent funding increase. DMRF urges this Subcommittee to show strong leadership in pursuing such a substantial funding increase.

For fiscal year 2009, DMRF recommends a funding increase of at least 6.5 percent for NIH and its Institutes and Centers.

For fiscal year 2009, DMRF recommends that the National Institute on Neurological Disorders and Stroke, the National Institute on Deafness and Other Communication Disorders, and the National Eye Institute be urged to increase their research activities regarding dystonia and partner with voluntary health organizations to promote dystonia research and awareness.

## 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 functional dystonia community.

## PREPARED STATEMENT OF THE ENDOCRINE SOCIETY

The Endocrine Society would like to submit the following testimony regarding fiscal year 2009 Federal appropriations for biomedical research, with emphasis on appropriations for the National Institutes of Health. The Endocrine Society is the world's largest and most active professional organization of endocrinologists representing over 14,000 members worldwide. Our organization is dedicated to promoting excellence in research, education, and clinical practice in the field of endocrinology. The Society is comprised of thousands of researchers who depend on Federal support for their careers and their scientific 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 National Institutes of Health (NIH) specifically has had a significant impact on the United States' 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.

Unfortunately, the gains experienced by the NIH during the doubling period have not kept pace with inflation. In fiscal year 2008, the NIH received only a \$300 million dollar increase and it may receive no increase in fiscal year 2009 unless Congress alters the President's budget request. These funding levels are significantly below the 3.5 percent increase needed simply to maintain NIH's existing purchasing power. In order to fully understand the importance of maintaining the growth experienced during the doubling period, policymakers must first understand the impact that research programs have on patients and scientists.

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. In addition to improving quality and length of life, these advances in treatment also reduce the health care costs of our Nation. Diabetes is a devastating condition that affects an increasingly large number of Americans and requires a large proportion of the Nation's healthcare spending. More than 20 million Americans are affected by either type 1 or type 2 diabetes, and 11 percent of the Nation's health care expenditures go to diabetes care. However, only about 3.5 percent of the National Institutes of Health (NIH) budget went to diabetes research in 2006. Congressional funding for diabetes research has been generous, but increasing incidence requires increased funding in order to stave off rising health care costs.

No new diabetes medications would have ever 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 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.

However, it is clear that there are many more pathways that remain to be discovered. These newly discovered pathways require continued research to bridge the gap from the basic lab bench and translate these discoveries for patients to use. The primary goals of medicine are to prevent and treat disease and to reduce suffering. Continued Federal support for basic science and clinical research in diabetes will go a long way toward attaining those goals.

These advances in diabetes treatment would not have been possible without the efforts of the scientists who have chosen to dedicate their lives' work to identifying the next treatment or cure. As the amount of real dollars allocated to Federal re-

search funding declines, so too do the opportunities for researchers. As a result, scientists are often forced to find other careers or move to other countries to continue their research, depleting the pool of talent that government agencies and pharmaceutical companies have to draw from. Fewer scientists and less research would result in this country losing its place as a leader in medical progress. The U.S. Government must acknowledge this potentially bleak future and place more value and emphasis on research and development efforts. Without these scientists in our workforce, many medical breakthroughs will either never happen or will happen as a result of overseas research.

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. For fiscal year 2009, The Endocrine Society recommends that the NIH receive \$31.1 billion in order to recoup the losses caused by biomedical inflation over the last few years, fund necessary new research programs, and build on the discoveries made during the doubling period.

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PREPARED STATEMENT OF THE FSH SOCIETY, INC.

Mr. Chairman, Honorable Senator Specter and Honorable Senator Tom Harkin, thank you for the opportunity to testify before your subcommittee.

I am here to remind you that muscular dystrophy (MD) is still taking its toll. As a patient with facioscapulohumeral muscular dystrophy (FSHD), I have experienced the constant loss of function this disease leaves in its wake.

We request this year in fiscal year 2009 immediate and necessary help for those of us coping with and dying from facioscapulohumeral muscular dystrophy, FSHD and MD, as we did in fiscal year 2008. Specifically we ask that the Senate and the Appropriations Subcommittee on Labor, HHS, Education and Related Agencies consider:

1. Resuming the 5 year doubling of the National Institutes of Health (NIH) budget. Over the past year the research funding situation has gone from bad to worse and we have lost opportunities to fund excellent research.

2. Appropriating \$80 million to MD research at the NIH in fiscal year 2009 and steadily increasing this amount to at least \$125 million annually over the next 5 years.

3. Making NIH funding comprehensive for basic research in each of the nine types of MD as well as creating an equitable distribution for each MD across the Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Center network, program projects, basic research projects, clinical research, training programs and translational research programs. We explicitly draw your attention to the subtle nuance of mandating NIH to have centers and comprehensive research portfolio "in all" the muscular dystrophies, versus, NIH having centers and a comprehensive research portfolio "in each of" the muscular dystrophies. This seemingly insignificant one word addition transforms death into life for all patients and families with MD.

Our first request calls for increasing the NIH budget and resuming the 5 year doubling. The wars in Iraq, Afghanistan, tax cuts and the turmoil in the financial markets have essentially halted any progress in biomedical research. We all know that America has fallen far behind in biomedical research funding. As a person with a disease it is hard to reconcile the generosity of the Congress towards the wars, and bailing out institutions that have put us all at financial risk, against the lack of action on behalf of sick and dying citizens. The NIH budget at \$29.2 billion is a miniscule fraction of these other expenses. Doubling a tiny fraction is still a tiny fraction. For those in Congress who ask the NIH where are the cures—consider that the NIH budget of \$29.2 billion covering countless thousands and thousands of diseases is a fraction of the market capitalization of a large pharmaceutical company covering a few disease areas. Consider also that the main job of NIH is basic science, not drug development, and that the pharmaceutical companies, the American public and people throughout the world benefit directly from the NIH investment in science. Please act now to refocus spending on American infrastructure before trust and confidence is lost.

Our second request calls for NIH to build and grow its muscular dystrophy (MD) disease area funding to a level commensurate with diseases of similar burden. A wide disparity still exists in funding for MD. This is a matter for both Appropriations and for the NIH with its wide discretion on funding for diseases. More funding would help balance out these disparities and accelerate treatments and cures for

diseases. We request that the Director of the NIH consider a more equitable amount for MD that is solidly in line with its disease peers at \$80 to \$125 million.

Our third request asks the Appropriations Committee to request that the Director of the NIH increase the amount of FSHD research and projects in its portfolios using all available mechanisms and interagency committees. Given the knowledge base and current opportunity for breakthroughs in ameliorating, treating and perhaps curing FSHD it is inequitable that only two of the twelve NIH institutes covering muscular dystrophy have a handful of research grants for FSHD. Why is FSHD research virtually non-existent in the Senator Paul D. Wellstone MD Cooperative Research Centers (CRCs)? Funding should include projects from the NIH roadmap, extramural programs, intramural programs, Senator Paul Wellstone MD CRCs and similar program projects that have a major focus on FSHD.

FSHD is the second most prevalent adult muscular dystrophy. The incidence of the disease is conservatively estimated to be 1 in 20,000. The prevalence of the disease, those living with the disease ranges from 15,000 to 40,000 Americans based on our increasing experiences with the disease and accurate diagnostic tests. For men, women, and children the major consequence of inheriting FSHD is a lifelong progressive and severe loss of all skeletal muscles. FSHD is a terrible, crippling and life shortening disease. It is genetically transmitted to children and it affects entire family constellations.

How is facioscapulohumeral muscular dystrophy (FSHD) research at the NIH doing in 2008, 7 years after the MD CARE Act 2001 was passed, and, 13 years after our first testimony in person before the Honorable Senator Harkin of this honorable Committee?

We applaud Dr. Story Landis, Director, National Institute of Neurological Disorders and Stroke (NINDS), and, current Chair of the Muscular Dystrophy Coordinating Committee (MDCC); Dr. Stephen I. Katz, Director, National Institute of Arthritis and Musculoskeletal Disorders (NIAMS) and past-Chairman of the MDCC; Dr. John Porter, Program Director Muscular Dystrophy, NINDS, and Executive Secretary of the MDCC, and; Dr. Glen Nuckolls, Program Director Muscular Dystrophy, NIAMS, for their extraordinary comprehension, insight, accuracy and speed with which the NIH Action Plan for Muscular Dystrophy was researched, compiled, written, and approved. The NIH is making significant investments to understand muscular dystrophy research needs and has made excellent choices in recruiting program staff with the ability to understand the extremely complex nature of all of the muscular dystrophies.

Between fiscal year 2006 and 2007, NIH overall funding for muscular dystrophy increased from \$39,913,000 to \$47,179,000, an 18 percent increase. Figures from the NIH Appropriations History for Muscular Dystrophy show that from the inception of the MD CARE Act 2001 funding has doubled for muscular dystrophy.

Between fiscal year 2006 and 2007, NIH funding for facioscapulohumeral muscular dystrophy (FSHD) increased from \$1,732,655 to \$4,108,555. In fiscal 2007, FSHD was 8.7 percent of the total muscular dystrophy funding (\$4.109 million/\$47.179 million).

#### NATIONAL INSTITUTES OF HEALTH (NIH) APPROPRIATIONS HISTORY <sup>1</sup>

[Dollars in millions]

Fiscal year	NIH overall	MD research	FSHD research	FSHD percent of MD
2000 .....	\$17,821	\$12.6	\$0.4	3.0
2001 .....	20,458	21.0	0.5	2.0
2002 .....	23,296	27.6	1.3	5.0
2003 .....	27,067	39.1	1.5	4.0
2004 .....	27,887	38.7	2.2	6.0
2005 .....	28,494	39.5	2.0	5.0
2006 .....	28,587	39,913	1.7	4.0
2007 .....	28,899	47,179	4.109	8.7
2008 .....	<sup>2</sup> 29,230	<sup>2</sup> 47,221	.....	.....

<sup>1</sup> Source.—NIH/OD Budget Office & NIH OCPL.

<sup>2</sup> Estimated.

Facioscapulohumeral muscular dystrophy (FSHD) is the second most prevalent adult muscular dystrophy after myotonic muscular dystrophy (DM). We are very concerned about the wide disparity in funding between the most widely recognized pediatric Duchenne muscular dystrophy (DMD) and the entire group of the other eight types of MD. DMD has exclusive funding from the Centers for Disease Control



(CDC), Department of Defense (DOD) and more than half (>50 percent) of NIH funding for MD. This is astounding considering facioscapulohumeral muscular dystrophy (FSHD) and myotonic dystrophy (DM) are each individually more prevalent than DMD and each received 5 percent and 15 percent respectively of total muscular dystrophy dollars as last reported by the NIH to Congress!

Between 2006 and 2007, the NINDS became the lead institute for funding in MD. Historically, the NIAMS in its mission statement has been primarily responsible for and has been the lead institute for muscle disease research. The Center for Scientific Review (CSR) routes the majority of MD grant applications to NIAMS based on its mission. In fiscal year 2007, NIAMS was the second largest contributor, followed by the National Institute of Child Health and Human Development (NICHD) as third, and the National Heart, Lung and Blood Institute (NHLBI) as fourth. It should be troubling that muscular dystrophy spending has declined significantly in several key institutes that could bring tremendous impact to these devastating diseases.

NATIONAL INSTITUTES OF HEALTH (NIH) MUSCULAR DYSTROPHY FUNDING BY INSTITUTE—FISCAL YEAR 2007<sup>1</sup>

[Dollars in millions]

Participating ICs	Fiscal year		Percent change
	2006 actual	2007 actual	
NINDS .....	\$12.697	\$19.347	+ 51.6
NIAMS .....	16.576	17.734	+ 7
NICHD .....	4.818	4.591	– 4.7
NHLBI .....	2.270	2.458	+ 8.3
NIA .....	1.865	1.882	+ 0.9
NCRR .....	0.770	0.679	– 11.8
NCI .....	0.495	0.426	– 13.9
NHGRI .....	0.391	0.161	– 58.8
NINR .....	0.031	.....	.....
NEI, NIMH, FIC, OD .....	.....	.....	.....

<sup>1</sup> Source.—NIH/OD budget office.

**NINDS.**—In fiscal year 2007, NINDS spent \$2,612,994 on FSHD and \$19,247,940 on MD. 47 projects, including Wellstone CRC components for a total of \$19,247,940 were funded. FSHD was 13.6 percent of NINDS MD funding. The NINDS funded, for FSHD, three research grants, one research fellowship, one research contract, one-quarter of a Wellstone MDCRC center and one-half of a Translational Research Center research grant for a total of six projects. NINDS funding for FSHD went up by \$1,191,398 or 83.8 percent. Total funding for MD by NINDS increased over the year by \$6,551,266 or 51.6 percent.

**NIAMS.**—In fiscal year 2007, NIAMS spent \$1,495,561 on FSHD and \$17,734,317 on MD. This comprises 89 projects, including Wellstone MDCRC components for a total of \$17,734,317. FSHD was 8.4 percent of NIAMS MD funding. The NIAMS funded, for FSHD, four research grants, one research contract, 2 percent of a Translational Research Center for a total of six projects. NIAMS funding for FSHD went up by \$1,184,502 or 381 percent. Total funding for MD by NIAMS increased over the year by \$1,158,000 or 7 percent.

**NICHD.**—In fiscal year 2007, NICHD spent \$0 on FSHD and of \$4,591,826 on all MD. 17 projects, including three Wellstone MDCRC centers were funded. FSHD was zero percent of NICHD MD. Total funding for FSHD by NICHD was \$0. Total funding for MD by NICHD decreased over the previous year by \$225,756 or 4.7 percent.

**NHLBI.**—In fiscal year 2007, NHLBI spent \$0 on FSHD and \$2.458 million on MD. FSHD was zero percent of NHLBI fiscal year 2007 MD funding. Total funding for FSHD by NHLBI remained at zero dollars. This should be of grave concern as respiratory insufficiency and failure is becoming increasingly recognized as a cause of poor quality of life and, even more significantly, of death in FSHD.

The MD CARE Act 2001 mandates the Director to intensify efforts and research in the muscular dystrophies, including FSHD, across the entire NIH. It should be very concerning that only two of the institutes at the NIH are funding FSHD. NICHD, NHLBI, NHGRI, NCI and NCRR are all aware of the high impact each could have on FSHD. FSHD is certainly still far behind when we look at the breadth of research coverage NIH-wide.

*Centers of Excellence.*—Wellstone MD Cooperative Research Centers (MDCRCs, U54s) are mandated by the MD CARE Act 2001 and, to date, have not been established to cover each of the nine types of MD. There is an inequitable distribution of research in each of the muscular dystrophies across the Wellstone centers with almost two-thirds of the entire center network, four out of six centers, focusing on DMD. FSHD has about a five (5) percent share of the entire current Wellstone centers portfolio. Today, the NIH has six Wellstone centers, but they have almost no presence for FSHD, and nothing at all for related dystrophies such as Emery-Dreifuss Muscular Dystrophy (EDMD) and Oculopharyngeal muscular dystrophy (OPMD).

I am here once again to remind you that FSH muscular dystrophy (FSHD) is taking its toll on your citizens. FSHD illustrates the disparity in funding across the muscular dystrophies and recalcitrance in growth over 20 years despite consistent pressure from appropriations language and Appropriations Committee questions, and an authorization from Congress mandating research on FSHD.

We implore the Congress to resume the doubling of NIH funding every 5 years. Under the current budget, research funding percentiles have reached the top tenth percentile and higher. With funding pay lines at 10 percent, plus or minus a few percent, excellent research proposals are going unfunded. We request that the Appropriations Committee act now to restore the lifeline to biomedical research in the United States to avoid an accelerated loss of researchers and clinicians.

We request that \$80 million to \$125 million annually be appropriated for muscular dystrophy. We all know that for a disease area to grow—grant applications must be received and grant applications must be funded. The majority of growth in any disease area at the NIH is obtained through unsolicited applications. In the widest sense, in order for NIH to increase the MD portfolio across the missions of applicable and participating institutes more funding is needed for the NIH. We request the Appropriations Committee help increase the number of unsolicited FSHD and MD grants awarded by lowering the pay lines with an increase in the overall pool of funds NIH works with.

We have learned from experience that the FSH Society as a volunteer health agency and the patients it represents serves a vital function in developing research. We develop an area of research to a point where the NIH can then push the research to much greater heights. The FSH Society has invested over \$2 million in the last 9 years into nearly 70 post-doctoral and research fellowships and grants. In the last 2 years, our understanding of how FSHD mechanistically works has dramatically increased. This, in turn, allows researchers to fill the gaps between mechanistic knowledge to translational research to clinical trials. This knowledge has dramatically increased thanks to the efforts of patients, the FSH Society, researchers, clinicians and the NIH. Investments from small non-profits like the FSH Society have allowed the global funding and initiation of novel challenging and promising research in FSHD. Two of the three research projects funded by NINDS are past FSH Society research fellows (5-R01-NS048859-04 M. Ehrlich, 5-R01-NS047584-05 R.G. Tupler). Three of the four research projects funded by NIAMS are past FSH Society research fellows (1-R01-AR-52027-01-A2 Y.W. Chen, 1-R01-AR-56129-01-A2 R.G. Tupler, 1-R21-AR-55876-01 S. van der Maarel) and the fourth project came from FSH Society patient networking activities (1-R01-AR-55877-01 Public Law Jones).

We request that the Director of the NIH be more proactive in facilitating both unsolicited and solicited grant applications on facioscapulohumeral muscular dystrophy, facioscapulohumeral disease, FSH muscular dystrophy and FSHD 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.

Thanks to your efforts and the efforts of your Committee, Mr. Chairman and Mr. Harkin, the Congress, the NIH and the FSH Society are all working to promote progress in facioscapulohumeral muscular dystrophy research. We are pleased to see FSHD funding from the NIH and Federal research agencies gaining traction. FSHD funding is just now beginning to grow. Our successes are just beginning and your continued support is crucial.

We ask you to fund biomedical research, fund the National Institutes of Health (NIH), fund muscular dystrophy (MD) research, and fund facioscapulohumeral muscular dystrophy (FSHD) research.

Mr. Chairman, thank you for this opportunity to testify before your committee.

## PREPARED STATEMENT OF FAMILIES USA

Families USA wishes to thank the subcommittee for the opportunity to submit this written testimony concerning federal funding for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). This statement highlights the importance of the medical research that is conducted and supported by NIH and the CDC in addressing global health problems, especially infectious disease pandemics.

Since 1982, Families USA has advocated for U.S. policies that increase access to affordable health care for all Americans. Recognizing that international health affects domestic health, and that research conducted by the United States can provide tremendous help to people around the world, Families USA launched its Global Health Initiative 2 years ago. The Global Health Initiative advocates for increased U.S. investment in research and development of medical interventions for infectious diseases that disproportionately affect low-income countries.

The drug industry has little interest in investing in diseases that predominantly affect low-income countries because there is little potential for profit. It is in our nation's self-interest to fill the current funding gap and provide the needed resources so that our agencies and institutes can continue to conduct necessary global health research.

## RESEARCH: A CRUCIAL TOOL FOR IMPROVING GLOBAL HEALTH

Turning the tide against complicated, deadly infectious disease pandemics such as HIV/AIDS, tuberculosis (TB), and malaria requires a comprehensive, multifaceted strategy. Research needs to be the cornerstone of any such strategy. Research is the only way to identify and develop new medical interventions to diagnose, prevent, and treat disease. To make progress in United States and global health, research is absolutely crucial.

Research that yields new and improved medical interventions will also increase the effectiveness of U.S. global aid programs that are already in place, such as the President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative (PMI), and the Global Fund to Fight AIDS, TB, and Malaria.

The National Institute of Allergy and Infectious Diseases (NIAID) has taken a leadership role in conducting the bulk of the global health research and development activities that are undertaken at NIH. Robust funding for NIAID is essential for addressing infectious disease crises around the globe and in the United States.

The Fogarty International Center ("Fogarty"), which is also part of NIH, plays a crucial role in addressing global health challenges by facilitating collaboration between United States and international researchers through its international training and global health research capacity building programs. Fogarty's programs facilitate the development of medical discoveries worldwide.

The CDC's global health programs are also vitally important to protecting Americans and people around the world from disease. Cuts to the CDC's budget undermine both the United States and the global public health infrastructures that are crucial to rapidly responding to new disease outbreaks and combating existing global pandemics. Yet, some of the CDC's global health programs have been flat-funded for years, and other global health programs can no longer carry out their critical mission due to limited funds.

## GLOBAL HEALTH RESEARCH MATTERS TO OUR NATIONAL INTERESTS

*Economic Interests.*—Many universities across the United States receive global health research funding from NIH and the CDC. This influx of cash spurs local economies. Moreover, in regions around the globe where disease prevalence is greatest, workforces suffer from substantially reduced productivity, and economic growth is hindered. In today's globalized economy, our economic health is intertwined with the economies of other nations.

*Health Interests.*—The SARS outbreak that happened in Canada a few years ago, and the 2007 incident involving an American traveling internationally with multi-drug resistant TB, make it all too clear that infectious diseases abroad pose a substantial threat to the United States. We desperately need new tools to combat these and other deadly diseases.

*National Security and Political Interests.*—In areas of the world where the infectious disease burden is greatest, the social structure of entire countries has been unraveling, paving the way for political unrest and undermining democracy in many regions of the world. To reverse this trend, we must give NIH and the CDC the resources they need to make progress in global health.

*Diplomatic Interests.*—We have a national diplomatic interest in funding global health research: As the wealthiest country on earth, we have the means to advance health and alleviate human suffering. Using our wealth to improve global health improves America's image and is an effective foreign policy tool.

*Humanitarian Interests.*—As a Nation of plenty and the leader of the free world, it is unconscionable for us to turn a blind eye to the plight of the vast majority of humankind.

The number of people impacted by infectious diseases is staggering:

- One billion people are affected by, and many millions are left permanently disabled by, neglected tropical diseases that you may never have heard of—infectious diseases that are found mainly in low-income tropical and subtropical regions. Examples include Chagas disease and leishmaniasis.
- There are about 350 to 500 million cases of malaria each year, and malaria kills 18 percent of children under age 5 in sub-Saharan Africa.
- Currently, 33 million people around the world have HIV/AIDS.
- Tuberculosis (TB) infects people worldwide: One-third of the planet has latent TB and is at risk of developing active TB. The risk of developing active TB is heightened in those with HIV/AIDS and those suffering from malnutrition.

#### HOW MUCH FUNDING IS NEEDED?

##### *NIH—Total Budget*

NIH needs a 6.7 percent increase above its fiscal year 2008 funding level across all institutes, centers, and offices, for a total budget of \$31.1 billion in fiscal year 2009.

Families USA's Global Health Initiative recommends a 6.7 percent increase in funding for fiscal year 2009 across all of NIH. This includes a 3.7 percent increase to keep pace with the projected rise in inflation from 2008 to 2009, plus an additional 3.0 percent to begin correcting for the historic underfunding of NIH (in recent years, the NIH budget has not kept pace with inflation).

##### *NIH—Global Health Programs*

NIAID needs an increase of \$83.1 million above its fiscal year 2008 funding level, on top of the overall NIH increase of 6.7 percent, for a total budget of \$5 billion in fiscal year 2009.

We determined the necessary funding level for NIAID by examining worldwide research needs for HIV/AIDS vaccines and microbicides, malaria, TB, and neglected tropical diseases. These research needs are based on the assessments of numerous organizations, for example, the Global Network for NTD Control, AVAC, IAVI, UNAIDS, the Alliance for Microbicide Development, Roll Back Malaria, WHO, and the Stop TB Partnership.

To fully address research needs in these areas (while maintaining the agency's current share of the world's public-sector spending), NIAID would need \$582 million more than it is currently budgeted (on top of the overall NIH adjustment of 6.7 percent). To implement this increase in a fiscally responsible time frame, our calculations spread the \$582 million increase over 7 years, yielding \$83.1 million per year.

The Fogarty International Center needs an increase of \$2.4 million above its fiscal year 2008 funding level, on top of the overall NIH increase of 6.7 percent, for a total budget of \$74 million in fiscal year 2009.

To make progress in combating diseases such as HIV/AIDS, TB, and malaria, Fogarty would need a 25 percent increase above its 2008 funding level. As with the recommended adjustment for NIAID, the adjustment for Fogarty would also be spread over 7 years. In 2009, this would amount to an additional \$2.4 million for Fogarty (on top of the overall NIH adjustment of 6.7 percent), or \$74.6 million in total funding.

##### *The CDC's Global Health Programs*

The CDC's global health programs need a \$35.5 million increase above their fiscal year 2008 funding levels, for a total budget of \$337.9 million in fiscal year 2009 (this excludes funds for pandemic flu preparedness).

As with NIH, CDC funding has been shortchanged for many years, especially funding for its global health programs. This places the Nation's and the World's health at risk.

Our assessment of gaps in the CDC's current funding and our evaluation of its prior funding indicate that CDC's global health programs need \$142 million more than they have right now, separate and apart from any funding for pandemic flu preparedness. However, we understand that the realities of the current fiscal environment will likely necessitate implementation of any funding increases over multiple years. Therefore, we recommend that funding for the CDC's global health pro-

grams be increased by a total of \$142 million over 4 years, updated annually thereafter for inflation. This amounts to \$337.9 million in fiscal year 2009, which is a \$35.5 million increase above fiscal year 2008 funding.

#### CALL FOR ACTION

People across the United States and throughout the world are looking to NIH and the CDC for new medical advances that will lead to a healthier tomorrow. Short-changing NIH and the CDC places everyone's health at risk. We urge the Subcommittee to fund NIH and the CDC at the levels specified above.

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#### PREPARED STATEMENT OF THE FRIENDS OF CDC

Chairman Harkin, ranking member Specter, and members of the subcommittee, thank you for the opportunity to submit testimony on behalf of the Friends of CDC to discuss infrastructure funding for the Centers for Disease Control and Prevention (CDC) in the fiscal year 2009 budget. My name is Oz Nelson, and I am the Retired Chair and CEO of United Parcel Service and the Co-Chair of the Friends of CDC.

I would like to begin my testimony by offering sincere thanks on behalf of the Friends of CDC for the efforts of the subcommittee in securing funding for CDC Buildings and Facilities in the fiscal year 2008 Labor, Health and Human Services Appropriations bill. We are extremely grateful for your commitment to this important effort.

Before I tell you more about the condition of the CDC and the need for continued Congressional action, I would like to tell you why I am involved in this effort and about the Friends of CDC. Following a 1999 CEO tour of several of CDC's totally inadequate labs and office facilities, the Corporate Friends of CDC was organized for the sole purpose of highlighting the need for infrastructure funding for the Centers for Disease Control at its two Atlanta-based campuses. This group currently includes AT&T, United Parcel Service, GE Power Systems, The Home Depot, Inc., Cox Enterprises, Inc, Southern Company, Theragenics Corporation, and HCA. It is a voluntary, civic minded group deeply concerned that the facilities at the nation's premier public health institution could be allowed to deteriorate to the point they were when this endeavor began.

Since their formation in 1999, the Friends have advocated with officials at CDC, HHS, OMB and Congress for full and timely funding of the CDC Buildings and Facilities Master Plan. During the last 8 years Congress has appropriated \$1.4 billion towards the Master Plan, resulting in an historic and far-reaching construction project that has changed the face of CDC. But the job is not yet complete. The total cost of the Master Plan is \$1.7 billion and to that end we are requesting \$250 million in the fiscal year 2009 budget for improving CDC buildings and facilities.

As you know, the range of CDC's assignments has grown tremendously over the past decade. The CDC is on the front lines of defense protecting the health of every American because of its ability to identify, classify, and recommend courses of action in dealing with a potential biological, radiological, or chemical attack in the United States or around the world. This being said, several of the CDC facilities still do not offer a sufficient level of security or an adequate support structure to CDC's scientists.

Since CDC began executing the Master Plan, a series of threats to the nation's health and security have emerged, ranging from terrorist attacks, to the rapid spread of the West Nile Virus, to the emergence of SARS, Avian Flu, Marburg Virus, and monkeypox. These threats continue to challenge CDC's capacity and plainly illustrate the need for additional funding to accelerate the CDC's Master Plan and enable the CDC to be better prepared and capable of responding to the range of public emergencies which the United States is likely to face in the coming years.

In addition to infectious diseases, CDC works on preventing chronic diseases such as cardiovascular disease, cancer, and diabetes. Other areas of CDC's activities include maximizing the immunization rates of children and adults; preventing a wide range of environmental diseases by preventing exposure to toxic chemicals; conducting examinations and surveys to produce data on the health of Americans; preventing and controlling injuries; protecting employees from workplace injuries and diseases; and the training of public health and other health care workers throughout the country.

Thanks to your support, CDC is making substantial progress in implementing the 10-Year Master Plan for buildings and facilities for the Atlanta-based portion of the Centers for Disease Control and Prevention. In addition, progress has been made on both the Edward R. Roybal Campus near Emory University and the Chamblee

Campus in construction of new labs and support buildings, upgrades to physical security, and upgrades to vital campus infrastructure such as electrical power and water.

The remaining funds needed by CDC to complete the Master Plan would be devoted to the following projects. CDC has entered into the planning phase for the construction of Buildings 24, 107, and 108. These Research Support Facilities will play an important role in allowing the CDC to accomplish its goal of providing adequate facilities for its workforce. As a result of these capital improvements, the agency will be better equipped to achieve its overarching goal of protecting the nation's public health.

Building 24, which will be located on the CDC's Roybal Campus, will be occupied by non-laboratory staff from the CDC's Coordinating Center for Infectious Diseases (CCID). With a cost of approximately \$134 million, of which \$63 million has been appropriated to date, this facility will primarily consist of office space for 1,100 occupants. Additionally, this facility will replace existing non-laboratory space currently being utilized by CCID staff on the Roybal Campus.

Buildings 107 and 108 will be located on the CDC's Chamblee Campus and be occupied by staff from the Coordinating Center for Health Promotion (CoCHP), which includes the National Center for Birth Defects and Developmental Disabilities (NCBDDD), the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), and the Office of Genomics and Disease Prevention. With a similar design to the Environmental Health Facility (Building 106), these research support facilities will cost approximately \$254 million to complete (\$127 million for each). No money has been appropriated to date for these buildings. When completed, the buildings will also house approximately 2,200 occupants, all of which are currently located in leased office space. This is critically important in allowing the agency to successfully consolidate many of its staff members from leased space into secure, CDC-owned facilities.

The investment in these facilities is critical to assuring that CDC scientists are physically and logistically equipped to protect our businesses and our families from the growing threats of terrorism and emerging diseases over the coming decades. The Friends of CDC respectfully request \$250 million in fiscal year 2009 to insure that the CDC is better prepared to face its current and prospective public health challenges.

Thank you for the opportunity to submit testimony on behalf of the Friends of CDC.

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#### PREPARED STATEMENT OF FRIENDS OF THE NATIONAL INSTITUTE ON AGING

Chairman Harkin and members of the subcommittee, thank you for the opportunity to submit testimony on the important role that the National Institute on Aging (NIA) plays among the National Institutes of Health (NIH) and the urgent need for increased appropriations to advance research supported by the 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. 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 guided by the Institute. Our testimony highlights recent advances resulting from NIA funding, as well as negative consequences that could occur if Congress does not provide sufficient appropriations for NIA research and training activities in fiscal year 2009.

As you know, the NIA leads national research efforts to better understand the nature of aging and to maintain the health and independence of Americans as they grow older. NIA's mission is to support and conduct a range of genetic, biological, clinical, social and economic research related to aging processes and diseases of the aged. One area where this mission is clearly reflected is in the research efforts of NIA investigators aimed at extending an individual's years of healthy life. Projects focused on achieving this goal include studies assessing the beneficial age-related effects of reducing caloric intake in laboratory animals, as well as the testing of compounds in these subjects with the potential to extend the years of disease-free life. Both approaches have produced promising results in a number of animal species, and may lead to insights into potentially beneficial human applications. By capitalizing on such successful studies and the identification of genes that influence longevity, investigators hope to delay the onset of disease and disability associated with human aging.

Many challenges will arise as Americans reach retirement age in increasing numbers. Currently, there are approximately 36 million Americans aged 65 and older.

That group is expected to double in size within the next 25 years, at which time at least 20 percent of the U.S. population will be older than 65. Of particular concern is the dramatic growth that is anticipated among those age 85 and over. By 2050, 19.4 million Americans will be over the age of 85. If rapid discoveries are not made now to reduce the prevalence of debilitating age-related disorders, the health-related costs associated with caring for the oldest and sickest Americans will place an unmanageable burden on patients, their families, and our fragile health care system. However, with proper investment further advances in the area of longevity science could yield tremendous health and economic benefits by shortening the period during which humans suffer from costly, debilitating diseases.

The single largest driver of healthcare costs in the United States is Alzheimer's disease. The NIA has been a leader in basic, translational, and clinical research focused on facilitating early diagnosis of Alzheimer's disease and developing more effective therapies and strategies for Alzheimer's prevention. NIA-supported research in this area remains focused on efforts to speed delivery of novel Alzheimer's therapies to patients. In fiscal year 2009 the NIA will continue its pre-clinical drug development program and pilot trials initiative, along with a cooperative agreement to conduct new clinical trials through the Alzheimer's Disease Cooperative Study. In addition, the NIA will advance work under the Alzheimer's Disease Neuroimaging Initiative (ADNI), which has provided necessary neuroimaging tools to view disease processes and assist researchers in developing and monitoring emerging treatments. NIA will also continue the Alzheimer's Disease Genetics Initiative (GI), which was established to identify the genes that contribute to the most common form of AD, late-onset. The need for progress in these areas becomes ever more important as the extraordinary costs to patients and families continue to grow.

Medicare spending on beneficiaries with Alzheimer's climbs steadily, reaching more than \$189 billion over the next decade. Adequate sustained resources must be provided in order for these programs to one day provide relief to the 5.2 million patients and their families currently living with Alzheimer's. If the onset of Alzheimer's could be delayed by 5 years, the projected population that is expected to suffer from the disease could be cut in half. If researchers are successful in achieving a modest delay in the rate of aging, health and economic benefits would be achieved that are greater than what would result from the elimination of cancer or heart disease alone. To achieve these powerful results, meaningful investments in aging research must be made now. Scientists are poised to make breakthroughs in the prevention and treatment of a host of age-associated diseases and conditions, but without sufficient funding for aging research, Americans are unlikely to see these breakthroughs occur during their lifetime.

Healthy longevity and Alzheimer's disease are just two of the NIA's important focus areas. Other promising research efforts supported by the NIA include projects to discover new Parkinson's and neurological disease susceptibility genes; to study the environmental risk-factors and genetic predisposition to obesity; and to uncover how the interplay between neurons and inflammatory immune cells can be harnessed to improve stroke outcomes. All of these conditions are prevalent among older adults and take a tremendous toll in health costs and lost quality of life.

Other work of critical importance conducted and funded by the NIA is in the area of behavioral and social science research. The NIA's behavioral and social science research programs have been instrumental in providing essential data on the socioeconomic and demographic implications of an aging population. These data are used by policymakers at all levels of government, including, at the Federal level, the Social Security Administration, Centers for Medicare and Medicaid Services, and Department of State, to inform the development and evaluation of public policy. Much of the productivity of the BSR program is attributable to researchers supported via its network of research centers, such as the Demography of Aging Centers, Roybal Centers for Applied Gerontology and Resource Centers for Minority Aging Research. The BSR program also supports large, accessible datasets utilized by scientists worldwide. One of the largest datasets, the Health and Retirement Study (HRS), is the leading source of combined data on health and financial circumstances of Americans over age 50 and a valuable resource to follow and predict trends for an aging America. NIA also partners with the U.S. Census Bureau on joint demographic studies of the elderly population and the Federal Forum on Aging, which is composed of 13 Federal departments and agencies, and collects, provides, and analyzes aging-related data. Data from these surveys are particularly important for understanding the budgetary impact of population aging. They also help Congress in budgetary considerations of population aging as it deliberates potential changes to public programs such as Social Security, Medicare, and Medicaid. With consistent funding, these surveys can continue to be seminal sources of information on the health and socioeconomic status of older Americans.

In the area of geriatrics and clinical gerontology, the NIA's work this year will be centered on reducing disease and disability among older people. This is critically important because the United States spends approximately \$26 billion per year on Medicare beneficiaries who lose the ability to remain fully independent. As individuals age, their risk for suffering from many diseases and disabling conditions increases dramatically. NIA's Geriatrics and Clinical Gerontology (GCG) Program examines age-related physical changes and their relationship to health outcomes, the maintenance of health and the development of disease, and specific age-related risk factors for disease. In fiscal year 2009 the NIA plans to initiate studies to determine why the elderly develop dangerous blood clots in their veins and arteries; to continue research increasing understanding of the unidentifiable causes of anemia in the elderly; and to conduct studies in nutrition, weight loss and exercise to measure their role in preventing age-related diseases like heart disease and certain cancers.

Since the end of the NIH's budget doubling in 2003, funding has been on a downward trajectory and many of the areas of research mentioned earlier have been impacted despite prioritization by the NIA. In the 5 years through 2008, a series of nominal increases and cuts has amounted to flat funding for NIH, and as a result it has lost approximately 11 percent in purchasing power due to inflation alone. For the NIA specifically, flat budgets are to blame for a 12.9 percent reduction in constant dollars for the Institute between fiscal year 2003 and fiscal year 2009. To operate in this environment the NIA and other institutes have not been able to fund increasing numbers of high-quality research grants each year. Those that are funded are subject to cost containment policies that decrease the funding level of new grants and reduce the funding level of existing grants. The NIA in particular must implement an 18 percent cut on average in recommended funding for individual competing grants.

NIH is the primary funder of biomedical research in this country. Approximately 85 percent of its budget goes to support investigators at universities and medical centers across the United States. But declining budgets are impeding progress. Because of a scarcity of resources, the overall success rate for NIH research grant applications has fallen from 32 percent to 24 percent since 1999. This means that only one in four research proposals can be funded by the NIH and fewer of them are funded on the first submission. The effect of this has been reluctance on behalf of new investigators to submit truly ground-breaking research proposals for consideration. While we recognize that there is enormous competition for Congressional appropriations each year, we believe that a continued slowdown in funding for the NIH will have a devastating impact on the rate of basic discovery and the development of interventions that could have the significant public health benefits for our aging population.

The Friends of the NIA supports a 6.6 percent increase in funding to \$31.1 billion for the NIH in fiscal year 2009. Such an increase would prevent the estimated 3.6 percent loss that the NIH will experience this year without an inflationary increase. This increase would begin to restore the NIH's ability to pursue new basic, translational, and clinical research opportunities. The \$31.1 billion would also allow the National Institute on Aging specifically to increase support of new and existing investigator initiated research projects and better facilitate the acceleration of discoveries to prevent, treat, and potentially cure a wide range debilitating age-related diseases and conditions among our growing population of older Americans.

Mr. Chairman, the Friends of the NIA thanks you for this opportunity to outline the challenges and opportunities that lie ahead as you consider the fiscal year 2009 appropriations for the NIH and we would be happy to furnish additional information upon request.

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PREPARED STATEMENT OF FRIENDS OF THE NATIONAL INSTITUTE FOR DENTAL AND CRANIOFACIAL RESEARCH

Chairman Harkin and distinguished Members of the Committee, the members of the Friends of the National Institute of Dental and Craniofacial Research (FNIDCR), a leading coalition of individuals, corporations, and institutions that understands the importance of dental, oral, and craniofacial health to our society, are requesting that fiscal year 2009 funding for the National Institute of Dental and Craniofacial Research (NIDCR) be appropriated at our recommended level of \$438 million, which is 1.5 percent of the total budget for the National Institutes of Health (NIH).

As it stands, the president's recommended level of fiscal year 2009 funding for NIDCR, \$390,535,000, is woefully inadequate and it is \$6 million below fiscal year 2008 funding that Congress passed last year. Moreover, it represents only 1.33 per-



cent of NIH's total budget. In fact, as NIH's budget doubled between 1998 and 2003, NIDCR's total budget decreased 13 percent. Since 2003, NIDCR funding has essentially flat-lined.<sup>1</sup>

#### NIDCR: A RENOWN LEADER IN RESEARCH

For 60 years, NIDCR has been the leading sponsor of research and research training in biomedical and behavioral sciences. Its mission is to "improve oral, dental and craniofacial health through research, research training, and the dissemination of health information."

NIDCR meets its mission by:

- Performing and supporting basic and clinical research;
- Conducting and funding research training and career development programs to ensure an adequate number of talented, well-prepared and diverse investigators is sustained;
- Coordinating and assisting relevant research and research-related activities among all sectors of the research community; and
- Promoting the timely transfer of knowledge gained from research and its implications to health professionals, researchers, and policy-makers; and on the overall well-being of our society.

#### NIDCR RESEARCH BENEFITS SOCIETY

Proper federal funding of NIDCR will transform the future of medical and dental practice to the benefit of our society and ease the burden on our nation's healthcare system. Examples of where NIDCR research has benefited, and will continue to benefit, society are:

*Tooth Decay.*—Fluorides and sealants have cut the rate of the number of American adults, aged 45 and older, who are without teeth by more than half since 1950s.

*Oral Cancer Detection.*—Twenty-two Americans die each day from oral cancer, and 39,000 people develop it every year. Survival rates are among the lowest of all the major cancers. It is difficult to detect and hard to predict its outcome.

NIDCR-supported research has yielded initial success with developing a fully-automated, all-in-one test device that can alert dentists if oral cancer is in the early stages of development in a patient. The portable device, which probes cells brushed from the mouth for a common sign of oral cancer, yields results in under ten minutes. Currently, a painful tissue biopsy is the method used to detect oral cancer and the results take days; not minutes.

*Salivary Diagnostics.*—The promising prospect of using saliva as a diagnostic fluid to identify an emerging disease is an example of the type of cutting-edge research being conducted and supported by NIDCR. Salivary Diagnostics possesses advantages over traditional blood testing, including the absence of needles and the ability to be administered on-the-spot.

*Genome-wide Association Studies.*—NIDCR is supporting the first genome-wide association studies on cleft lip/cleft palate and dental carries. This is being done in collaboration between epidemiologists, geneticists, informatics experts, and environmental scientists. The studies offer significant potential for understanding the molecular and genetic basis of cleft lip/cleft palate and dental carries with the goal of improving the ability to predict and manage them.

Moreover, NIDCR research benefits millions of Americans with:

- Periodontal Disease
- Chronic Dry Mouth
- Chronic Facial and Oral Pain, and
- Bone and Cartilage Regeneration

All of these diseases and ailments lead to two million hospitalizations and 100,000 deaths annually at a cost of \$100 billion to our nation's healthcare system.

#### Oral Health Disparities Centers

Finally, through community-based disparities research funded by NIDCR, a difference is being made in meeting the health needs of our nation's low-income, underserved, and high-risk populations. Sadly, this need was made apparent with the tragic passing of 12-year-old Deamonte Driver who died from a tooth infection in 2007.

NIDCR is committed to eventually eliminating oral health disparities by planning to fund Centers to Reduce Oral Health Disparities this summer. The Centers will

<sup>1</sup> American Dental Education Association.

continue to perform interventions to determine the best methods for preventing oral disease and applying research findings in communities with health disparities.

#### RECOMMENDATION

Simply stated, proper funding of the National Institute for Dental and Craniofacial Research is essential to the overall health and well-being of our fellow Americans. Moreover, we firmly contend that medical discoveries and advances from NIDCR funding lead to improvements in dental practices and change the scope of public health policies across the nation. Whether it is detecting a clear link between bacteria in the mouth and heart disease—or discovering how saliva can be used as an indicator of how healthy a human being is—we all benefit when we make oral health research a priority.

Therefore, based upon the merits of the research conducted by NIDCR, we respectfully request the Subcommittee to fund NIDCR at \$438 million, or 1.5 percent of the total NIH budget, so that it can realize the full potential of its worthy mission.

Thank you for the opportunity to present our written testimony before the Subcommittee.

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#### PREPARED STATEMENT OF PATRICIA S. HARRISON

On behalf of our country's public broadcasting system, I want to thank Chairman Tom Harkin and ranking member Arlen Specter for allowing me to submit this written testimony in support of the Corporation for Public Broadcasting's (CPB) fiscal year 2009 appropriations requests.

Mr. Chairman and members of the subcommittee, it is no secret that the media landscape is changing at a rapid pace. Public broadcasting, or what we now like to call "public service media," was established 40 years ago as a change agent, focused on providing "programs and services which inform, enlighten and enrich the public" as an antidote to what former Federal Communications Commission Chairman Newton Minow referred to as the "vast wasteland." Today, the wasteland remains in a much larger and ever-evolving scale, but the good news is so does our mission. What remains evergreen, in the midst of this rapid change, is public service media's authenticity and our connection to our audience, a connection that has been there from the beginning. That is why our traditional broadcast platforms continue to serve millions of people each week with the high quality content we are known for. At the same time, we have a long track record of supporting innovative efforts to use digital media in even more creative ways to respond to community needs. This new landscape can also facilitate a renewed partnership with the American people, reaching diverse audiences and learning from them.

Public media's commitment to education is historic and continues today preparing children from low income families to succeed in school. Ninety seven percent of the nation's public television stations are utilizing new media applications to deliver educational services to their communities. Through Ready to Learn, children are being prepared to learn before they begin kindergarten. This year, Reading is Fundamental (RIF) honored Iowa Public Television and KUED-TV (Salt Lake) as two of 25 Programs of Excellence. Each year RIF honors projects for successfully partnering with outside organizations to advance children's literacy in their communities. The 25 were selected from approximately 3,500 RIF programs nationwide.

We are preparing children to learn and measuring the results. In communities throughout the country, stations like Maryland Public Television are providing summer reading camps where children experience that learning can be fun. And educating does not stop at primary school. Vegas PBS Virtual High School launched in 1996, by request of the local Clark County School District (CCSD), to help lower their 9 percent dropout rate. In the first year 238 students enrolled in the four "most failed" high school courses. As of 2007 the program expanded to include a catalog of 60 courses offered via VHS, DVD, on demand broadband and live interactive Internet offerings. In the last 3 years, between 5,000 and 7,000 were served. In 2005, a parallel program offering online Advanced Placement courses was joined with the Vegas PBS offerings to create the CCSD Virtual High School. Last year all but one of the 38 comprehensive 4 year high schools in Clark County (the nation's 5th largest school district) had between one and 22 graduates who received their degree as a result of taking two or more Virtual High School classes. Further, our community focused stations are dealing with other issues that impact at a local level, whether the issue is healthcare or help for children with disabilities. Because of a KETC-TV (St. Louis) health initiative, viewers learned about the danger of high blood pressure and the need to get regular screening. A Head Start childcare

provider credits this program and the outreach beyond the broadcast with saving her life.

Many stations are taking a page from Ideastream, a joint venture between public television and radio in Cleveland, Ohio, which is leading the way in a coalition of concerned organizations and corporate partners to reverse the decline in science, technology, engineering and math (STEM) achievement of students in the state. Another STEM Collaborative—including Maryland Public Television, Alabama Public Television, Arkansas Public Television, and Kentucky Public Television—is working to build a library of digital education material for middle school math students that will be useful to middle school students in those states and across the country.

As President and CEO of CPB, I have seen firsthand how public service media is filling an important need on behalf of America's teachers, children, families and communities. We serve as a vital community connector and in some states, a lifeline on issues impacting our families, our children's education and safety, our health and environment. At a time of great economic uncertainty, we are there helping beyond the broadcast with tangible help. In this important election year, stations are serving as a reliable and trusted source for information. Throughout 2008, for example, Wisconsin Public Television and Wisconsin Public Radio have joined to provide that state's citizens with programming related to local and national elections. In addition, a one-stop voter information website, [wisconsinvote.org](http://wisconsinvote.org), launched in January 2008, is the centerpiece of Wisconsin public broadcasting's efforts.

In our ongoing conversation with the American people we are asking them how we can serve them even better as our society continues to deal with new challenges. And they are responding through the first ever public awareness initiative, telling us how public media serves as their "source" throughout the year for news beyond a soundbite, for opportunities for their children and for help in times of national emergency.

Station facilities are increasingly serving as community centers, where partnerships with other organizations are fostered to help youth or seniors, or address an issue impacting the community. Further, thousands of hours of community service programming, including millions of dollars of investment in education are directly employed at a local level to make a difference. Public media, on air and online, through content that matters, is a national treasure—a treasure that has a real and lasting impact on American families.

Accordingly, with the support of the public broadcasting system, CPB has begun to invest in public broadcasting stations' essential—but not widely known—work in communities across America to increase recognition of public broadcasting as a valuable resource that informs, enlightens and enriches public life. In fiscal year 2008, through this public awareness initiative, we are working with stations to develop models of community engagement that will increase the public's understanding of the role of public broadcasting stations in their communities.

However, if public media is going to continue to deliver on its promise to serve the American people, to treat them as citizens and not just as consumers, and to provide a safe place where children can learn, a continued and increased federal investment in this national treasure is essential. American public service media is a collection of over 1,150 locally-owned television and radio stations that deliver free, universally available, non-commercial, high quality programming and services to communities throughout the country. Each week, more than 80 million Americans view public television and more than 27 million listen to public radio for programming that covers public affairs, science, history and the arts. Many others access our rich array of web sites, classroom media, activity guides for parents and caregivers, job training services and GED programs. From a federal investment currently amounting to less than \$2.00 per American a year, public broadcasting leverages \$2.3 billion in programming and services.

#### REQUEST FOR APPROPRIATIONS

CPB requests a \$483 million advance appropriation for fiscal year 2011. This amount represents a 15 percent increase over the \$420 million advance appropriation provided for fiscal year 2010, and comes after several years of flat funding, which has left public broadcasters struggling to serve their communities' existing needs, while simultaneously providing additional services made possible by the digital revolution. CPB has received advance appropriations since the mid-1970's, and we believe this practice remains essential. It ensures the continued existence of a political firewall, protecting public broadcasting's autonomy in programming decisions, and it affords public broadcasters—who raise approximately 84 percent of their revenues from non-federal sources—a key measure of certainty in their business planning.

CPB has been concerned about public broadcasting's uncertain financial picture, caused by both funding shortfalls and the demands of the digital transition. To better understand these challenges, CPB engaged Booz Allen Hamilton to conduct a financial assessment of public broadcasting, looking at current conditions and forecasting financial trends for the fiscal year 2011–2015 timeframe. The assessment projected current trends into the future, and more importantly considered the additional costs of the new services public broadcasters expect to deliver to their communities.

The assessment team examined types and levels of services that public broadcasters will seek to provide to their communities. These included providing additional educational content, increased use of both television and radio multicasting to deliver additional content, increased use of emerging media platforms to reach new users and increased use of news/talk format by radio stations. Booz Allen found that, assuming a current level of service and no increase in CPB's appropriation, the public broadcasting system would see a deficit beginning in fiscal year 2011. This projection does not take into account the opportunity for public broadcasters to further benefit their communities through increased services made possible by digital technology. Booz Allen estimated that these plans would require significant increases in both CPB's appropriation and other funding sources. Together, these total approximately \$3 billion in fiscal year 2011. Although the Public Broadcasting Act of 1967 envisions a greater level of federal support of public broadcasting (up to 40 percent), in recent years the federal contribution through the CPB appropriation has amounted to about 16 percent of public broadcasting revenues. On this basis, we are requesting that the CPB appropriation rise to \$483 million in fiscal year 2011.

As you know, CPB's general appropriation is allocated according to a statutory formula that ensures funds go directly to the people and organizations that create and deliver highly valued programs and services. The Public Broadcasting Act of 1967 directs that over 70 percent of CPB funds go directly to public television and radio stations as community service grants. The Act also directs 6 percent of our appropriation to system support activities such as station interconnection operating grants, music copyright fees, Independent Television Services (ITVS) administration and the Minority Consortia.

In addition to our base appropriation, CPB is requesting \$40 million in fiscal year 2009 for the continuing conversion to digital technology. While 95 percent of television transmitters and 75 percent of radio transmitters have been converted, this is only a part of the challenge. CPB research from Fall 2007 indicates that public television stations will require up to \$90 million in additional funding to complete their primary stations' basic transition to digital and they will also need equipment to participate in the Department of Homeland Security's Digital Emergency Alert System project. In addition, rural television and radio stations will begin converting over 1,600 translators, which relay the primary station signal to remote areas. Both television and radio stations will also need funding for equipment that will allow them to provide programming on multiple streams to take advantage of their digital capacity. Additionally, CPB seeks to further develop the American Archive project, which would digitize, store and make available a treasure trove of public broadcasting content for educational, cultural and entertainment uses.

CPB also requests \$27 million as the second installment of an anticipated three-year \$73 million funding request for the replacement of public radio's interconnection system. CPB is statutorily obligated to provide for the interconnection needs of public broadcasters.

Finally, CPB is requesting \$32 million in fiscal year 2009 for Ready To Learn (RTL), the goal of which is to raise the reading levels of children ages 2–8 who live in high-poverty environments. Ready To Learn is a partnership between CPB, the Public Broadcasting Service (PBS) and the U.S. Department of Education. We are working in collaboration with WGBH (Boston), Sesame Workshop and Out of the Blue Enterprises, leading reading and media researchers and 20 local public broadcasting stations. In 2008, we will launch the new multi-platform children's series: Martha Speaks and in January 2009, The New Electric Company. We also anticipate delivering a new pre-K reading curriculum, expanding the reach of summer reading camp for kids and launching a new website called PBS KIDS Island, [readytolearnreading.org](http://readytolearnreading.org), that will allow parents and caregivers a way to see what their children are learning by offering kids a structured path for reading game play. We will continue to test the effectiveness of RTL resources in 20 target markets that have been selected from throughout the country based on low National Assessment of Educational Progress reading scores, significant populations of children in poverty, and local stations that are proven leaders in delivering quality educational services to their community.

Thank you again for your consideration of these requests. The continued federal investment in this system will ensure that Americans, whatever their age, ethnicity or economic status, will have access to quality television and radio services for themselves and their families. Your investment will ensure that our country's public service media will continue to educate, entertain, and inform, and move us to do more for our communities and country, inspiring us to be citizens, not just consumers.

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#### PREPARED STATEMENT OF THE HEART RHYTHM SOCIETY

The Heart Rhythm Society (HRS) thanks you and the Subcommittee on Labor, Health and Human Services and Education for your past and continued support of the National Institute of Health, and specifically the National Heart, Lung and Blood Institute (NHLBI).

The Heart Rhythm Society, founded in 1979 to address the scarcity of information about the diagnosis and treatment of cardiac arrhythmias, is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. The Heart Rhythm Society serves as an advocate for millions of American citizens from all 50 States, since arrhythmias are the leading cause of heart-disease related deaths. Other, less lethal forms of arrhythmias are even more prevalent, account for 14 percent of all hospitalizations of Medicare beneficiaries.<sup>1</sup> Our mission is to improve the care of patients by promoting research, education and optimal health care policies and standards. We are the preeminent professional group, representing more than 4,200 specialists in cardiac pacing and electrophysiology.

The Heart Rhythm Society recommends the subcommittee renew its commitment to supporting biomedical research in the United States and recommends for fiscal year 2009 Congress provide NIH with \$31.1 billion, a funding increase of 6.5 percent. This translates into an increase of \$3.1 billion for the National Heart, Lung, and Blood Institute. This increase will enable NIH and NHLBI to sustain the level of research that leads to research breakthroughs and improved health outcomes. In particular, the Heart Rhythm Society recommends Congress support research into abnormal rhythms of the heart.

HRS appreciates the actions of Congress to double the budget of the NIH in recent years. The doubling has directly promoted innovations that have improved treatments and cures for a myriad of medical problems facing our nation. Medical research is a long-term process and in order to continue to meet the evolving challenges of improving human health we must not let our commitment wane. Furthermore, NIH research fuels innovation that generates economic growth and preserves our nation's role as a world leader in the biomedical and biotech industries. Healthier citizens are the key to robust economic growth and greater productivity. Economists estimate that improvements in health from 1970 to 2000 were worth \$95 trillion. During the same time period, the United States invested \$200 billion in the NIH. If only 10 percent of the overall health savings resulted from NIH-funded research, our investment in medical research has provided a 50-fold return to the economy.<sup>2</sup>

Unfortunately, since the end of the doubling in 2003, funding for NIH has failed to keep pace with biomedical inflation. As a result 13 percent of NIH's purchasing power has been lost. Because of this NIH has been unable to fully fund existing multi-year grants, thus stalling life-saving discoveries. If these vacillations in funding continue, future generations of researchers will become discouraged from pursuing a career in basic science and laboratories' resources could be strained to the point of forcing lay-offs and even closure.

#### RESEARCH ACCOMPLISHMENTS

In the field of cardiac arrhythmias, NIH-funded research has advanced our ability to treat atrial fibrillation and thus prevent the devastating complications of stroke. Atrial fibrillation is found in about 2.2 million Americans and increases the risk for stroke about 5-fold. About 15–20 percent of strokes occur in people with atrial fibrillation. Stroke is a leading cause of serious, long-term disability in the United States and people who have strokes caused by AF have been reported as 2–3 times more likely to be bedridden compared to those who have strokes from other causes. Each

<sup>1</sup>Heart Rhythm Foundation, Arrhythmia Key Facts, 2004 <http://www.heartrhythmfoundation.org/facts/arrhythmia.asp>.

<sup>2</sup>Murphy, KM and Topel, RH, The Value of Health and Longevity, National Bureau of Economic Research Working Paper Series, Working Paper 11405, June 2005.

year about 700,000 people experience a new or recurrent stroke and in 2002 stroke accounted for more than 1 of every 15 deaths in the United States. Ablation therapy however is providing a cure for individuals whose rapid heart rates had previously incapacitated them, giving them a new lease on life.<sup>3</sup>

Important advances have also been made in identifying patients with heart failure and those who have suffered a heart attack and are at risk for sudden death. The development, through initial NIH-sponsored research, and implantation of sophisticated internal cardioverter defibrillators (ICD's) in such patients has saved the lives of hundreds of thousands and provides peace of mind for families everywhere, including that of Vice-President Cheney's. A new generation of pacemakers and ICDs is restoring the beat of the heart as we grow older, permitting us to lead more normal and productive lives, reducing the burden on our families, communities and the healthcare system. Arrhythmias and sudden death affect all age groups and are not solely diseases of the elderly.

Research advances in molecular genetics have provided us the root basis for life-threatening abnormal rhythms of the heart associated with a wide range of inherited syndromes including long and short QT, Brugada syndromes, and hypertrophic cardiomyopathies. Inroads have been achieved in the identification of cardiac arrhythmias as a cause of Sudden Infant Death Syndrome (SIDS) and the genetic basis for a new clinical entity associated with sudden death of young adults was uncovered earlier this year. This knowledge has provided guidance to physicians for better detection and treatment of these sudden death syndromes reducing mortality and disability of infants, children and young adults. Individuals who survive an instance of sudden death often remain in vegetative states, resulting in a devastating burden on their families and an enormous economic burden on society. These advances have translated into sizeable savings to the health care system in the United States. Researchers are also developing a noninvasive imaging modality for cardiac arrhythmias. Despite the fact that more than 325,000 Americans die every year from heart rhythm disorders, a noninvasive imaging approach to diagnosis and guided therapy of arrhythmias, the equivalent of CT or MRI, has previously not been available.

The NIH-funded Public Access Defibrillation (PAD) Trial was also able to determine that trained community volunteers increase survival for victims of cardiac arrest. It had already been known that defibrillation, utilizing an automated external defibrillator (AED), by trained public safety and emergency medical services personnel is a highly effective live-saving treatment for cardiac arrest. A NIH-funded trial however was able to conclude that placing AED's in public places and training lay persons to use them can prevent additional deaths and disabilities.<sup>4</sup>

Without NIH support, these life-saving findings may have taken a decade to unravel. The highly focused approach utilizing basic and clinical expertise, funded through Federal programs made these advances a reality in a much shorter time-period.

#### BUDGET JUSTIFICATION

These impressive strides notwithstanding, cardiac arrhythmias continue to plague our society and take the lives of loved ones at all ages, nearly one every minute of every day, as well as straining an already burdened health system. Sudden Cardiac Arrest is a leading cause of death in the United States, claiming an estimated 325,000 lives every year, or one life every 2 minutes.<sup>5</sup> The burden of morbidity and mortality due to cardiac arrhythmias is predicted to grow dramatically as the baby boomers age. Atrial fibrillation strikes 3–5 percent of people over the age of 65,<sup>6</sup> representing a skyrocketing economic burden to our society in the form of healthcare treatment and delivery. Cardiac diseases of all forms increase with advancing age, ultimately leading to the development of arrhythmias. Effective drug therapy for the management of atrial fibrillation is one of the greatest unmet needs in our society today and additional research is needed to address this problem. NIH research pro-

<sup>3</sup>American Stroke Association and American Heart Association, Heart Disease and Stroke Statistics—2005 Update, 2005 <http://www.americanheart.org/downloadable/heart/1105390918119HDSStats2005Update.pdf>.

<sup>4</sup>National Heart Lung and Blood Institute, NIH, Public Access Defibrillation by Trained Community Volunteers Increases Survival for Victims of Cardiac Arrest, November 2003 <http://www.nhlbi.nih.gov/new/press/03-11-11.htm>.

<sup>5</sup>Heart Rhythm Foundation, The Facts on Sudden Cardiac Arrest, 2004 [http://www.heartrhythmfoundation.org/its\\_about\\_time/pdf/provider\\_fact\\_sheet.pdf](http://www.heartrhythmfoundation.org/its_about_time/pdf/provider_fact_sheet.pdf).

<sup>6</sup>Heart Rhythm Society, Atrial Fibrillation & Flutter, 2005 [http://www.hrspatients.org/patients/heart\\_disorders/atrial\\_fibrillation/default.asp](http://www.hrspatients.org/patients/heart_disorders/atrial_fibrillation/default.asp).

vides the basis for the medical advances that hold the key to lowering health care costs.

The above progress we have witnessed in recent years will provide treatments for this illness, only if the resources continue to be available to the academic scientific and medical community. However, the budgets appropriated by Congress to the NIH in the past 3 years were far below the level of scientific inflation. These vacillations in funding cycles threaten the continuity of the research and the momentum that has been gained over the years. While HRS recognizes that Congress must balance other priorities, sustaining multi-year growth for the biomedical research enterprise is critical. A central objective of the doubling of the NIH budget was to accelerate solutions to human disease and disability. NIH is now engaging in the next generation of biomedical research to translate basic research and clinical evidence into new cures. Our ability to bring together uniquely qualified and devoted investigators and collaborators both at the basic science level and in the clinical arena is a vital key to our success. Funding models however show that a threshold exists, below which NIH will not be able to maintain its current scope and number of grants, let alone expand its programs to address new concerns and emerging opportunities. Furthermore, the United States is in danger of losing its leadership role in science and technology. The United States faces growing competition from other nations, such as China and India, which are working to invest more of their GDP's into building state-of-the art research institutes and universities to foster innovation and compete directly for the world's top students and researchers.<sup>7</sup>

It is for this reason that we are asking for your support to increase NIH appropriations by 6.5 percent for a fiscal year 2009. The Heart Rhythm Society recommends Congress specifically acknowledge the need for cardiac arrhythmia research to prevent sudden cardiac arrest and other life threatening conditions such as sudden infant death syndrome, definitive therapeutic approaches for atrial fibrillation and the prevention of stroke, and other genetic arrhythmia conditions. Thank you very much for your consideration of our request.

If you have any questions or need additional information, please contact Nevena Minor, Manager of Legislative Affairs at the Heart Rhythm Society (nminor@hrsonline.org or 202-464-3431).

Thank you again for the opportunity to submit testimony.

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#### PREPARED STATEMENT OF THE HEPATITIS B FOUNDATION

This testimony is being provided to highlight 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 and members of the subcommittee, thank you for giving the Hepatitis B Foundation (HBF) the opportunity to testify as the subcommittee begins to consider funding priorities for fiscal year 2009.

My name is Dr. Timothy Block, and I am the volunteer President and Co-founder of the Hepatitis B Foundation (HBF) and its research institute. I am also 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 more than 18 years ago because someone very close to us was affected.

Today, the HBF is still 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; outreach staff manages a comprehensive website which receives almost 1 million visitors each year and a national patient conference; and public health professionals implement research-based 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 in rate, liver cancer is the fastest growing in incidence in the United States. The numbers of people chronically infected with HBV will knock your socks off: there are 400 million people worldwide. Without intervention, as many as 100 million will die from an awful 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. Additionally, although all ethnic groups are affected it disproportionately affects Asians and Africans. That is, nearly 1 in 10 Asian Americans are chronically infected with hepatitis B.

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<sup>7</sup>Task Force on the Future of American Innovation, *The Knowledge Economy: Is the United States Losing its Competitive Edge?*, February 16, 2005.

But, the news is not all grim. There have been tremendous advances in research and in the control and treatment of hepatitis B over the past 30 years. There is a good vaccine to prevent infection; although, there is now a question as to how long lasting the protection is, if given in infancy. Unfortunately, for the 400 million people already infected worldwide, the vaccine is too late.

For those already infected, there are now several medications that can be taken to control viral replication and prevent disease progression to end-stage liver disease and/or liver cancer; thereby, reducing mortality and the need for liver transplantation. However, most cases of cirrhosis or liver cancer are diagnosed in the late stages, and current methods to treat liver cancer are in the dark ages, literally, and early diagnosis of liver disease is also primitive. HBV screening as part of liver cancer prevention and detection is thought to be one of the best hopes for effective management.

Thus, we were getting close to solutions, but lack of sustained support for public health measures and scientific research is threatening to allow the problems to come roaring back. Clearly, the Nation is faced with a major public health challenge that cannot be ignored. If we don't act with urgency, more and more people will suffer. Let me share just a few examples to dramatize the risks to us all.

The recent crisis in a Nevada clinic, where as many as 40,000 people were placed at risk for infection with HBV, HCV and HIV, is a problem that the Centers for Disease Control and Prevention (CDC) thinks might just be the "tip of the iceberg". The Nevada incident highlights critical deficiencies with national surveillance of chronic hepatitis B and C infections that are needed to rapidly identify problems such as the one that occurred in the Nevada clinic.

The frightening increase in the incidence of liver cancer, while most other cancer rates are on the decline, represents another example of shortcomings in our system. In the United States, 20,000 babies are born to mothers infected with hepatitis B 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.

But, fortunately, there is a good and proven way to avoid these tragedies. The vaccine and medications were the result of successful innovation and public/private partnerships between industry, academia and the government. People concerned about this problem continue to turn to Congress and the CDC and the National Institutes of Health (NIH). The CDC and NIH have formulated plans and have the ability to, if not solve the problem, get it entirely under control.

Mr. Chairman, may I now turn attention to requests regarding two Federal agencies that are critical in our effort to help people concerned with hepatitis B: the CDC and the NIH.

#### THE CENTERS FOR DISEASE CONTROL, DIVISION OF VIRAL HEPATITIS

We believe a strong, well equipped CDC is our best hope to manage the public health problem of hepatitis B. The DVH has had "flat funding" for the past 5 years, despite the urgency and growth of this problem. 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. Currently, DVH focuses primarily on acute hepatitis A, B and C. While that's been very successful in decreasing new infections, little has been done about chronic hepatitis B and C, which impacts more than 6 million Americans and if left untreated, often leads to fatal liver failure or liver cancer.

The HBF calls for a "zero tolerance" policy against new HBV infections, particularly among newborns, and against leaving infected pregnant women uneducated and unprotected. All pregnant women who test positive for hepatitis B should be referred to appropriate follow-up care and treatment. With a safe vaccine and six approved therapies for hepatitis B, no woman or child should be left behind. HBF also urges an expansion of cooperative agreements to test and validate evidence-based interventions focused on the mother-child transmission issue, and the prevention and management of HBV in high-risk ethnic communities.

The HBF supports increased resources to build the capacity for the Division of Viral Hepatitis to improve public health interventions by building a robust national active surveillance of chronic HBV and HCV, strengthening State and local viral hepatitis prevention networks, and educating the community and providers to raise awareness about the importance of early detection and intervention of chronic hepatitis. Strengthening chronic hepatitis B education, testing, and referral to care programs will make an enormous difference in decreasing new infections and decreasing the mortality and morbidity associated with chronic viral hepatitis.

Both Drs. Kevin Fenton and John Ward, of the CDC, have shown great leadership and spoken eloquently on the state of hepatitis B in the United States. Dr. Ward,



for example, has observed that "Hepatitis B is the deadliest disease that can be prevented through infant vaccination." Dr. Ward also recognizes the need for recommendations to ensure HBV-infected pregnant women are educated and referred to care, rather than treated merely as vessels of disease. More investment in DVH, however, is required to bolster their programs to address the problems of chronic viral hepatitis.

To meet these needs, we request \$50 million in fiscal year 2009 for the DVH. This would allow for a comprehensive, aggressive approach. However, an additional annual increase of at least \$5 million, beginning in fiscal year 2009, is considered the minimum increase needed to sustain existing program and allow for minor reinforcements, in particular, to fund an Institute of Medicine Study to characterize and document the true burden of chronic viral hepatitis disease in the United States, which is urgently needed.

Overall, the HBF joins with the CDC Coalition, a nonpartisan coalition of more than 100 groups, in supporting \$7.4 billion for the Centers for Disease Control and Prevention in fiscal year 2009. The CDC programs are crucial to the health of all Americans and key to maintaining a strong public health infrastructure to protect us from threats to our health. At a time when the CDC is faced with unprecedented challenges and responsibilities ranging from chronic disease prevention, eliminating health disparities, bioterrorism preparedness, to combating the obesity epidemic the administration has cut the CDC's budget by \$412 million. We urge the committee to restore this cut and fund the CDC at \$7.4 billion.

#### THE NATIONAL INSTITUTES OF HEALTH

We depend upon the U.S. NIH to search for new interventions to treat people with hepatitis B and liver cancer.

In fiscal year 2008, NIH is expected to spend approximately \$42 million on hepatitis B funding overall. Although it is unseemly to compare one disease with another, since for anyone affected it is the disease that afflicts them that is the most important, it may be useful to know that the NIH currently spends \$2.9B on HIV and billions on biodefense. Current estimates predict that HBV research funding will be flat or decline for fiscal year 2009.

Please help correct this situation. There are good plans that show how an additional \$40 million per year can make transformational beneficial advances for HBV research. If this is not possible in the current funding climate, we urge that the level of funding for HBV research be increased by at least 6.5 percent in fiscal year 2009.

Mr. Chairman, I would like to take this opportunity to commend the leadership of NIH, and especially the leadership of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Cancer Institute, and the National Institute of Allergy and Infectious Diseases for their continued interest in liver disease research. They have performed admirably with the limited resources they are provided; however, more is needed.

The NIH published a 10 year Liver Disease Research Action Plan in 2004, and to date, NIDDK has succeeded in several important areas such as funding a network of HBV Clinical Research Centers and hosting the first HBV Consensus Conference focused on identifying best treatment practices for chronic hepatitis B infections. The growing number of treatment options is encouraging and suggests a strong rationale for conducting a consensus conference to provide state-of-the-art treatment guidelines for the practicing physician community.

Mr. Chairman, HBF joins the Ad Hoc Group for Medical Research Funding, a coalition of some 300 patient and voluntary health groups, medical and scientific societies, academic research organizations and industry, in recommending \$31.2 billion (6.5 percent increase) for the National Institutes of Health in fiscal year 2009. The fiscal year 2009 Administration budget request for NIH is flat compared to fiscal year 2008 funding levels, which is due to the effects of biomedical inflation, and translates to a cut. In the five years through 2008, NIH has lost approximately 11 percent in purchasing power due to inflation. Therefore, if the President's fiscal year 2009 request becomes law, NIH will have lost one-seventh of its purchasing power due to inflation.

#### 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 than proposed by the administration.

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 funding for fiscal year 2009 programs:

- In fiscal year 2009, restore the CDC budget to \$7.4 billion, with a \$50 million increase to the Division of Viral Hepatitis (or at least an increase of \$5 million) to strengthen the public health response to chronic viral hepatitis; and
- In fiscal year 2009, provide a 6.5 percent increase for the NIH bringing the total funding level to \$31.2 billion, including a \$40 million increase per year for hepatitis B research.

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 HEPATITIS C APPROPRIATIONS PARTNERSHIP

The Hepatitis C Appropriations Partnership, whose members advocate for increased Federal support for hepatitis C prevention, testing, education, research, and treatment, respectfully submits testimony for the record regarding Federal funding for Federal adult hepatitis programs in the fiscal year 2009 Labor, HHS and Education Appropriations legislation. HCAP appreciates the Committee's past support for these important public health programs.

As you craft the fiscal year 2009 Labor, HHS and Education Appropriations legislation, we urge you to consider the following critical funding needs to appropriately address the HCV epidemic:

- Include \$50 million for the Centers for Disease Control and Prevention's (CDC) Division of Viral Hepatitis (DVH);
- Continue \$20 million for hepatitis B vaccination for adults through the Section 317 Vaccine Program;
- Continue funding commitment for Community Health Centers;
- Increase funding for the Ryan White Program to support additional case management, provider education and the coverage of HCV drug therapies; and
- Increase funding for the National Institutes of Health to support their Action Plan for Liver Disease Research.

Approximately 6.25 million Americans are infected with the hepatitis C virus (HCV) and hepatitis B virus (HBV). Chronic viral hepatitis is now one of the leading killers of Americans living with HIV/AIDS. In addition, chronic viral hepatitis is the leading cause of liver cancer, now among the top 10 killers of Americans over the age of 25 years. Overall, the death rate for HCV-related deaths in the United States is expected to triple by 2019.

It is critical that Americans know whether they are hepatitis C-infected in order to mitigate disease burden and to prevent transmission. These include simple steps like abstaining from alcohol use, exercising and maintaining a healthy diet. There are effective pharmaceutical treatment options available as well.

#### PREVENTION

HCAP requests a minimum increase of \$32.4 million in fiscal year 2009 for the Centers for Disease Control and Prevention's (CDC) Division of Viral Hepatitis (DVH) to enable State and local health departments to provide basic core public health services. Of this increase, we request a doubling of funding for State adult viral hepatitis prevention coordinators from \$5 million to \$10 million. DVH currently receives \$17.6 million to address hepatitis C, of which States receive an average award of \$90,000 to fund a coordinator. The coordinator position receives precious little above personnel costs, leaving little to no money for the provision of public health services such as education programs for the public and health professionals, hepatitis counseling, testing, and referral, or hepatitis A and B vaccine for adults. In addition, there are no funds for surveillance of chronic viral hepatitis, which would allow States to better target their limited resources. Due to lack of funding, CDC treats hepatitis outbreaks as sentinel events rather than systematically addressing hepatitis B and C epidemics with over 6 million Americans infected. Addressing one outbreak at a time is neither cost-effective nor is it prevention. Simply put, in the absence of an HCV vaccine the government can invest in prevention now or wait until public systems are overwhelmed by the costs of chronic liver disease, including liver transplantation.

The greatest remaining challenge for hepatitis A and B prevention is the vaccination of high-risk adults. High-risk adults account for more than 75 percent of all

new cases of hepatitis B infection each year and annually result in an estimated \$658 million in medical costs and lost wages. In fiscal year 2007, CDC allowed States to use \$20 million of 317 Vaccine funds to vaccinate high risk adults for hepatitis B. States are integrating vaccination into service programs for persons with risk factors for infection (e.g., STD clinics, HIV counseling and testing sites, correctional facilities and drug treatment clinics). By targeting high-risk adults, including those with hepatitis C, for vaccination, the gap between children and adults who have not benefited from routine childhood immunization programs can be bridged. HCAP requests a continuation of \$20 million in fiscal year 2009 for hepatitis B vaccination.

#### TREATMENT

Access to available treatments and treatment support services are critical to combat co-infection morbidity. While there are no dedicated funding streams for medical management and treatment of hepatitis C, low-income patients can and do seek services at Community Health Centers (CHCs). HCAP supports your continued commitment to increasing resources for CHCs.

Many low-income individuals co-infected with HCV and HIV can obtain services through the Ryan White Programs and because of that, HCAP urges you to provide increased Ryan White resources. Only half the State's AIDS Drug Assistance Programs (ADAP) are able to provide HCV and HIV treatments to co-infected clients. Increased resources are also needed to improve provider education on HCV medical management and treatment, to cover additional case management for patients undergoing treatment and to allow more States to add HCV therapies and HCV viral load tests to their ADAP formularies.

#### RESEARCH

Finally, research is needed to increase understanding of the pathogenesis of hepatitis C, improve HCV treatments that are currently difficult to tolerate, develop clinical strategies to slow the progression of liver disease among persons living with HCV, and develop a vaccine to prevent HCV infection. The Liver Disease Branch, located within the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH), has developed an Action Plan for Liver Disease Research. HCAP requests full funding for NIH to support the recommendations and action steps outlined in this Action Plan for Liver Disease Research.

A strong public health response is needed to meet the challenges of this infectious disease impacting over four million Americans. We welcome the opportunity to work with you and your staff on this important issue.

As you craft the fiscal year 2009 Labor-HHS appropriations bill, we ask that you consider all of these critical funding needs. It is essential that the United States continue to demonstrate its commitment to fighting the ongoing domestic and global HIV/AIDS, viral hepatitis, and STD epidemics. The National Alliance of State and Territorial AIDS Directors thank the chairman, ranking member and members of the subcommittee, for their thoughtful consideration of our recommendations. Should you have any questions or comments, feel free to contact Laura Hanen, Coalition Director, Hepatitis C Appropriations Partnership, (202) 434-8091 or lhanen@nsatad.org. Thank you very much.

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#### PREPARED STATEMENT OF THE HEPATITIS FOUNDATION INTERNATIONAL

##### SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2009

A funding level of \$7.4 billion for the Centers for Disease Control and Prevention, an increase of \$1.28 billion over fiscal year 2008.

A funding level of \$50 million for the Center for Disease Control and Prevention's Division of Viral Hepatitis, an increase of \$32 million over fiscal year 2008.

A funding increase of at least 6.5 percent over fiscal year 2008 for the National Institutes of Health.

Urge the Centers for Disease Control and Prevention, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration to work with voluntary health organizations to promote liver wellness, expand health education, and improve primary prevention of unhealthy lifestyle behaviors.

Currently, five types of the hepatitis virus have been identified, ranging from type A to type E. All of these types cause acute, or short-term, viral hepatitis. The Hepatitis B, C, and D viruses can also cause chronic hepatitis, in which the infection is prolonged, sometimes lifelong. While treatment options are available for many pa-

tients, individuals with chronic viral hepatitis B and C represent a significant number of the patients that require a liver transplant. Treatments presently have limited success and there is no vaccine available for hepatitis C, the most prevalent of these diseases.

#### HEPATITIS A

The hepatitis A virus (HAV) is contracted through fecal/oral contact (i.e. fecal contamination of food, water, and diaper changing tables if not cleaned properly), and sexual contact. In addition, eating raw or partially cooked shellfish contaminated with HAV can spread the virus. Children with HAV usually have no symptoms; however, adults may become violently ill, suddenly experiencing jaundice, fatigue, nausea, vomiting, abdominal pain, dark urine/light stool, and fever. While there is no treatment for HAV, recovery tends to occur spontaneously over a 3 to 6 month period. About 1 in 1,000 with HAV suffers from a sudden and severe infection that can require a liver transplant. A highly effective vaccine can prevent HAV and is recommended for all children and individuals who have chronic liver disease or clotting factor disorders, in addition to those who travel or work in developing countries.

#### HEPATITIS B

Hepatitis B (HBV) claims an estimated 5,000 lives every year in the United States, even though therapies exist that slow the progression of liver damage. Vaccines are available to prevent hepatitis B, but their effectiveness is limited. This disease is spread through contact with the blood and body fluids of an infected individual and from an HBV infected mother to child at birth. Unfortunately, due to both a lack in funding to vaccinate adults and the absence of an integrated preventive education strategy, transmission of hepatitis B continues nearly unabated. Additionally, there are significant disparities in the occurrence of chronic HBV-infections. For Example, Asian Americans represent four percent of the population; however, they account for more than half of the 1.3 million chronic hepatitis B cases in the United States. Current treatments do not cure hepatitis B, but appropriate treatment can help to reduce the progression to liver cancer and liver failure. Yet, many are not treated. Preventive education and universal vaccination are the best defenses against hepatitis B.

#### HEPATITIS C

Infection rates for hepatitis C (HCV) are at epidemic proportions. Unfortunately, many individuals are not aware of their infection until many years after they are infected. This creates a dangerous situation, as individuals who are infected unknowingly spread the disease. The Centers for Disease Control and Prevention (CDC) estimates that there are over 4 million Americans who have been infected with hepatitis C, of which over 2.7 million remain chronically infected, with 8,000–10,000 deaths each year. Additionally, the death rate is expected to triple by 2010 unless additional steps are taken to improve outreach and education on the prevention of hepatitis C and scientists identify more effective treatments and cures. As there is no vaccine for HCV, prevention, education, and treatment of those who are infected serve as the most effective approach in halting the spread of this disease.

#### PREVENTION IS THE KEY

The absence of information pertaining to the liver and hepatitis in education programs over the years has been a major factor in the spread of viral hepatitis through unknowing participation in liver damaging activities. Adults and children need to understand the importance of the liver and how viruses and drugs can damage its ability to keep them alive and healthy. Many who are currently infected are unaware of the behavioral risks which expose them to viral infections, and ultimately, liver damage.

Knowledge is the key to prevention. Preventive education is essential to motivate individuals to protect themselves and avoid behaviors that can cause life-threatening diseases. Primary prevention that encourages individuals to adopt healthy lifestyle behaviors must begin in elementary schools when children are receptive to learning about their bodies. In addition to educating individuals at a critical age, schools provide access to one-fifth of the American population.

Individuals need to be motivated to assess their own risk behaviors, to seek testing, to accept vaccination, to avoid spreading their disease to others, and to understand the importance of participating in their own health care and disease management. The CDC needs to support education programs to train teachers and

healthcare providers in effective communication techniques, and to evaluate the impact preventive education has on reducing the incidence of hepatitis and substance abuse.

For fiscal year 2009, HFI recommends that the Centers for Disease Control and Prevention (CDC), The National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA) be urged to work with voluntary health organizations to promote liver wellness, education, and prevention of viral hepatitis, sexually transmitted diseases, and substance abuse.

For fiscal year 2009, HFI recommends that the CDC, particularly the Division of Adolescent and School Health (DASH), work with voluntary health organizations to promote liver wellness with increased attention toward childhood education and prevention, particularly through partnerships between school districts and non-governmental organizations.

#### CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

To effectively implement the CDC's National Hepatitis C Prevention Strategy an estimated \$100 million is need for the Divisions of Viral Hepatitis (DVH). However, DVH has been flat funded at just under \$18 million for many years. This chronic underfunding has resulted in severely limited resources for State Adult Hepatitis Coordinators. The available Federal resources often only cover a hepatitis coordinators salary which leaves them begging, borrowing, and dealing to provide necessary services.

Budget difficulties at the CDC are not solely limited to DVH. The CDC's important mission has been eroded by years of funding cuts. As you are aware, the fiscal year 2009 President's Budget Request seeks to deepen these cuts by recommending a reduction of \$433 million in budget authority. Considering the threats of bioterrorism, pandemic influenza, a marked rise in the incidence of hepatitis, and the increasing prevalence of a number of other conditions, the CDC's budget must receive a substantial increase to effectively protect the public health.

For fiscal year 2009, HFI recommends a funding level of \$7.4 billion for the CDC, an increase of \$1.28 billion over fiscal year 2008.

For fiscal year 2009, HFI recommends a funding level of \$50 million for the DVH, an increase of \$32 million over fiscal year 2008.

#### NATIONAL INSTITUTES OF HEALTH (NIH)

Investment in the NIH has led to an explosion of knowledge that has advanced understanding of the biological basis of disease and developed strategies for disease prevention, diagnosis, treatment, and cures. NIH-supported scientists remain our best hope for sustaining momentum in pursuit of scientific opportunities and new health challenges. For example, research into why some HCV infected individuals resolve their infection spontaneously may prove to be life saving information for others currently infected.

As you are aware, recent years of near level-funding at NIH have negatively impacted the mission of its Institutes and Centers. For this reason, HFI applauds efforts like Senators Tom Harkin (D-IA) and Arlen Specter's (R-PA) adopted amendment to the fiscal year 2009 Senate Budget Resolutions which calls on appropriators to provide NIH with a 10.3 percent funding increase. HFI urges this Subcommittee to show strong leadership in pursuing such a substantial funding increase.

For fiscal year 2009, HFI recommends a funding increase of at least 6.5 percent for NIH and its Institutes and Centers.

#### HEPATITIS FOUNDATION INTERNATIONAL (HFI)

HFI is dedicated to the eradication of viral hepatitis, a disease affecting over 500 million people around the world. We seek to raise awareness of this enormous worldwide problem and to educate and motivate people to adopt healthy lifestyle behaviors to reduce the incidence of viral hepatitis and other blood-borne pathogens.

Our mission has four distinct components:

- To educate the public, patients and professionals about the prevention, diagnosis and treatment of viral hepatitis.
- To prevent viral hepatitis and promote healthful lifestyles.
- To serve as advocates for hepatitis patients and the medical community worldwide.
- To support research into prevention, treatment, and cures for viral hepatitis.

## PREPARED STATEMENT OF THE HIV MEDICINE ASSOCIATION

The HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA) represents more than 3,600 physicians, scientists and other health care 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 and the world, lead HIV prevention programs, and conduct research to advance HIV prevention and treatment options. They are medical providers that specialize in HIV medicine and work in communities across the country. We urge you to sustain the three-pronged response of the United States to the AIDS pandemic by adequately supporting:

- the research programs necessary to improve prevention and treatment options spearheaded by the National Institutes of Health (NIH);
- the surveillance and prevention programs that help to identify people with HIV and reduce HIV transmission led by the Centers for Disease Control and Prevention; and
- the health care safety-net programs that are critical to providing people with limited resources with access to lifesaving HIV treatment through the Ryan White CARE Act programs at the Health Resources and Services Administration (HRSA).

Past Federal investments in HIV/AIDS programs have led to a revolution in HIV care. We developed treatments that effectively suppress this deadly virus and supported programs that provided lifesaving HIV treatment to people across the country regardless of their health insurance status. Many of our members have seen patients make remarkable recoveries that allow them to live healthier, more productive lives. However, we are concerned about our ability to sustain this success given our country's failure to prioritize support for domestic discretionary programs outside of defense and homeland security. The impact of our diminished investment in health is already being felt and will be far-reaching and long lasting as our communities' public health infrastructures weaken and our capacity to lead the world in discovering new therapies for controlling deadly diseases such as HIV erodes. If we do not act to increase our investments in these programs, we risk losing the next generation of scientists and clinicians necessary to continue the critical work of preventing new infections, providing effective care and treatment and advancing the science necessary to end the pandemic. The funding requests in our testimony largely reflect the consensus of the Federal AIDS Policy Partnership (FAPP), a coalition of HIV/AIDS organizations from across the country, and are estimated to be the amounts necessary to sustain and strengthen our investment in combating HIV disease.

## CDC'S NATIONAL CENTER FOR HIV, STD, TB PREVENTION (NCHSTP)

HIVMA strongly supports substantial increases in funding for the CDC's NCHSTP. Our prevention efforts are stymied by insufficient funding to support a comprehensive HIV strategy. Meanwhile, the number of people living with HIV in the United States continues to grow and the CDC is expected to increase its estimate of the new HIV infections that are occurring annually in the United States from 40,000 to 60,000. Resources are desperately needed to halt this trend and support a robust HIV prevention portfolio that includes identifying people with HIV earlier in infection through increased HIV screening. Tuberculosis is the major cause of AIDS-related mortality worldwide. It is critical that we shore up our ability as a Nation to address tuberculosis, especially drug-resistant tuberculosis here in the United States and in the developing world. With regard to these programs, we urge at least an increase of \$608 million for domestic HIV prevention and surveillance programs and a funding level of \$300 million for CDC's Division of Tuberculosis Elimination.

A comprehensive prevention strategy is necessary to reduce the number of new HIV infections occurring each year. According to the CDC, at least 25 percent of people with HIV infection in the United States do not know it and more than 39 percent of people with HIV infection progress to AIDS within 1 year of diagnosis. We strongly support the CDC initiative to integrate HIV screening into medical care. The expansion of HIV testing is critical to identifying individuals with HIV earlier to prevent or delay disease progression and to reduce further transmission of the disease. We are seriously concerned about the lack of Federal resources available to State health departments and institutions for implementing these programs.

A more robust HIV prevention budget also is needed to strengthen HIV surveillance systems and to target uninfected individuals who engage in high-risk behaviors. Both are important to dramatically reduce the 40,000 to 60,000 new HIV infections estimated to occur each year in the United States. We must increase support

for science-based, comprehensive programs. We are seriously concerned that the resources committed to supporting a broad-based prevention agenda have diminished while funding for unproven and unscientific abstinence-only programs has increased. We strongly encourage Congress to halt this troubling trend. Additional resources are needed to address the high prevalence rates among vulnerable populations, e.g., men and women of color and men who have sex with men. It is short sighted to compromise these programs in order to support newer initiatives.

Funding for HIV prevention activities at the CDC should be increased by at least \$608 million. These resources should be utilized to restore the cuts in HIV prevention cooperative agreements with state and local health departments; to enhance core surveillance cooperative agreements with health departments and to expand HIV testing in critical health care venues by funding testing infrastructure, the purchase of approved testing devices, including rapid tests and confirmatory testing.

Funding to support the prevention, control and elimination of tuberculosis must increase substantially if we are going to make headway against this deadly disease and to address the emerging threat of highly drug resistant tuberculosis. HIVMA supports at least a \$159.6 million increase in funding for the CDC's Division of Tuberculosis Elimination.

#### HIV/AIDS BUREAU OF THE HEALTH RESOURCES AND SERVICES ADMINISTRATION

HIVMA supports a total commitment of at least \$2.78 billion, an increase of \$614.5 million for the Ryan White CARE Act program. This recommendation includes a \$134.6 million increase for the AIDS Drug Assistance Program (ADAP) and an increase of \$100.5 million for Part C (Title III). The Health Resources and Services Administration (HRSA) oversees programs that are vital to our communities' health care safety nets—and to the ability of our clinician members to provide HIV care and treatment to many of their patients living with HIV/AIDS. CARE Act funding helps us to meet the serious and complex needs of people with HIV/AIDS who are uninsured or underinsured by supporting the delivery of primary medical care, prescription drugs, diagnostic tests, mental health services, substance abuse treatment, and dental services in our communities.

We strongly support a substantial increase in CARE Act funding and would propose that the majority of new funding be targeted to HIV medical care. In particular, we support major increases for medical services offered under Parts A, B, C, and D and to the AIDS Drug Assistance Program (ADAP) to ensure that individuals with HIV/AIDS have access to a base line of lifesaving medical care and prescription drugs regardless of where they live. Funding increases are urgently needed for Part C programs. Many of the programs are treating more patients with fewer grant dollars and are struggling to meet the growing demand for HIV care in their communities. After several years of inadequate funding, we estimate that Part C programs require an increase of \$83.3 million in Federal funds. HIV clinical programs depend on funding from multiple parts of the CARE Act to create the comprehensive services that our patients need. We strongly encourage you to support funding increases of \$213 million for Part A, \$95 million for the Part B base and \$48 million for Part D.

More than a quarter century into the HIV epidemic, we are seeing the graying of our Nation's HIV clinical workforce, and we have serious concerns about ensuring a new generation of HIV medical providers to care for Americans with HIV. We increasingly hear about HIV care coverage gaps and clinical programs with challenges in hiring and retaining medical staff. We must address this issue before its effects are felt in increases in morbidity and mortality from HIV. We are delighted that legislation reauthorizing the President's Emergency Program for AIDS Relief authorizes resources to ensure that there is an adequate workforce to provide prevention, care and treatment services in developing countries. We must also attend to HIV medical workforce needs at home. We respectfully urge you to include at least \$1 million in this year's Labor-HHS-Education appropriations bill for a study to evaluate the capacity of the HIV medical workforce as well as potential strategies to increase the numbers of young physicians, nurse practitioners and physician assistants entering HIV medicine.

#### NATIONAL INSTITUTES OF HEALTH (NIH)

HIVMA strongly supports an increase of \$4.38 billion for all research programs at the NIH including a \$450 million increase for the NIH Office of AIDS. This level of increase is vital to halting the erosion of our Nation's medical research programs and to sustain the pace of research that could improve the health and quality of life for millions of Americans. The failure to sustain the U.S. investment in biomedical research is taking its toll in deep cuts to clinical trials networks and signifi-

cant reductions in the numbers of high quality, investigator-initiated grants that are approved. We are deeply concerned about the significant decrease in support for original research. With only one in four research applications receiving funding, the pipeline for critical discoveries and HIV scientists is dwindling and our role as a leader in biomedical research is at serious risk.

In the arena of AIDS research, multiple years of inadequate funding levels that do not even keep pace with medical inflation threaten our ability to develop new therapeutics, to discover effective prevention technologies, and to finance vaccine development. A robust and comprehensive portfolio was responsible for the dramatic gains that we made in our HIV knowledge base, gains that resulted in reductions in mortality from AIDS of nearly 80 percent in the U.S. and in other countries where treatment is available. Additionally, our remarkable discoveries helped us to reduce the mother to child HIV transmission rate from 25 percent to nearly 1 percent in the United States and to very low levels in other countries where treatment is available.

A continued robust AIDS research effort is essential to sustain and to accelerate our progress in offering more effective prevention technologies; developing new and less toxic treatments for our; and supporting the basic research necessary to continue our work developing a vaccine that may end the deadliest pandemic in human history. Our failure to make an adequate investment in this lifesaving research compromises our ability to compare and evaluate optimum treatment and prevention strategies in resource-poor countries, and limits our ability to understand the appropriate role of new classes of antiretrovirals that are currently in development here at home for treatment and prevention. The sheer magnitude of the number of people still living with HIV/AIDS—more than 1 million people in the United States; 33 million people globally—demands an increased investment in AIDS research if we are going to truly eradicate this devastating disease.

We also strongly support the NIH's Fogarty International Center (FIC) and recommend an expansion of its programs and funding. The FIC training programs play a critical role in developing self-sustaining health care infrastructures in resource-limited countries. These important programs offer invaluable training and mentoring to indigenous physicians from the countries hardest hit by the HIV pandemic and other deadly infectious diseases, such as malaria and tuberculosis. Physicians trained through the FIC are able to develop research programs that more effectively address the health care, cultural and resource needs of their country's residents while also fostering the development of ongoing, robust research and clinical programs.

Our Nation has made significant strides in responding to the HIV/AIDS pandemic here at home and around the world, but we have lost ground in recent years, particularly domestically, as funding priorities have shifted away from public health and research programs. This retreat on past investments in AIDS research through NIH, surveillance and prevention programs through the CDC, and care and treatment through the Ryan White CARE Act program place the remarkable advancements of the past two decades in serious jeopardy. We have an opportunity to reverse this trend and to move forward with a budget that prioritizes funding for scientific discovery, public health, and care and treatment for those without resources or adequate insurance. With the support of this Congress, we have the opportunity to further 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 world.

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#### PREPARED STATEMENT OF THE INFECTIOUS DISEASES SOCIETY OF AMERICA

The Infectious Diseases Society of America (IDSA) appreciates this opportunity to bring attention to the disastrous cuts proposed for leading infectious disease programs in President Bush's fiscal year 2009 budget. Should these cuts go into effect, the Nation's and world's ability to control and contain an ever-increasing number of infectious diseases threats will be severely diminished. As many recent news stories have shown, existing and emerging infections continue to challenge Americans in U.S. hospitals and communities as well as people around the globe. These infections include HIV/AIDS, methicillin-resistant *Staphylococcus aureus* (MRSA), Tuberculosis (TB) including extensively drug-resistant (XDR) TB, malaria and other resistant and susceptible organisms, such as *Escherichia coli*, *Pseudomonas aeruginosa*, *Neisseria gonorrhoeae*, *Acinetobacter baumannii*, and *Klebsiella* species.

IDSA represents more than 8,000 infectious diseases physicians and scientists devoted to patient care, education, research, prevention, and public health. Our members care for patients of all ages with serious infections, including meningitis, pneu-



monia, TB, antibiotic-resistant bacterial infections such as MRSA, and those with cancer or transplants who have life-threatening infections caused by unusual microorganisms, food poisoning, and HIV/AIDS, as well as emerging infections like severe acute respiratory syndrome (SARS).

Especially hard-hit in this year's budget is the Centers for Disease Control and Prevention (CDC), the primary Federal agency responsible for conducting and supporting public health protection through health promotion, prevention, preparedness, and research. CDC would see a cut of nearly half a billion dollars in its total budget, to \$5.9 billion. IDSA instead recommends increasing funding for CDC to \$7.4 billion, roughly a 15 percent increase over current funding. This corresponds well with the Professional Judgment delivered last year by CDC Director Julie Gerberding, which said that \$7.2 billion would be needed in fiscal year 2008 to properly fund CDC.

Within the CDC budget, IDSA is especially concerned about the slashing of the Infectious Diseases program budget, which would be reduced by more than \$34 million, to \$1.9 billion. Last year, Dr. Gerberding told Congress the program needed an increase of nearly \$315 million in fiscal year 2008, but CDC received less than one-fifth of that amount. IDSA recommends an fiscal year 2009 funding level of \$2.1 billion for CDC's Infectious Diseases programs.

Within the Infectious Disease programs' proposed budget, the agency's already severely strapped Antimicrobial Resistance budget would be further cut to \$16.5 million. This vital program is necessary to help combat the rising crisis of drug resistance, a critical medical problem marked most publicly by the upsurge in MRSA infections. A CDC-supported report published last October in the *Journal of the American Medical Association* indicated that invasive MRSA infections kill more than 19,000 Americans annually—more than emphysema, HIV/AIDS, or Parkinson's disease. In response to the acute MRSA problem and the growing antimicrobial resistance epidemic, IDSA recommends increasing fiscal year 2009 funding for resistance programs at CDC by \$16 million, to a total of \$33 million. Such funding increases will enable CDC to strengthen the National Healthcare Safety Network, which supports surveillance of drug-resistant healthcare associated infections, gather morbidity and mortality data related to resistance, track the development of dangerous resistant bugs as they develop, educate physicians and parents about the need to protect the long-term effectiveness of antibiotics, and strengthen infection control activities across the United States.

In addition, a proposed \$26 million cut (which represents a more than 20 percent reduction, to \$103.6 million) to CDC's "Other Emerging Infectious Diseases" line item would hobble the agency's core infrastructure and ability to respond to new threats as they emerge. Past and existing threats have included rabies, rotavirus, food-borne diseases, Ebola, SARS, and others. The proposed cut would severely affect CDC laboratory capacity, research grants to academic partners, and support for State public health departments and public health laboratories and would reduce CDC's flexibility in setting priorities and taking action against new infections that emerge throughout the year. IDSA recommends, at a minimum, that the Other Emerging Infectious Diseases line item be increased to \$145 million for fiscal year 2009.

The section 317 Program at CDC has been one of our country's greatest public health achievements. In part through the section 317 Program that provides funding for immunization to States and other jurisdictions, the United States has made significant progress toward eliminating vaccine-preventable diseases among children. At a time when new CDC-recommended vaccines are available and a greater commitment to immunizations for both children and adults is necessary, the proposed cuts to this program will undermine access to a critical intervention that saves lives and millions of dollars in unnecessary medical spending. Therefore, IDSA is recommending a funding level for the Section 317 Program of \$802 million.

IDSA also supports changes which will significantly strengthen the Section 317 Program's support for adult and adolescent immunization. Each year, more than 46,000 adults die of vaccine-preventable diseases (VPDs). Costs related to illnesses from adult VPDs are approximately \$10 billion. Distinct funding floors for adult vaccine purchase and infrastructure are needed in amounts sufficient to cover immunization of the majority of under-insured and uninsured adults with all CDC-recommended vaccines.

Recent cuts have eroded national TB control programs, which is especially concerning as threats from XDR and multi-drug resistant TB grow. As news reports on incidences of TB have shown, CDC is stretched extremely thin in their ability to respond and control TB outbreaks. A total of \$300 million is needed across CDC for efforts to prevent, control and eliminate TB.

The budget request for HIV prevention and surveillance activities at CDC also is woefully inadequate. These programs are critical to reducing the number of new HIV cases occurring annually in the United States. Sufficient resources must be devoted to HIV prevention to support CDC's portfolio of prevention programs, including the initiative to identify people with HIV/AIDS earlier through routine HIV screening. This program will lead to lifesaving care sooner and will help to prevent further transmissions. IDSA supports funding of \$1.3 billion for these programs in fiscal year 2009. We also support funding of \$2.78 billion for the Ryan White CARE Act programs within the Health Resources and Services Administration, including \$299.3 million for Part C programs. Ryan White programs are vital to our health care safety net and are struggling to meet the need for HIV services in communities across the country.

The President also proposes to flat-fund the National Institutes of Health (NIH) in fiscal year 2009, which represents a continued setback for this important agency. 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. However, since 2003, NIH has lost 13 percent of its purchasing power due to the rate of biomedical research inflation and stagnating annual budgets. Because of the flat budget, three out of four research proposals submitted to NIH are not funded. Peer reviewers are forced to become more risk averse, leading to a narrowing of scientific vision and a diminishing rate of medical advancement. Without medical advancements, thousands of Americans will have to wait longer for the cures they need.

The President's budget proposal does not come close to reaching the authorized funding level of \$32.8 billion set for fiscal year 2008 contained in the NIH Reform Act, which passed in 2006. Therefore, IDSA is recommending an increase of at least \$1.9 billion in fiscal year 2009 for NIH, to a total of \$31.1 billion. This increase would return the budget to historical growth (equaling the rate of biomedical research inflation plus approximately 3 percent).

NIH's Fogarty International Center is at the forefront of global health and is a leader in extending the United States Federal biomedical enterprise abroad. It taps innovative thinking from all parts of the world and fosters important scientific partnerships. Through Fogarty, the United States has supported research and research training programs conducted by both United States and foreign investigators across a wide range of infectious diseases and needs, including HIV/AIDS, malaria, and tuberculosis. The Center's efforts have led to improved local health outcomes—but so much more can be done. For this reason, IDSA strongly supports increasing Fogarty's funding level in fiscal year 2009 to \$100 million—an increase of \$33 million. These additional resources will enable Fogarty to increase research training initiatives, forge new partnerships between United States and foreign research institutions, and conduct much-needed implementation research to increase the effectiveness of international programs.

IDSA also proposes an increase in antimicrobial resistance research funding at NIH of \$100 million in fiscal year 2009, bringing it to a total of \$321 million. This funding level would allow NIH to strengthen clinical research and establish a clinical trials network to study resistant infections as well as antibacterial use and development. Well-designed, multi-center randomized controlled trials would create an excellent basis of evidence from which coherent and defensible recommendations could be developed.

Additionally, in the Agriculture appropriations bill, IDSA would propose that antimicrobial resistance programs at the Food and Drug Administration receive at least a \$10 million increase in new funding in fiscal year 2009, bringing its resistance funding to \$34 million. This would allow FDA to establish and periodically update antibiotic susceptibility breakpoints based on testing and data collection, including through the purchase of vendor data; fund Critical Path initiatives for antibiotics; more aggressively review the safety of antibiotic use in food animals; and quicken its pace in developing critical guidance for industry on antibiotic clinical trial designs.

The Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA) holds great potential to encourage and facilitate the development of new medical countermeasures and technologies. Congress authorized \$1.07 billion for this mission; however, since BARDA's creation in December 2006, only \$201 million has been provided. We are disappointed that Congress' and the administration's intent in creating BARDA have not been actualized. The current funding level has not allowed HHS to establish an active, robust advanced research and development portfolio for biomedical products. An analysis conducted by the Center for Biosecurity indicates that \$817 million in fiscal year 2009

would be required to support one year of advanced development for just the 32 candidate medical countermeasures against biological threats currently in development. IDSA recommends that \$850 million of multi-year appropriations be allocated to BARDA in fiscal year 2009 to fund biological therapeutics, diagnostics, and technologies. Such funding would help ensure the availability of resources throughout the advanced stages of development and the flexibility for BARDA to partner effectively with developers.

IDSA commends the BARDA Influenza and Emerging Disease Program for taking great strides to advance our knowledge and ability to produce a safe and efficacious pre-pandemic vaccine. However, many challenges remain, including complexities of vaccine manufacturing and surge capacity as well as the timely production of a more closely-matched pandemic strain vaccine. For this critical program to continue to move forward, IDSA strongly encourages the Congress to fund the Influenza and Emerging Disease Program at \$1.29 billion, to be available over multiple years. This increase over the budget proposal would include \$308 million for advanced vaccine development, \$234 million for vaccine stockpiling, and \$248 million for antiviral stockpiling.

Funding for pandemic influenza preparedness at other agencies within HHS has also been proposed in fiscal year 2009. We were greatly disappointed last year when the final omnibus appropriations bill included only \$74 million for pandemic flu, rather than the \$948 million requested. This year's budget request would fund ongoing pandemic flu activities at the Federal agencies at \$313 million. IDSA strongly supports this funding.

Today's investment in infectious disease research, prevention, and treatments will pay significant dividends in the future by dramatically reducing health care costs and improving the quality of life for millions of Americans. In addition, U.S. leadership in infectious diseases research and prevention will translate into worldwide health benefits. We urge the subcommittee to continue to demonstrate leadership and foresight in this area by appropriating the much-needed resources outlined above in recognition of the lives and dollars that ultimately will be saved.

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PREPARED STATEMENT OF THE INTERNATIONAL FOUNDATION FOR FUNCTIONAL  
GASTROINTESTINAL DISORDERS

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2009

A minimum 6.5 percent Funding Increase for the National Institutes of Health and its Institutes and Centers.

Urge the National Institutes of Health to Expand the Research Portfolios on Functional Gastrointestinal Disorders, Like Irritable Bowel Syndrome.

Provide Adequate Resources for the National Institutes of Health to Effectively Implement the Soon-to-be-Released Long-Range Research Plan for Digestive Diseases, Currently Being Drafted by the National Commission on Digestive Diseases.

Thank you for the opportunity to present this written statement regarding the importance of functional gastrointestinal and motility disorders research.

Since our establishment in 1991, the International Foundation for Functional Gastrointestinal Disorders (IFFGD) has been dedicated to increasing awareness of functional gastrointestinal and motility disorders among the public, health professionals, and researchers. On the federal level, we are currently assisting the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) with creation of their Long-Range Research Plan for Digestive Diseases as a member of the National Commission on Digestive Diseases (NCDD). Also, IFFGD recently worked with the NIDDK, the National Institute of Child Health and Human Development (NICHD), and the Office of Medical Applications of Research (OMAR) on the NIH State-of-the-Science Conference on the Prevention of Fecal and Urinary Incontinence in Adults, which was held in December of last year.

The majority of diseases and disorders we address have no cure and treatment options are often limited. We have yet to completely understand the mechanisms of the underlying conditions. Patients face a life of learning to manage a chronic illness that is accompanied by pain and an unrelenting myriad of gastrointestinal 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 human toll is not only on the individual but also on the family. In essence, these diseases account for lost potential for the individual and society.

## IRRITABLE BOWEL SYNDROME (IBS)

IBS strikes people from all walks of life. It affects 30 to 45 million Americans and results in significant human suffering and disability. This chronic disease is characterized by a group of symptoms, which include abdominal pain or discomfort associated with a change in bowel pattern, such as loose or more frequent bowel movements, diarrhea, and/or constipation. Although the cause of IBS is unknown, we do know that this disease needs a multidisciplinary approach in research and treatment.

IBS can be emotionally and physically debilitating. Due to persistent bowel unpredictability, individuals who suffer from this disorder may distance themselves from social events, work, and even may fear leaving their home.

A strategic plan for IBS is currently a component of the NCDD's Long-Range Research Plan for Digestive Diseases. For fiscal year 2009, IFFGD urges Congress to review the NCDD's Long-Range Research Plan for Digestive Diseases and provide NIDDK with the resources necessary to effectively implement the plan's recommendations.

## 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 in 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.

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 can cause fecal incontinence. 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 increasingly aged 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 process of stigmatization as it applies to the experience of individuals with fecal incontinence.

In December of last year, 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 2009, 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 complication is Barrett's esophagus, a potentially pre-cancerous 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.

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 symptoms of differing 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 provide the necessary funding for the expansion of the research activities at NIDDK and the Office of Research on Women's Health (ORWH) regarding functional gastrointestinal (GI) disorders and motility disorders. This increased funding will allow for the growth of new research on functional GI disorders and motility disorders at NIDDK and ORWH, and implementation of the strategic plan on IBS research.

Recent years of near level-funding at NIH have negatively impacted the mission of its Institutes and Centers. For this reason, IFFGD applauds efforts like Senators Tom Harkin (D-IA) and Arlen Specter's (R-PA) adopted amendment to the fiscal year 2009 Senate Budget Resolutions which calls on appropriators to provide NIH with a 10.3 percent funding increase. IFFGD urges this Subcommittee to show strong leadership in pursuing such a substantial funding increase.

For fiscal year 2009, IFFGD recommends a funding increase of at least 6.5 percent for NIH and its Institutes and Centers.

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 2009 funding for myeloma cancer programs. The IMF, the oldest and largest myeloma foundation, is 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 they need and deserve, the IMF advocates on-going and significant Federal funding for myeloma research and its application. The IMF stands ready to work with pol-

icymakers to advance policies and programs that work toward prevention and a cure for myeloma and for all other forms of cancer.

#### MYELOMA BACKGROUND

Myeloma is a cancer in the bone marrow affecting production of red cells, white cells and stem cells. It is also called “multiple myeloma,” because multiple areas of bone marrow may be involved. Myeloma is the second most common blood cancer after lymphomas, affecting an estimated 750,000 people worldwide and its prevalence appears to be increasing significantly.

No one knows the exact causes of myeloma. Doctors can seldom explain why one person develops this disease and another does not. Research has shown that people with certain risk factors such as age and race are more likely than others to develop myeloma. Growing older increases the chance of developing multiple myeloma as most people with myeloma are diagnosed after age 65. However, in recent years the diagnosis of myeloma in people 40 years of age and younger appears to have become more common as our ability to detect and diagnose this disease has improved. The risk of myeloma is highest among African Americans and lowest among Asian Americans.

Scientists are studying other possible risk factors for myeloma. Toxic chemicals (for example, agricultural chemicals and Agent Orange used in Vietnam), radiation (including atomic radiation), and several viruses (including HIV, hepatitis, herpes virus 8, and others) are associated with an increased risk of myeloma and related diseases.

According to the American Cancer Society, 19,920 Americans will be diagnosed with myeloma and 10,690 will lose their battle with this disease in 2008. Even while they live with the disease, myeloma patients can suffer debilitating fractures and other bone disorders, severe side effects of their treatment, and other problems that profoundly affect their quality of life, and significantly impact the cost of their health care. Despite these grim statistics, significant gains in the battle against myeloma have been made through our Nation’s investment in cancer research and its application. Research holds the key to improved myeloma prevention, early detection, diagnosis, and treatment, but such breakthroughs are meaningless unless we can deliver them to all Americans in need.

#### 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). The IMF has joined with the broader health community in advocating a \$30.81 billion budget for NIH in fiscal year 2009. This will allow NIH to sustain and build on its research progress resulting from the recent doubling of its budget while avoiding the severe disruption to that progress that would result from a minimal increase. Myeloma research is producing extraordinary breakthroughs—leading to new therapies that translate into longer survival and improved quality of life for myeloma patients. Although myeloma was once considered a death sentence with limited options for treatment, today there are dozens of drugs in clinical trials for myeloma in the United States alone, and several recently-developed drug regimens can be used in sequence to help myeloma patients maintain their daily routines for years and even decades. To that end, the IMF calls upon Congress to allocate \$5.26 billion to the National Cancer Institute (NCI) in fiscal year 2009 to continue our battle against myeloma and its sequelae.

#### 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 joins with our partners in the cancer community—including One Voice Against Cancer (OVAC)—in calling on Congress to provide additional resources for the CDC to support and expand much-needed and proven efforts in such areas as cancer prevention, early detection, and risk reduction. Specifically, the IMF advocates the appropriation of \$445.5 million in fiscal year 2009 for CDC’s cancer prevention and control initiatives.

Within that allocation, the IMF specifically advocates \$5.5 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 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 \$5.5 million in fiscal year 2009 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.

#### 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 2009 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 2009 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 represents a slight increase over the amount approved by Congress last year 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 pace with inflationary impacts or increased demands for training. The situation is of particular concern given recent mine accidents and the additional training requirements that states have already put in place or that may be required under new MSHA regulations, especially those pursuant to the MINER Act.

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. In this regard, we want to express our continued strong support for the Small Mines Initiative and are hopeful that the amount budgeted for this worthwhile program will provide for the effective operation of MSHA's Small Mines Office.

In closing, we should also note that MSHA's grants to the States also allow us to provide other services to the Nation's miners and to mine operators in such areas as mine accident investigations and occupational diseases, including silicosis and "black lung".

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.

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PREPARED STATEMENT OF THE JEFFREY MODELL FOUNDATION

Mr. Chairman and members of the subcommittee: Thank you for the opportunity to present this testimony to the Subcommittee. My name is Vicki Modell and, along with my husband Fred, we created the Jeffrey Modell Foundation (JMF) in 1987 in memory of our son, Jeffrey, who died at the age of 15 as a result of a life long battle against one of the estimated 140 primary immunodeficiency (PI) diseases.

The Jeffrey Modell Foundation is an international organization with its headquarters in New York City. In the 21 years since we established it, the Foundation has grown into the premier advocacy and service organization on behalf of people afflicted with primary immunodeficiency diseases. As a demonstration of the extent to which the JMF leads in the field, please consider the following:

- The Foundation has created Jeffrey Modell Research and Diagnostic Centers at 38 academic and teaching hospitals from coast to coast in the United States and throughout the world. The Centers funded by the Jeffrey Modell Foundation are located in Boston, Los Angeles, New York City, Philadelphia, Seattle, Stanford, San Francisco, Miami, Milwaukee, Dallas, Chicago, and others. The JMF Referral Network includes 350 physicians at 180 Centers in 53 countries spanning 6 continents.
- The Foundation conducts a national physician education and public awareness campaign, currently funded with approximately \$2.9 million appropriated by this subcommittee to the Centers for Disease Control and Prevention (CDC) and awarded by contract to the JMF. To date, the Foundation has leveraged the Federal money to generate in excess of \$90 million in donated media with hundreds of thousands of placements on television, radio, print, and other public media, as well as a 30-minute program produced for PBS. The campaign has also included physician symposia, conducted for CME credits in locations throughout the country. It has also included mailings to physicians in a variety of specialist and primary care fields, including pediatrics and several pediatric specialties, family practice, and internal medicine, as well as school nurses, clinical and registered nurses and daycare centers.
- In addition, the Foundation has long been a provider of direct patient services such as KIDS Days that give young people an opportunity to meet and share experiences with others similarly situated in their communities in a fun atmosphere that encourages a feeling of normalcy in patients. This was something that Jeffrey never experienced and one of the things we wanted to address from the beginning of the Foundation. We also offer a hotline that serves patients 24 hours a day.

First and foremost, Mr. Chairman, I am here today to thank you and all the members of this subcommittee on both a personal and a professional level. Personal because whenever Fred and I come to Washington, whether it is to testify here before the committee or to meet with the members of the subcommittee individually in their offices, every Member of Congress and every member of your staffs are unfailingly polite, courteous, interested and caring. The response that we receive, and the warmth and understanding that we enjoy, makes this a labor of love for us.

Professional because over the 16 years that we have been coming to Washington, we have been given the opportunity to build a partnership with the Congress, the Centers for Disease Control and Prevention, the National Institutes of Health, as well as with our own supporters in the private sector, including industry and other concerned donors. We believe that we have maximized the benefits for patients from the support that this subcommittee has afforded us. I would like to take a few minutes to discuss where we are and, more importantly, where we are going with your continued support.

CENTERS FOR DISEASE CONTROL AND PREVENTION

This subcommittee is currently funding CDC with \$2.9 million for physician education and public awareness of immune deficiencies. I am delighted to report that the President's recommended budget for fiscal year 2009 continues the program at its fiscal year 2008 level. The Jeffrey Modell Foundation operates the program under a contract with CDC, with whom we have a very strong relationship.

Since the campaign's inception, it has generated nearly \$100 million in donated media, including television and radio spots, magazine ads, billboards, airport signs



and other print media. It has also enabled us to raise additional funding from the private sector—both individuals and the pharmaceutical industry. To this point, every \$1 provided by the subcommittee to this program has been leveraged into more than \$10 for this education and awareness program. Also, visits to the website have increased by more than 50 percent from approximately 600,000 per month to over 900,000 per month. Continuing to incorporate “new media” into the campaign will extend its reach, particularly to young parents and others.

Most importantly, Mr. Chairman, I am delighted to report to you that the program that this subcommittee has funded is having exactly the impact that all of us hoped it would when it was created. Allow me to give you some specifics. This data was recently published in the scientific journal *Immunology Research*. 169 physicians from 85 Jeffrey Modell Diagnostic and Referral Centers responded to a survey relating to PI. Baseline reports for the period before the Education and Awareness program and reports for the year following the program were compared. The results were striking.

- The number of patients diagnosed at these centers went from approximately 5,900 at baseline to over 31,000 in the follow up, an annual increase of 132 percent.

- Patient referrals from generalists to specialists increased by 87 percent.

- The number of diagnostic tests performed went up by an astounding 656 percent.

- There was a 102 percent annual increase in the number of patients receiving treatment.

- Finally, patients receiving intravenous immunoglobulin went up by 81 percent.

But, it is fair of this subcommittee to ask “so what?” What difference does it make to the health of these patients if they are now in treatment? What is the real impact in a real world sense on the patients that are found?

Eighty five centers responded to a survey assessing 532 patient records and again the data are amazing. Comparing patients’ charts for the year before diagnosis and the year after diagnosis, the following conclusions are reached:

- Acute infections are down 72 percent.

- Physician/hospital/ER visits are down 83 percent.

- Severe infections are down 86 percent.

- Pneumonias are down 79 percent.

- Days with chronic infections are down 72 percent.

- Time on antibiotics is down 56 percent.

- Days in the hospital are down 73 percent.

- School/work days missed are down 74 percent.

But, again, the subcommittee might ask, “How does diagnosing and treating patients improve the public health and help reduce health care costs?” That is a fair question and one we are prepared to answer.

The economic impact of PI diagnosis was carefully assessed comparing the costs of treatment before diagnosis and after. In round numbers what we learned was that the average annual cost of health care for an undiagnosed patient is \$103,000 per year. The same costs for the same patients in the year after diagnosis are \$23,000. The gross annual savings is \$80,000 per patient. The NIH estimates that at least 500,000 cases of PI are undiagnosed in the United States, thus the economic impact of undiagnosed PI patients to the healthcare system of the United States totals over \$40 billion annually.

Mr. Chairman, this program is working. We are respectfully requesting that the funding level in the President’s budget receive just a five percent cost of living increase so that we can continue to build on the success we have had to date.

#### NEWBORN SCREENING PROGRAM

As described above, early diagnosis is critical to the health of patients and to saving the healthcare system money. And, there are few better examples of early diagnosis than newborn screening. The JMF has worked long and hard to support the development of a newborn screening program for Severe Combined Immune Deficiency (SCID), the most severe and deadly form of PI.

Early detection of SCID through newborn screening is vital because bone marrow transplants cure over 98 percent of infants who have the procedure before developing any serious infections. The treatment costs less than \$10,000. However, if an infant receives a transplant after developing severe infections, the success rate is only between 50 and 60 percent; the costs associated with the treatment of these infants can be as high as \$1 million.

After working with NIH and a private company to develop a screening test for SCID, we collaborated with the CDC to hold a meeting in Atlanta on this topic with

scientists and public health officials from around the country. The result was a commitment from the State of Wisconsin to run a pilot program for SCID testing. The pilot program screened 10,000 babies in 2007. I am delighted to report that this program developed into general population screening effective January 1, 2008. Every baby born in Wisconsin is being tested for SCID. Next year, Mr. Chairman, I hope to report on the success of this project.

The Wisconsin project was funded by the State, Children's Hospital and the JMF. The fiscal year 2008 Omnibus Appropriations bill contains \$1.0 million to expand this pilot program to at least two additional States. We hope to have results for you on this next year as well. And, Mr. Chairman, we are asking that the \$1.0 million be restored to the fiscal year 2009 appropriations bill so that this life-saving and money-saving endeavor can go forward in more States.

#### NATIONAL INSTITUTES OF HEALTH

Mr. Chairman, in addition to CDC, the Jeffrey Modell Foundation has a long history of working closely with the National Institutes of Health on the scientific research issues that surround primary immunodeficiencies. We have long enjoyed a strong collaborative relationship with several institutes and want to inform the subcommittee of the exciting new initiative we are undertaking.

In our frequent meetings with the world's top researchers in this field, we have become increasingly concerned that the constraints on the NIH budget are having a negative impact on researchers' ability to stay in this field and to develop the next generation of PI researchers.

After doing a series of meetings around the NIH, we have reached an agreement to enter into a collaborative research program. The JMF will bring its resources to the NIH and match Federal funding on a research initiative that will be targeted at jumpstarting the field and moving the science forward through the normal peer-review channels.

Our partners in this endeavor—NIAID, NICHD, NHLBI and NIDDK—are working now to craft the announcement of the availability of this funding. We are envisioning a multi-institute, multi-disciplinary program that will generate up to \$14 million in new research. There remains so much to learn, particularly when it comes to the causes and cures at the molecular level. For this program, all we are seeking is a strongly encouraging paragraph of report language that has been submitted by at least two of your colleagues.

Again, this is an initiative that we are looking forward to coming back to you next year with good news about the success we anticipate we will be having by the time your committee reconvenes.

#### CONCLUSION

With the support the Jeffrey Modell Foundation has received from this subcommittee over the years, we have been able to increase the public's awareness of PI and most importantly improve and save lives. We are grateful for your past and continued support. While we understand that the subcommittee must make difficult decisions in this fiscal environment, please remember that the Foundation has successfully leveraged Federal dollars to expand the reach of all of our activities. Frankly, the collaboration between the Federal Government and the Jeffrey Modell Foundation has been a model for successful public-private collaborations. The impact of every Federal dollar spent on the education and awareness campaign, on newborn screening, and on research has been exponentially increased by our commitment to bring the Foundation's resources to bear. This is a real working partnership, because as always we ask only for a hand, never for hand-out.

Mr. Chairman, again, we are delighted to have the opportunity to present to the subcommittee and stand ready to continue to work with you.

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#### PREPARED STATEMENT OF THE MARCH OF DIMES FOUNDATION

The 3 million volunteers and 1,400 staff members of the March of Dimes Foundation appreciate the opportunity to submit the Foundation's Federal funding recommendations for fiscal year 2009. The March of Dimes is a national voluntary health agency working to improve the health of mothers, infants and children by preventing birth defects, premature birth and infant mortality through research, community services, education, and advocacy. The volunteers and staff of the March of Dimes urge the subcommittee to provide the funding increases recommended below.

## NATIONAL INSTITUTES OF HEALTH (NIH)

The March of Dimes joins the larger research community in recommending a \$1.9 billion increase in funding for the NIH bringing total Federal support to over \$31 billion. Since the doubling of NIH's budget was completed in 2003, the agency has lost 15 percent of its purchasing power due to biomedical inflation. With the threats to children's health, and the economic and societal costs associated with long-term disabilities and care, it is imperative to increase the overall investment in medical research.

*Office of the Director*

The March of Dimes strongly supported congressional approval of \$110.9 million for the National Children's Study (NCS) in fiscal year 2008 Consolidated Appropriations Act, allowing for implementation of the next phase of the study. The Foundation urges the subcommittee to include within the Office of the Director \$192.3 million (\$81.4 million increase) for the NCS in fiscal year 2009. While the amount may seem substantial, it is dwarfed by the cost of treating the diseases and conditions the study is designed to address. The NCS holds the potential to provide data on the causes of birth defects and premature birth, including, but not limited to, the role that diabetes and pre-diabetic conditions may play in birth defects, and the impact of infection and inflammation in stimulating pre-term delivery.

*National Institute of Child Health and Human Development (NICHD)*

The March of Dimes recommends \$1.34 billion for NICHD in fiscal year 2009. In recent years, the NICHD has made a major commitment to enhance our understanding of the factors that result in premature birth and to develop strategies to prolong pregnancy so that infants are born at full term. Since 1981, the preterm birth rate in the United States has increased 30 percent resulting in 543,000 premature births in 2006—or 1 in 8 newborns. Any woman can have a preterm baby and in about a third of the cases, the causes remain unknown.

In 2006, the Institute of Medicine (IOM) report entitled, "Preterm Birth: Causes, Consequences and Prevention" found that the annual economic burden associated with preterm birth in the United States was at least \$26.2 billion, or \$51,600 per infant born preterm, and that there are persistent disparities in preterm birth rates among different racial and ethnic groups.

The NICHD supported research including work done through the Maternal-Fetal Medicine Units (MFMU), Neonatal Research (NR) and the Genomics and Proteomics Networks must continue. Specifically, over the past year NICHD funded clinical trials to investigate the impact of administering a derivative of progesterone to reduce preterm labor and delivery in women with a short cervix and women with multiple gestations. The findings from these clinical trials will further enhance our understanding of the causes of preterm labor and delivery.

## CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

*National Center on Birth Defects and Developmental Disabilities (NCBDDD)*

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. Of particular interest to the March of Dimes is NCBDDD's birth defects program that includes surveillance, research and prevention activities. For fiscal year 2009, the Foundation requests an increase of \$3 million to support the National Birth Defects Prevention Study and an additional \$2 million for folic acid education. These modest increases are sorely needed to continue progress in reducing the incidence of birth defects.

As the causes of nearly 70 percent of birth defects are unknown, it is important to continue to fund the National Birth Defects Prevention study—the largest case controlled study of birth defects ever conducted—to unveil the causes and to prevent birth defects. The nine centers located in Massachusetts, New York, North Carolina, Georgia, Texas, Arkansas, Iowa, Utah, and California participating in the study identify infants with major birth defects; interview mothers about medical history, environmental exposures and lifestyle before and during pregnancy; and collect DNA samples to study gene-environment interactions. With nearly 11 years worth of data and samples collected and \$85 million invested, this study is a rich source of information on possible causes of birth defects.

Several years of erosion in funding make it critical to provide a \$3 million increase for the National Birth Defects Prevention Study in fiscal year 2009. Without this increase CDC will be unable to maintain operation of all nine Centers of Excellence and will lose the capacity to conduct important analyses of genetic samples.

NCBDDD also funds State birth defects tracking systems, programs to prevent birth defects and improve access to health services for children with birth defects. Surveillance forms the backbone of a vital, functional and responsive public health network. Additional resources are sorely needed to help States seeking assistance. Finally, NCBDDD is conducting a national public and health professions education campaign designed to increase the number of women taking folic acid. CDC estimates that up to 70 percent of neural tube defects (NTDs) could be prevented if all women consume folic acid prior to becoming pregnant and although progress is being made, according to a recent CDC analysis, 60 percent of women of child-bearing age are still not consuming the daily recommended amount of folic acid making it more important than ever that CDC be provided the resources it needs to expand its educational campaign.

#### *Safe Motherhood/Infant Health*

The National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health works to promote optimal reproductive and infant health. The March of Dimes recommends a \$5 million increase, as authorized in the PREEMIE Act (Public Law 109–450), for CDC to expand epidemiological studies to evaluate the social, biological, and medical factors associated with preterm birth, in an effort to identify ways to prevent preterm birth and racial disparities. Finding the causes and preventing preterm birth is complex and requires research that examines medical, social, infection related, genetic, environmental and behavioral factors. Currently, CDC works with a number of universities and organizations to support research into the causes of preterm birth and the reasons for disparities between racial and ethnic groups. It is essential that this work continue.

#### *National Immunization Program*

CDC's National Immunization Program provides grants to State, local, and territorial public health agencies to reduce the incidence of disability and death resulting from vaccine preventable diseases. Yet nearly 1 million 2 year olds in the United States have not received the one or more recommended vaccines. The March of Dimes urges the Subcommittee to continue its longstanding policy of ensuring that Federal vaccine programs are well funded. For fiscal year 2009, the March of Dimes recommends \$802.4 million. These funds are needed to reach more children as well as to account for vaccine price increases and introduction of new vaccines.

#### *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. For fiscal year 2009 the Foundation recommends a funding level of \$101.254 million for CDC's fiscal year 2009 global polio eradication program. The U.S. Government must maintain its commitment to the worldwide polio eradication initiative that promises to save lives and reduce unnecessary health-related costs globally.

#### *National Center for Health Statistics*

The National Center for Health Statistics (NCHS) provides data essential for both public and private research and programmatic initiatives. The National Vital Statistics System and the National Survey on Family Growth, for example, are the principal sources of information on the utilization of prenatal care and on birth outcomes, including preterm delivery, low birthweight and infant mortality. The March of Dimes supports a funding level of \$125 million, an increase of \$11 million over fiscal year 2008, to ensure the continuation of NCHS' central role in monitoring the Nation's health.

### HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

#### *Newborn Screening*

Newborn screening is a vital public health activity used to identify and treat genetic, metabolic, hormonal and functional conditions that, if left untreated, can cause disability, mental retardation, serious illnesses or even death. Parents are often unaware that while nearly all babies born in the United States are screened, the number and quality of these tests vary from State to State. The March of Dimes, the American Academy of Pediatrics and the American College of Medical Genetics recommend that every baby born in the United States be screened for 29 treatable conditions. As of March 2008, only 19 States and the District of Columbia screen for all 29 conditions.

Federal support for State newborn screening is provided through the Maternal and Child Health Block Grant, Special Projects of Regional and National Signifi-

cance (SPRANS). The Foundation urges a \$4.9 million SPRANS set-aside for newborn screening activities (an increase of \$3 million over fiscal year 2008). This funding is needed to support State efforts to improve programs, acquire innovative testing technologies and increase capacity to reach and educate health professionals and parents with accurate information on newborn screening programs and follow up services.

#### *Healthy Start*

The Healthy Start Initiative is a collection of community-based projects focused on reducing infant mortality, low birthweight and racial disparities in perinatal outcomes. The March of Dimes strongly supports Healthy Start and recommends a funding level of \$110 million in fiscal year 2009 to help decrease the Nation's unacceptably high rate of infant mortality.

#### *Maternal and Child Health Block Grant*

Title V of the Social Security Act, the Maternal and Child Health (MCH) Block Grant, provides assistance for community-based programs (i.e.: home visiting, respite care for children with special health care needs and supplementary services for pregnant women and children enrolled in Medicaid and SCHIP), but Federal support has not kept pace with increased enrollment and demand for services. The March of Dimes therefore recommends full funding of the MCH Block Grant at the authorized level of \$850 million.

### FISCAL YEAR 2009 FEDERAL FUNDING RECOMMENDATIONS

[In millions of dollars]

Program	Fiscal year 2008 funding	March of Dimes fiscal year 2009 recommendation
National Institutes of Health (Total) .....	29,230	31,130
National Children's Study .....	110.9	192.3
National Institute of Child Health & Human Development .....	1,255	1,340
National Human Genome Research Institute .....	487	519
National Center on Minority Health and Disparities .....	200	213
Centers for Disease Control and Prevention (CDC) .....	6,375	7,400
Save Motherhood/Infant Health (NCCDPHP) .....	42.3	47.3
Birth Defects Research & Surveillance .....	13.7	16.7
Folic Acid Education Campaign .....	2	4
Immunization .....	523	802
Polio Eradication .....	98	101
National Center for Health Statistics .....	114	125
Health Resources and Services Administration (Total) .....	6,948	7,948
Maternal and Child Health Block Grant .....	666	850
Newborn Screening .....	1.9	4.9
Newborn Hearing Screening .....	12	12
Consolidated (Community) Health Centers .....	2,065	2,313
Healthy Start .....	100	110
Agency for Healthcare Research and Quality .....	335	360

### PREPARED STATEMENT OF THE MEDICAL LIBRARY ASSOCIATION AND THE ASSOCIATION FOR ACADEMIC HEALTH SCIENCES LIBRARIES

#### SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2009

(1) A minimum 6.5 percent funding increase for the National Institutes of Health and the National Library of Medicine.

(2) Support for the National Library of Medicine's Urgent Facility construction needs.

(3) Continued support for the Medical Library community's role in the National Library of Medicine's Outreach, Telemedicine, Disaster Preparedness and Health Information Technology Initiatives.

On behalf of the Medical Library Association (MLA) and the Association of Academic Health Sciences Libraries (AAHSL), thank you for the opportunity to present testimony regarding fiscal year 2009 appropriations for the National Library of Medicine (NLM).

MLA is a nonprofit, educational organization with more than 4,500 health sciences information professional members worldwide. Founded in 1898, MLA pro-

vides lifelong educational opportunities, supports a knowledgebase of health information research, and works with a global network of partners to promote the importance of quality information for improved health to the health care community and the public.

AAHSL is comprised of the directors of the libraries of 142 accredited American and Canadian medical schools belonging to the Association of American Medical Colleges (AAMC). AAHSL's goals are to promote excellence in academic health sciences libraries and to ensure that the next generation of health professionals is trained in information-seeking skills that enhance the quality of healthcare delivery.

As you are aware, recent years of near level-funding at the National Institutes of Health (NIH) have negatively impacted the mission of NLM. For this reason, MLA and AAHSL applaud efforts like Senators Tom Harkin (D-IA) and Arlen Specter's (R-PA) adopted amendment to the fiscal year 2009 Senate Budget Resolutions which calls on appropriators to provide NIH with a 10.3 percent funding increase. MLA and AAHSL are urging this Subcommittee to show strong leadership in pursuing such a substantial funding increase. For fiscal year 2009, MLA and AAHSL are recommending a funding increase of at least 6.5 percent for NIH and NLM. A 6.5 percent funding increase would allow NLM to adequately address 5 key areas that are at the core of its mission. They are:

#### THE GROWING DEMAND FOR THE NLM'S BASIC SERVICES

It is a tribute to NLM that demand for its services and expertise continues to grow. As the world's foremost digital library and knowledge repository in the health sciences, NLM provides critical infrastructure in the form of data repositories and integrated services, such as GenBank and PubMed which are helping to advance science to individualized medicine based on our unique genetic differences.

As the world's largest and most comprehensive medical library, services based on NLM's traditional 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. NLM is a national treasure and support for its programs and services could not be more important at the present time. 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 all come to expect.

#### OUTREACH AND EDUCATION

NLM has taken a leadership role in promoting educational outreach aimed at public libraries, secondary schools, senior centers and other consumer-based settings. 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.

Currently at the University of Iowa (UI), the Empowering Public Health/Patient Safety Outreach through the Community Partnerships program is providing train-the-trainer sessions in local settings to instruct public health educators and community program planners on developing patient safety programming for consumers.

Perhaps most notably, with help from the 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 with access to high quality, easily understood health information. "Go Local" is another exciting feature of MedlinePlus that enables local and state agencies and others to participate by creating sites that link the MedlinePlus information seeker to local pharmacies, doctors and other health and social services. This service also provides a platform for enhancing public access to the information needed to prepare for and respond to disasters and emergencies. For example, UI librarians have begun a project to link MedlinePlus health topic pages to local health resources by geographic areas, including hospitals, physicians, nursing homes, support groups, health screening providers and many others. This will allow health consumers to link directly from a health topic, for example asthma, to local services such as clinics, pulmonary specialists, and support groups in the geographic area selected.

Yet another service is NLM's clinical trials database, which lists more than 53,000 United States and international trials for a wide range of diseases. The clinical trials database is a free and invaluable resource to patients and families who are interested in participating in cutting-edge treatments for serious illnesses. Last September, Congress took a major step to improve the transparency of clinical trials for drugs and devices by passing legislation that greatly expands mandatory registration of clinical trials in ClinicalTrials.gov, requires submission of summary trial results data for the first time, and imposes significant penalties for non-compliance.

MLA and AAHSL thank Congress for efforts to improve public access to information regarding the results of clinical trials, but remain concerned that no additional funds have been appropriated to support this major new NLM responsibility. MLA and AAHSL applaud the success of NLM's outreach initiatives, particularly those initiatives that reach out to medical libraries and health consumers. We ask the subcommittee to encourage NLM to continue to coordinate its outreach activities with the medical library community in fiscal year 2009.

#### EMERGENCY PREPAREDNESS AND RESPONSE

MLA and AAHSL are pleased that NLM has established a Disaster Information Management Research Center to expand NLM's capacity to support disaster response and management initiatives, as recommended in the NLM Board of Regents Long Range Plan for 2006–2016, we ask the subcommittee to show its support for this initiative, which has a major objective ensuring continuous access to health information and effective use of libraries and librarians when disasters occur. Following Hurricane Katrina, NLM worked with health sciences libraries across the country to provide health professionals and the public with access to needed health and environmental information by: (1) quickly compiling web pages on toxic chemicals and environmental concerns, (2) rapidly providing funds, computers and communication services to assist librarians in the field who were restoring health information services to displaced clinicians and patients and (3) rerouting interlibrary loan requests from the afflicted regions through the National Network of Libraries of Medicine.

#### HEALTH INFORMATION TECHNOLOGY AND BIOINFORMATICS

NLM has played a pivotal role in creating and nurturing the field of medical informatics, most notably through the creation of GenBank and a wide array of related scientific data and analysis tools which provide critical infrastructure for the Nation's researchers.

For nearly 35 years, NLM has supported informatics research and 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 health record systems have benefited from NLM grant support.

MLA and AAHSL encourage the Subcommittee to continue their support of NLM's medical informatics and genomic science initiatives. MLA and AAHSL also request support for health information technology initiatives at the Office for the National Coordinator for Health Information Technology and the Agency for Healthcare Research and Quality that build upon initiatives housed at NLM.

#### NLM'S FACILITIES NEEDS

Over the past two decades NLM has assumed many new responsibilities, particularly in the areas of biotechnology, health services research, and high performance computing and consumer health. As a result, NLM has had tremendous growth in its basic functions related to the acquisition, organization and preservation of an ever-expanding collection of biomedical literature and expanded staff. NLM now houses 1,100 staff in a facility built to accommodate only 650. This increase in the volume of biomedical information and in the number of personnel has led to a serious space shortage. Digital archiving has added to the challenge, as materials must often be stored in multiple formats and as new digital resources consume increasing amounts of storage space. As a result, the space needed for computing facilities has also grown, further squeezing out staff. In order for NLM to continue its mission as the world's premier biomedical library, a new facility is urgently needed. The NLM Board of Regents has assigned the highest priority to supporting the acquisition of a new facility. Further, Senate Report 108–345 that accompanied the fiscal year 2005 appropriations bill acknowledged that the design for the new research facility at NLM had been completed, and the subcommittee urged NIH to assign a high priority to this construction project so that the information-handling capabili-

ties and the good of biomedical research are not jeopardized. MLA and AAHSL encourage the subcommittee to provide the resources necessary to construct a new facility for NLM.

Thank you for the opportunity to present the views of the medical library community.

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PREPARED STATEMENT OF THE MELANOMA RESEARCH FOUNDATION

Mr. Chairman and members of the subcommittee, I thank you for providing me the opportunity to submit testimony to the Senate Labor, Health and Human Services Appropriations Subcommittee. I am Randy Lomax, and I am a melanoma survivor and chairman of the board of the Melanoma Research Foundation.

MELANOMA RESEARCH FOUNDATION

The Melanoma Research Foundation (MRF) is committed to research, education and advocacy in our national battle to find more effective treatments and, ultimately, a cure for this disease. We are the primary U.S. non-profit organization serving the melanoma community and welcome your partnership and support of our efforts.

Our programs and services include:

- Research.*—In 2008 we are investing \$1 million to fund melanoma research grants. These include 14 Career Development Awards (\$50,000 per year for a maximum of 2 years) and 3 Established Investigator Awards (\$100,000 per year for a maximum of two years). We are committed to attracting the best and brightest young scientists to melanoma research and to funding long-term scientists on the cutting edge of finding answers. We are also supporting the Society for Melanoma Research, the international organization of melanoma scientists, through an annual grant which supports ongoing efforts as well as their annual educational convention.
- Education.*—In addition to this website, we manage the Melanoma Patients Information Page ([www.melanoma.org](http://www.melanoma.org)), the international chat room for the melanoma community; and distribute a quarterly newsletter of information, activities and resources. MRF also sponsors educational symposia around the United States. I encourage you to check our website to see where and when these symposia will be held in 2008. In 2007 we initiated a “Melanoma 101” teleconference with a leading melanoma clinician that provided a personal opportunity to both learn more about this disease, as well as asking questions of a leading physician in the melanoma field. We will continue these teleconferences in 2008.
- Advocacy.*—MRF is active in Washington, DC. We work to keep melanoma awareness a high priority with elected officials and to encourage their support of research funding. As well, we are in ongoing communications with the National Cancer Institute of the National Institutes of Health. To increase our presence with federal officials, MRF spearheaded the creation of a Melanoma Alliance of all melanoma organizations in the United States and is the primary supporter of this new organization.

MELANOMA AND SKIN CANCER FACTS

The statistics on melanoma and skin cancer are staggering and impact all Americans. The following background information on melanoma has been taken from the introductory section of the National Cancer Institutes’ “Community-Oriented Strategic Action Plan for Melanoma Research”:

- Incidence of Melanoma is High and is Increasing.*—The American Cancer Society estimated that in 2007, there were almost 60,000 new cases of melanoma, the most serious form of skin cancer, and more than 8,000 deaths. The NCI has documented a 619 percent increase in the annual incidence of melanoma and a 165 percent increase in the annual mortality from 1950 to 2000. Melanoma continues to be the fifth leading type of new cancer diagnosis in the United States. The mortality rate of melanoma for persons ages 16–29 is exceeded only by breast cancer, cervical cancer and non-Hodgkin’s Lymphoma. Furthermore, while the death rates for other common cancers such as breast, colon, and prostate cancer are declining, death rates for melanoma have increased over the past 25 years.
- Melanoma Results in Lost Years in the Lives of Americans.*—Melanoma primarily affects individuals in the prime of their lives—the mean age for diagnosis of melanoma is 50, while for many other cancers it is 65 to 70. Advanced



melanoma takes a greater toll than other solid tumors in terms of productive life-years lost. Approximately \$1.5 billion is spent in the United States each year on treatment of melanoma.

Despite these alarming statistics, there is no cure for melanoma. There has been progress in the clinical management of melanoma, but the only curative treatment available is surgery to remove the primary tumor or lymph nodes prior to metastasis. For patients with advanced melanoma, their median lifespan is less than one year.

#### SKIN CANCER PREVENTION AND CDC

Research funding for the prevention of skin cancer has been disproportionately low. Skin cancer stands alone as the cancer for which incidence and mortality are rising unabated while the best means for combating the disease, prevention and early detection, continues to be severely underutilized. In part, this is related to the fact that less than 2 percent of the Centers for Disease Control and Prevention's cancer control budget is devoted to prevention of skin cancer. For fiscal year 2009, we are requesting that the CDC's skin cancer prevention program receive \$5 million for public and professional education.

#### MELANOMA RESEARCH AND THE NIH

The Melanoma Research Foundations joins the biomedical advocacy community within urging the Appropriations Committee to provide a 6.5 percent increase in funding for the National Institutes of Health in its fiscal 2009 Labor, Health and Human Services, Education and Related Agencies Appropriations bill.

However, we understand the challenges facing the Appropriations Committee, and the problems created by the President's proposed budget for non-defense discretionary spending, which fails to offer any increase for NIH over the fiscal 2008 enacted level. For that reason, we respectfully request the Committee's support for report language encouraging the National Cancer Institute to be more strategic in investing the limited dollars for melanoma research that it does receive.

By way of background, we at MRF have been working with Congress, the NCI, and the extramural research community, to develop a strategic plan for melanoma research. The fiscal 2007 Senate Appropriations Committee (Senate Report No. 109-287) requested that the NCI to convene a panel of extramural and intramural scientists and consumers to identify the current shortfalls and promise of melanoma research and develop a 5-year strategic plan for melanoma research that recommends new directions and targets for future research.

In response to that language, the NCI convened a workshop in February 2007, and from the recommendations of that meeting prepared a "Community-Oriented Strategic Action Plan for Melanoma Research," which was submitted to Congress in July of last year. This Strategic Plan identified three over-arching transformational melanoma research opportunities: reducing melanoma mortality through prevention and early detection; streamlining the development of personalized melanoma diagnosis and treatment; and improving melanoma survival. The panel also identified three cross-cutting, resource-building initiatives that are needed to support efforts to address the three transformational research opportunities: creating a Melanoma Investigators Consortium; promoting sharing of melanoma biospecimens, cell lines, animal models, and research data; and creating a critical mass of researchers in melanoma.

The Congress renewed its interest in NCI's progress in implementing the recommendations of the "Strategic Plan for Melanoma Research" in the fiscal 2008 Senate Appropriations Committee Report. That report "strongly encourage[d] the NCI to devote sufficient funds in the areas of research opportunity identified by the plan and issue program announcements in those areas." The Appropriations Committee went on to request the Cancer Institute "to report by July 1, 2008, on steps it has taken to implement the plan."

Mr. Chairman, the melanoma advocacy and extramural research community have been working with NCI and we agree that there are specific opportunities NCI can take advantage of to advance melanoma research. Those opportunities are:

- targeted therapies in melanoma, including searching for the genes that drive melanoma, inhibiting pathways that drive melanoma, and developing biomarkers for classification, detection, risk assessment and therapy selection;
- host response in melanoma, including developing strategies to target inhibitory immune cells and to augment the specific and innate immune response; and
- melanoma prevention, including identification of mechanisms by which intense sun exposure lead to the development of melanoma, developing applications of

imaging technology for early detection, and making progress toward facilitating a randomized trial of screening for melanoma.

We have included language for the fiscal year 2009 committee report that encourages the NCI to invest its melanoma research dollars on the strategic areas identified above.

Thank you, Mr. Chairman, for providing me the opportunity to represent the community of people affected melanoma and to present written testimony before the Committee on the need for increased funding for NIH and NCI and ensuring that the dollars NCI has for research in melanoma are strategically used according to the plan developed by the research community.

#### NATIONAL CANCER INSTITUTE

*Melanoma.*—The Committee is aware of the ongoing dialogue between the National Cancer Institute and the advocacy and extramural research community on prioritizing NIH-funded melanoma research, starting with the 2005 Roadmap for New Opportunities in Melanoma Research and most recently with the 2007 Community-Oriented Strategic Action Plan for Melanoma Research.

The Committee is further aware of the advocacy and research community's effort to further prioritize melanoma research into three categories: targeted therapies in melanoma (basic), host response in melanoma (clinical); and prevention, including exploring the feasibility of a randomized trial of screening for melanoma. In a period of limited resources, the Committee encourages the NCI to better target its funds to those areas of research opportunity identified above—basic, clinical, and prevention—and utilize all available mechanisms, including program announcements, to target research in those areas. The Committee requests the NCI to report by July 1, 2009, on steps it has taken to implement those strategic investments in melanoma research.

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#### PREPARED STATEMENT OF MENDED HEARTS

I am Robert A. Scott, National Advocacy Chairman for Mended Hearts Inc., a heart disease support group with more than 300 chapters across the United States and Canada. In 2007, accredited Mended Hearts volunteers visited about 3,000 heart patients in more than 400 hospitals throughout the United States.

As a walking testimony of the benefits of NIH-supported heart research, I would like to share my story. In 1998, at age forty-eight, I suffered my first heart attack while playing volleyball. While at Woonsocket, Rhode Island's Landmark Medical Center, doctors diagnosed me as suffering a so called silent heart attack. I learned that as many as 4 million Americans experience this type of episode—a heart attack with no warning.

After being stabilized, I was transferred to Roger Williams Hospital, in Providence, Rhode Island for a heart catheterization—the gold standard for diagnosis of heart problems. The procedure showed that I had a blockage in my artery that required a stent to open it. Also, it showed that the lower chamber of my heart was damaged, resulting in congestive heart failure that could be controlled with medicine. A stent was inserted in my artery in Rhode Island Hospital.

In 1999, I received another heart catheterization in Miriam Hospital because of the damage to my heart from the silent heart attack. However, this time, I was told that my artery could not be repaired with a stent and that I needed heart bypass surgery the next morning. Calling me a high risk patient because of my age and my weakened heart, my surgeon encouraged me to find a doctor in Boston because my heart might not start again. However, he assured me that if this happens they had a device that could keep me alive for only seven hours. Thank goodness, he told me that in Boston they had another device that could keep me alive for 7 months while they located a replacement heart. In less than 10 hours, I went from the possibility of needing another stent, heart bypass surgery, and a heart transplant. My journey with heart disease continued.

My next stop was to visit my local cardiologist in Woonsocket who estimated my survival rate at 20 percent, but he thought I would survive the heart bypass surgery. Thankfully, he was right and I survived heart bypass surgery.

But my journey didn't end there. My congestive heart failure was causing my heart to beat irregularly, so an implantable defibrillator was inserted to control the problem in 2002. However, this device had to be replaced nearly 4 years later. My story continues in 2007 where I started experiencing daily chest pain and shortness of breath. Yet another heart catheterization showed that I needed an additional stent, but this time in Miriam Hospital. After the procedure, the doctor told me the original heart bypass surgery was no longer effective. Although I was scared, my

doctors comforted me by explaining that a new medical innovation could save my life—a drug eluting stent. They explained that it could open up the original blockage from my silent heart attack. My doctor explained that if these state-of-the art stents had been available in 1998, I would not have had to have heart bypass surgery.

Today, heart attack, stroke and other cardiovascular diseases remain our Nation's most costly and No. 1 killer and a major cause of disability. Thanks to medical research supported by the NIH, I am alive today. I am concerned that NIH continues to invest only 7 percent of its budget on heart research and a mere 1 percent on stroke research when there are so many people in our country just like I am. Enhanced NIH funding dedicated to heart and stroke research will bring us closer to a cure for these often deadly and disabling diseases.

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#### PREPARED STATEMENT OF THE MONTGOMERY COUNTY STROKE ASSOCIATION

I am Flora Ingenhouz, a psychotherapist in private practice in Silver Spring, Maryland. I have always been in excellent health and live an active, healthy lifestyle. Doctors always commented on my low blood pressure and my excellent cholesterol numbers. But I suffered a stroke 2 years ago. It was a shock to me and my family, friends and clients.

One morning 2 years ago, when doing a load of laundry, I had no idea how to set the dials, despite the fact that I had used them weekly for the last 10 years. I stood there for what seemed an eternity before I figured out how to set the dials.

Next I went to do yoga. In one of the poses, I noticed my right arm was hanging limp. When my husband asked me a question, my answer was just the opposite of what I wanted to say. I caught my error and tried again, but it soon became clear that something was wrong. My symptoms kept getting worse.

When we walked into the ER, my right leg was weak, and I could not sign my name at the desk. Twelve hours later, I could not move my right side, and my speech was reduced to yes and no. Not a good thing for a psychotherapist, where language is a primary tool!

In the ER, a CT scan showed a hemorrhagic or bleeding stroke where an artery burst, destroying millions of brain cells within minutes, affecting my speech and my ability to perform activities like dressing in the correct order. Also, my right arm and leg were extremely weak. However, I could understand everything, and I was never completely paralyzed. But, I was scared.

I was in intensive care for 4 days of observation and lots of testing, but the tests provided no answers. Two days after my stroke, while still in intensive care, I started occupational, physical and speech therapy. It was extremely challenging to feed myself with my right hand, requiring all my concentration. After a meal or brushing my teeth, I was exhausted. Speaking was the hardest of all. My brain seemed devoid of words.

After being stabilized, I was transferred to the National Rehabilitation Hospital. For a week, I endured speech, physical, occupational and recreational therapies.

Speech therapy was the hardest, but also the most important given my profession. Several times, the speech therapist challenged me to the brink of tears.

After a week at the Rehabilitation Hospital, I went home and to outpatient therapies. Speech therapy lasted the longest. After being discharged from speech therapy, I still had deficits in my organizational skills and abstract thinking.

As I struggled with starting to see my clients again, I slid into a deep depression. I was not confident that I could continue to practice. For months, I saw no point in living. Recovery from my post-stroke depression was harder than the recovery of my arms and legs and even speech!

Being a psycho-therapist, I know how to treat depression, so I went to a psychiatrist who prescribed anti-depressant medication and, I also found a psychotherapist.

After months on anti-depressants and excellent psychotherapy, my depression began to lift. I continue on the drugs and to see my psychotherapist. Emotionally, the aftermath of my stroke cut deep.

I am fortunate that 2 years post-stroke, I am back to my practice full-time. I lead support groups for stroke survivors and caregivers through the Montgomery County Stroke Association and serve on its Board. I now lecture on stroke, stroke prevention and stroke recovery. I also founded "hope for stroke"—individual and family counseling for stroke survivors and caregivers. In addition, I have participated in a NIH study about stroke recovery.

Once again, I am in excellent health and have resumed my active life style. I thank my brain for having the capacity to work around the dead cells. But most of all, I thank my therapists for my recovery. Their ability to zero in so effectively would not have been possible without NIH research.

Because stroke is a leading cause of death and disability and major cost to society, I urge you to provide stroke research with a significant funding increase. I am concerned that NIH continues to invest only 1 percent of its budget in stroke research. Thank you.

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#### PREPARED STATEMENT OF THE NATIONAL ALLIANCE TO END HOMELESSNESS

The National Alliance to End Homelessness (the Alliance) is a nonpartisan, non-profit organization which represents a united effort to address the root causes of homelessness and challenge society's acceptance of homelessness as an inevitable by-product of American life. These partners are local faith-based and community-based nonprofit organizations and public sector agencies that provide homeless people with housing and services such as substance abuse treatment, job training, and physical health and mental health care.

#### SUMMARY OF APPROPRIATIONS GOALS

##### *Moving Forward to End Homelessness*

- Communities across America are working toward ending homelessness. Communities are using Federal, State, and local funds to help homeless persons maintain housing. It is important that this progress not be undermined. To this end, the Alliance recommends the following:
  - Allocate an additional \$44 million for services for homeless people within SAMHSA's PRNS accounts of the Center for Mental Health Services and Center for Substance Abuse Treatment.
  - Increase funding to Projects for Assistance in Transition from Homelessness (PATH) to \$75 million.
  - Increase the Runaway and Homeless Youth Act Programs to \$140 million.
  - Provide a \$248 million increase in the Community Health Center program within Health Resource Services Administration. This would result in a \$21.5 million increase in the Health Care for the Homeless program.
  - Fund Education for Homeless Children and Youth services at its full authorized level of \$85 million.
  - Increase funding for the Homeless Veterans Reintegration Program to \$50 million.

##### *Connecting Homeless Families, Individuals, and Youth to Mainstream Services*

- People experiencing homelessness also depend on mainstream programs such as the ones below to live day to day and once housed, remain housed. The Alliance recommends the following to meet this goal:
  - Fund the Social Services Block Grant at \$2.8 billion
  - Reject cuts and fund the Community Services Block Grant at \$700 million
  - Appropriate \$60 million in education and training vouchers for youth exiting foster care under the Safe and Stable Families Program.
  - Fund the Community Mental Health Services Performance Partnership Block Grant at \$482.9, a \$61.9 million increase.
  - Fund the Substance Abuse Prevention and Treatment Block Grant at \$1.858 billion

#### BACKGROUND

Our 2007 report, *Homelessness Counts*, estimates that 744,313 people are homeless on any given night. This includes 98,452 families with children and 23 percent of homeless people are defined as chronically homeless; these are people with a disability and have been homeless repeatedly or continuously for 12 months. Successful interventions for all homeless populations couple housing with an appropriate level of services for the family or individual. We call on Congress to adequately fund programs that assist States and local entities in developing permanent housing and providing the necessary social services to end homelessness for all Americans.

#### DETAILED PROGRAM DESCRIPTIONS

##### *Goal #1.—Moving Forward to End Homelessness*

###### *Support Services for Permanent Supportive Housing Projects*

The Alliance recommends allocating an additional \$44 million for services in permanent supportive housing within SAMHSA's Center for Mental Health Services and Center for Substance Abuse Treatment. Years of reliable data and research demonstrate that the most successful intervention to solve chronic homelessness is

linking housing to appropriate support services. Current investments by SAMHSA in homeless programs are highly effective and cost efficient. Last year, the Department of Health and Human Services updated its 2004 report entitled *Ending Chronic Homelessness: Strategies for Action*. While acknowledging some success since 2004, the strategic plan explained that personal and programmatic barriers to mainstream programs, such as Medicaid, TANF, Medicare and general substance abuse and mental health services funds, still exist and must be overcome to end homelessness.

*Projects for Transition Assistance from Homelessness (PATH)*

The Alliance recommends that Congress increase PATH funding to \$75 million and adjust the funding formula to increase allocations for small States and territories.

PATH provides outreach to eligible consumers and ensures that those consumers are connected with mainstream services. Under the PATH formula grant, approximately 30 States share in the program's annual appropriations increases. The remaining States and territories receive the minimum grant of \$300,000 for States and \$50,000 for territories. These amounts have not been raised since 1991. To account for inflation, the minimum allocation should be raised to \$600,000 for States and \$100,000 for territories. Amending the minimum allocation requires a legislative change. If the authorizing committees do not address this issue, we hope that appropriators will explore ways to make the change through appropriations bill language.

*Runaway and Homeless Youth Programs*

The Alliance recommends funding the Runaway and Homeless Youth Act (RHYA) programs at \$140 million. RHYA programs end homelessness by: engaging youth living on the street with Street Outreach Programs, quickly providing emergency shelter and family crisis counseling through the Basic Centers, or providing supportive housing that helps young people develop lifelong independent living skills through Transitional Living Programs. Last year, the Congressional Research Service issued a report complimenting the good work of RHYA programs but detailing the gaps in services due to limited funding. For example, only one-tenth of the youth who connect with a RHYA program are able to receive services. It is essential that Congress increase this program.

*Community Health Centers (CHC) and Health Care for the Homeless (HCH) programs*

The Alliance recommends a \$248 million increase in the CHC program. This would result in a \$21.5 million increase in the HCH program. Persons living on the street suffer from health problems resulting from or exacerbated by being homeless, such as hypothermia, frostbite, and heatstroke. In addition, they often have infections of the respiratory and gastrointestinal systems, tuberculosis, vascular diseases such as leg ulcers, and hypertension.<sup>1</sup> Health care for the homeless programs are vital to prevent these conditions from becoming fatal. Congress allocates 8.7 percent of the Consolidated Health Centers account for HCH projects.

*Education for Homeless Children and Youth*

The Alliance recommends funding Education for Homeless Children and Youth (EHCY) at \$85 million. School is the most important potential source of stability for homeless children. The mission of the EHCY program is to ensure that these children can continue to attend school and thrive. The EHCY program, within the Department of Education's Office of Elementary and Secondary Education, removes obstacles to enrollment and retention by establishing liaisons between schools and shelters and providing funding for transportation, tutoring, school supplies, and the coordination of statewide efforts to remove barriers.

*Homeless Veterans Reintegration Program (HVRP)*

The Alliance recommends that Congress increase HVRP funding to \$50 million. HVRP, within the Department of Labor's Veterans Employment and Training Service (VETS), provides competitive grants to community-based, faith-based, and public organizations to offer outreach, job placement, and supportive services to homeless veterans. HVRP is the primary employment services program accessible by homeless veterans. It is estimated that this program only reaches about two percent of the overall homeless veteran population. An appropriation at the authorized

<sup>1</sup> Harris, Shirley N, Carol T. Mowbray and Andrea Solarz. Physical Health, Mental Health and Substance Abuse Problems of Shelter Users. *Health and Social Work*, Vol. 19, 1994.

level of \$50 million would enable HVRP grantees to reach approximately 19,866 homeless veterans.

*Goal #2.—Connecting Homeless Families, Individuals and Youth to Mainstream Services*

*Social Services Block Grant (SSBG)*

The Alliance recommends that Congress increase SSBG funding to \$2.8 billion. SSBG funds are essential for programs dedicated to ending homelessness. In particular, youth housing programs and permanent supportive housing providers often receive State, county, and local funds which originate from the SSBG. As the U.S. Department of Housing and Urban Development has focused its funding on housing, programs that provide both housing and social services have struggled to fund the service component of their programs. This gap is often closed using Federal programs such as SSBG.

*Community Services Block Grant (CSBG)*

The Alliance recommends that Congress reject cuts and fund CSBG at \$700 million. Funding cuts for CSBG will destabilize the progress communities have made toward ending homelessness by not only ending services directly provided by CSBG funds but limiting a community's ability to access HUD dollars. Community Action Agencies (CAAs), which are the primary local recipients of CSBG funding, are directly involved in housing and homelessness services. In several communities, CAAs lead the Continuum of Care (CoC). CoCs coordinate local homeless service providers and the community's McKinney-Vento Homeless Assistance Grant application process with the Department of Housing and Urban Development. In the fiscal year 2004 CSBG Information Systems report published by the HHS, CAAs reported administering \$207.4 million in Section 8 vouchers, \$30 million in Section 202 services<sup>2</sup> and \$271.1 million in other HUD programs which includes homeless program funding.<sup>3</sup>

*Foster Youth Education and Training Vouchers (ETV)*

The Alliance recommends that Congress appropriate \$60 million in ETV for youth exiting foster care under the Safe and Stable Families Program. The ETV program offers funds to foster youth and former foster youth to enable them to attend colleges, universities and vocational training institutions. Students may receive up to \$5000 a year for college or vocational training education. The funds may be used for tuition, books, housing, or other qualified living expenses. Given the large number of people experiencing homelessness who have a foster care history, it is important to provide assistance such as ETV to stabilize youth and prevent homelessness.

*Community Mental Health Performance Partnership Block Grant (MHBG)*

The Alliance recommends that Congress appropriate \$482.9 million for the MHBG. The MHBG provides flexible funding to States to provide mental health services. Ending homelessness requires Federal, State, and local partnerships. Additional mental health funds will give States the resources to improve their mental health system and serve all people with mental health disorders better, including homeless populations. For example, MHBG funds can be used to pay for services linked to housing for homeless people, thereby meeting the match requirements for projects funded through Shelter Plus Care or the Supportive Housing Program.

*Substance Abuse Prevention and Treatment Block Grant (SAPT)*

The Alliance recommends that Congress appropriate \$1.858 billion for the SAPT Block Grant. The SAPT Block Grant is the primary source of Federal funding for substance abuse treatment and prevention for many low-income individuals, including those experiencing homelessness. Studies have shown that half of all people experiencing homelessness have a diagnosable substance use disorder. States need more resources to implement proven treatment strategies and work with housing providers to keep homeless, especially chronically homeless populations stably housed.

CONCLUSION

Homelessness is not inevitable. As communities implement plans to end homelessness, they are struggling to find funding for the services homeless and formerly

<sup>2</sup>Section 202 is dedicated to housing from elderly and disabled individuals and families.

<sup>3</sup>U.S. Department of Health and Human Services, Administration of Children and Families. The Community Services Block Grant Fiscal Year 2004 Statistical Report. Prepared by the National Association for State Community Services Programs.

homeless clients need to maintain housing. The Federal investments in mental health services, substance abuse treatment, employment training, youth housing, and case management discussed above will help communities create stable housing programs and change social systems which will end homelessness for millions of Americans.

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PREPARED STATEMENT OF THE NATIONAL ALLIANCE FOR EYE AND VISION RESEARCH  
(NAEVR)

EXECUTIVE SUMMARY

NAEVR requests fiscal year 2009 NIH funding at \$31 billion, or a 6.6 percent increase over fiscal year 2008, to balance the biomedical inflation rate of 3.6 percent and to begin to restore NIH's purchasing power. Although NAEVR commends the congressional leadership's actions to significantly increase NIH funding above the Administration's budget request in fiscal year 2008 appropriations, the net 0.46 percent increase meant a net loss in NIH purchasing power. For 5 consecutive years, NIH funding has failed to keep pace with the biomedical inflation rate and NIH has lost more than 10 percent of its purchasing power. The administration's fiscal year 2009 budget, which proposes to freeze the NIH budget at the fiscal year 2008 level, threatens to further hinder the momentum of discovery leading to treatments that are saving lives—as well as restoring the quality of life—and maintaining the Nation's competitive edge in medical research. Secure and consistent funding for health and scientific research must be part of the nation's long-term strategies for sustained economic growth. NIH is a world-leading institution and must be adequately funded so that its research can reduce healthcare costs, increase productivity, improve quality of life, and ensure our Nation's global competitiveness.

NAEVR requests that Congress make vision health a top priority by funding the NEI at \$711 million in fiscal year 2009, or a 6.6 percent increase over fiscal year 2008. The NEI was flat funded in fiscal year 2008, meaning that over the past five funding cycles it has lost 18 percent of its purchasing power, reducing the number of grants by 160, which threatens its impressive record of breakthroughs in basic and clinical research that have resulted in treatments and therapies to save and restore vision, as well as to prevent eye disease. Vision impairment/eye disease is a growing, major public health problem that disproportionately affects the aging and minority populations, costing the United States \$68 billion annually in direct and societal costs, let alone reduced independence and quality of life. Adequately funding the NEI is a cost-effective investment in our nation's health, as it can delay, save, and prevent expenditures, especially to the Medicare and Medicaid programs.

*Fiscal year 2009 NEI funding at \$711 million enables it to lead collaborative research reflecting the new paradigm of 21st century healthcare that is predictive, preemptive, personalized, and participatory*

NEI research addresses the NIH's overall major health challenges as set forth by NIH Director Elias Zerhouni, M.D.: an aging population; health disparities; the shift from acute to chronic diseases; and the co-morbid conditions associated with chronic diseases (e.g., diabetic retinopathy as a result of the epidemic of diabetes). NEI research responds to Dr. Zerhouni's vision for NIH research that is collaborative and cost-effective and meets the 21st century "P4Medicine" paradigm of predictive, preemptive, personalized, and participatory research and clinical practice. For example:

- One-quarter of all genes identified to date through NEI's collaboration with the Human Genome Project is associated with eye disease, such as age-related macular degeneration (AMD), retinitis pigmentosa (RP), and glaucoma. NEI-funded researchers have discovered gene variants strongly associated with an individual's risk of developing AMD, the leading cause of blindness in older Americans. These variants, responsible for about 60 percent of the cases of AMD, are associated with the body's inflammatory response and may relate to other inflammation-associated diseases, such as Alzheimer's and Parkinson's.
- NEI is currently conducting the second phase of its Age-Related Eye Disease Study (AREDS), which follows up on initial findings that high levels of dietary zinc and antioxidant vitamins (Vitamins C, E and beta-carotene) are effective in reducing vision loss in people at high risk for developing advanced AMD—by a magnitude of 25 percent. NEI estimates that 1.3 million Americans would develop advanced AMD if no treatment was given, and if all individuals at risk engaged in the AREDS supplement regimen, more than 300,000 of them would avoid advanced AMD and any associated vision loss during the next 5 years.
- NEI's collaborative research into factors that promote or inhibit new blood vessel growth has resulted in the first generation of ophthalmic drugs approved by

the Food and Drug Administration (FDA) to inhibit abnormal blood vessel growth in “wet” AMD, thereby stabilizing and restoring vision, and NEI’s Diabetic Retinopathy Clinical Research (DRCR) Network is further evaluating these drugs for treatment of macular edema associated with diabetic retinopathy (DR). In March 2008, NEI-funded researchers announced that damage from both AMD and DR was prevented and even reversed when the protein Robo4 was activated in mouse models that simulate the two diseases. Robo4 treated and prevented the diseases by inhibiting abnormal blood vessel growth and by stabilizing blood vessels to prevent leakage. Since this “Robo4 Pathway” research used animal models from drug development, the time required to test this approach in humans could be shortened, expediting approvals for new therapies.

These examples primarily reflect NEI’s trans-Institute research within NIH. The NEI has also collaborated with other Department of Health and Human Services (DHHS) agencies, specifically to share the results of its basic and clinical research which may impact the product approval and reimbursement processes. For example:

- In a March 2008 meeting, NEI collaborated with FDA’s drug and device Centers to consider the appropriateness of new clinical endpoints in glaucoma clinical trials. Advances in visual imaging technologies—many of which emerged from collaborative research between the NEI and the National Institute of Biomedical Imaging and Bioengineering (NIBIB)—have enabled researchers to better detect structural changes in the nerve fiber layer of the retina and contours of the optic nerve head. These structural changes could potentially be used as a direct endpoint in a clinical trial, rather than a surrogate endpoint such as elevated intra-ocular pressure, when appropriately correlated to functional changes in vision to assure clinical significance of a new therapy. This meeting, which followed a November 2006 joint NEI–FDA meeting on clinical endpoints in AMD and DR clinical trials, represents the cost-effectiveness of NEI funding, as its research results may ultimately shorten the time and cost associated with clinical trials and facilitate approval of new diagnostics/therapies.
- In collaboration with the Centers for Medicare and Medicaid Services (CMS), NEI has launched the Comparison of AMD Treatments Trial (CATT), a comparative effectiveness study of the two drugs used to block growth of abnormal blood vessels in patients with the “wet” form of AMD. NEI’s collaboration with CMS could guide clinical practice and reduce costs to the Medicare program.

*The NEI’s diminished purchasing power jeopardizes its ability to follow up on research breakthroughs from past investment*

Congress must adequately fund NEI so it can initiate promising new research, pursue results that have emerged from previous breakthroughs, and offer up its “fair share” of funding in its extensive collaborations. The number of NEI grants has declined by 160 over the past 5 years, from 1,214 in fiscal year 2004 to 1,054 in fiscal year 2008, representing myriad “lost opportunities”—any one of which could have been the key to curing eye disease or restoring vision. Examples of such lost opportunities include:

- Ocular gene therapy holds great promise for retinal degenerative diseases, in which nearly 200 gene defects have been implicated. Investigators supported by NEI and private-funding organization Foundation Fighting Blindness (FFB) have begun human clinical trials of a gene therapy to treat Leber Congenital Amaurosis (LCA), a rapid retinal degeneration that blinds infants in the first year of life. Previous research has restored vision in dogs with LCA, and the results of the human clinical trials are forthcoming. Although the NEI could expand this program to target more diseases, current budget realities limit further research.
- Promising protocols proposed within the Diabetic Retinopathy Clinical Research Network will not be funded. The DRCR Network is a large, multi-center study that engages ophthalmologists and optometrists, many in community health centers, in basic and clinical research. Past NEI diabetes networks developed laser treatments for DR that save \$1.6 billion annually in federal disability payments.
- NEI funding for epidemiological studies is already limited, which jeopardizes future research into the basis/progression of eye disease in additional ethnic populations, such as Asian and Native Americans. Past NEI studies identified a three-fold greater risk of glaucoma in African Americans and glaucoma as the leading cause of irreversible vision loss in African Americans and Hispanics.
- NEI will not be able to fund proposed new Clinical Research Networks for AMD and for neuro-ophthalmic disorders. The latter could assist in understanding visual disorders associated with Traumatic Brain Injuries (TBI), especially



those currently being incurred in record numbers by soldiers in Iraq and Afghanistan.

NEI research into other significant eye disease programs such as cataract will be threatened, along with quality of life research programs into low vision and chronic dry eye. This occurs at a time when the U.S. Census cites significant demographic trends that will increase the public health problem of vision impairment and eye disease, such as the first wave of 78 million Baby Boomers celebrating their 65th birthday in 2010, with about 10,000 Americans turning 65 each day for 18 years afterward.

*Eye disease is a major public health problem increasing health costs, reducing productivity, and diminishing quality of life*

The 2000 U.S. Census reported that more than 119 million people in the United States were age 40 or older—he population most at risk for an age-related eye disease. The NEI estimates that more than 38 million Americans age 40 and older currently 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. Although the current annual cost of vision impairment and eye disease to the United States is \$68 billion, it does not fully quantify the impact of direct healthcare costs, lost productivity, reduced independence, diminished quality of life, increased depression, and accelerated mortality. This presents a major public health problem and financial challenge to the public and private sectors.

In public opinion polls over the past 40 years, Americans have consistently identified fear of vision loss as second only to fear of cancer. As recently as March 2008, the NEI's Survey of Public Knowledge, Attitudes, and Practices Related to Eye Health and Disease reported that 71 percent of respondents indicated that a loss of their eyesight would rate as a "10" on a scale of 1 to 10, meaning that it would have the greatest impact on their day-to-day life. As a result, federal funding for the NEI is a vital and cost-effective investment in the health, and vision health, of our nation as the treatments and therapies emerging from research can preserve and restore vision.

NAEVR urges fiscal year 2009 NIH and NEI funding at \$31 billion and \$711 million, respectively.

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#### PREPARED STATEMENT OF THE NATIONAL ALLIANCE ON MENTAL ILLNESS

Chairman Harkin, Senator Specter and members of the subcommittee, I am Anand Pandya, MD, President of the National Alliance on Mental Illness (NAMI). I am pleased today to offer NAMI's views on the subcommittee's upcoming fiscal year 2009 bill. With 210,000 members, NAMI is the Nation's largest grassroots organization representing persons with serious brain disorders and their families. Through our 1,200 affiliates in all 50 States, we support education, outreach, advocacy and research on behalf of persons with serious brain disorders such as schizophrenia, manic depressive illness, major depression, severe anxiety disorders and major mental illnesses affecting children.

The cost of mental illness to our Nation is enormous. It is estimated that the direct and indirect cost of untreated mental illness to our Nation exceeds \$82 billion annually. However, these direct and indirect costs do not measure the substantial and growing burden that is imposed on "default" systems that are too often responsible for serving children and adults with mental illness who lack access to treatment. These costs fall most heavily on the criminal justice and corrections systems, emergency rooms, schools, families and homeless shelters. Moreover, these costs are not only financial, but also human in terms of lost productivity, lives lost to suicide, and broken families. Investment in mental illness research and services are—in NAMI's view—the highest priority for our Nation and this subcommittee.

#### NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH) RESEARCH FUNDING

The National Institute of Mental Health (NIMH) is the only Federal agency whose main objective is to fund biomedical research on serious mental illnesses. Through research, NIMH and the scientists it supports seek to gain an understanding of the fundamental mechanisms underlying illnesses that obstruct thought, emotion, and behavior and an understanding of what goes wrong in the brain in mental illness. NIMH strives, at the same time, to hasten the translation of this basic knowledge into clinical research that will lead to better treatments and ultimately be effective in our complex world with its diverse populations and evolving health care systems.

For fiscal year 2009, the President is proposing \$1.407 billion for scientific and clinical research at the National Institute of Mental Health (NIMH). This is only a \$2 million increase above the fiscal year 2008 level, far below the level needed to keep pace with medical research inflation. Since 2003, the end of the 5-year effort by this subcommittee to double biomedical research funding, the NIH has lost nearly 15 percent of its purchasing power as a result of flat budgets. If this trend is not reversed, the consequences for advancing mental illness research will be devastating. If NIMH funding continues to lag, we will lose the chance to define the individualized strategies and future medication options that this vital research heralds. A third generation of antipsychotic medication for schizophrenia, stronger antidepressant medication for depression and treatment strategies for bipolar disorder that improve long-term outcomes, are crucially important to those who suffer and will not be realized without further support from the Federal Government.

Further, we will be unable to fund in the United States whole genome studies for serious mental illness which could transform the understanding of the causes and risk factors for these devastating illnesses and open new avenues for effective treatment. Likewise, we will be unable to advance schizophrenia and bipolar research progress, for example, understanding if early intervention with medication, therapy and rehabilitation will prevent disability or morbidity in persons with new onset schizophrenia. Finally, continued flat funding for NIMH will prevent us from addressing the epidemic of suicide in this country, including a substantial number of our young people who die or are disabled before their lives have truly started and the elderly who are cheated from their retirement years.

For fiscal year 2009, NAMI supports the recommendations of the Ad Hoc Group on Medical Research and the Mental Health Liaison Group for a 6.5 percent increase for the overall NIH budget and a similar increase for the NIMH. This would boost NIMH funding to \$1.499 billion and allow the agency to regain lost purchasing power and keep pace with the Biomedical Research and Development Price Index.

#### REDEFINING NIMH TO ITS MISSION

NAMI applauds NIMH's efforts to re-align the Institute along 3 core principles: relevance, traction, and innovation.

- Relevance refers to relevance to the mission. NIMH should continue its strong support of basic science, but as the NAMHC workgroup recommends in its report (<http://www.nimh.nih.gov/council/brainBehavioralScience.cfm>) some research areas are more relevant than others.
- Traction refers to the capacity for rapid progress in research areas where new tools, such as 2-photon imaging, yield definitive answers to long-standing questions.
- Innovation is often endangered during periods of limited budget growth. This work is highly relevant and NIMH is gaining traction, but unless a priority is placed on such "discovery" science, this unprecedented opportunity for innovation may not receive the support it deserves.

It is critical for us to move beyond the current universe of palliative treatments for serious mental illness. Even with optimal care, some children and adults living with serious mental illness will not be able to achieve recovery (as defined as permanent remission). As NIMH Director Dr. Tom Insel has noted, consumers and families need rapid, effective treatments that target the core pathophysiology of serious mental illnesses and the tools for early detection. Mental illness research can develop new diagnostic markers and treatments, but this will require defining the pathophysiology of these illnesses. NIMH now has the research tools necessary. Now is the time to set an ambitious goal of finding cures to these extremely disabling illnesses. However, NIMH must have the resources it needs to support this critical research agenda.

#### FUNDING FOR PROGRAMS AT SAMHSA'S CENTER FOR MENTAL HEALTH SERVICES (CMHS)

The Center for Mental Health Services (CMHS)—part of the Substance Abuse and Mental Health Services Administration (SAMHSA)—is the principal Federal agency engaged in support for State and local public mental health systems. Through its programs CMHS provides flexible funding for the States and conducts service demonstrations to help States move toward adoption of evidence-based practice. Overall, the President is proposing a \$209 reduction for the SAMHSA—dropping funding down to \$3.025 billion for fiscal year 2009. Within CMHS, funding would be reduced by \$144 million, largely through reductions and terminations of a number of demonstration and technical assistance programs.

The President's request for major activities at CMHS for fiscal year 2009 is as follows:

- The Mental Health Block Grant—Proposed for a current freeze at \$421 million,
- The PATH Homeless Formula Grant—\$60 million, a \$7 million increase above current levels,
- Children's Mental Health—\$114 million, a \$12 million increase above current levels, and
- PAIMI Protection & Advocacy—\$34 million, a \$1 million reduction.

Beyond seeking to impose level funding for these SAMHSA programs, the President's budget seeks \$144 million in overall reductions to Programs of Regional and National Significance (PRNS) at CMHS, dropping the fiscal year 2008 appropriation from \$299.3 million, down to \$155.3 million. PRNS are largely demonstration, targeted capacity expansion and other discretionary activities at the agency. Most of these reductions would come through terminating research demonstration programs and technical assistance programs.

Among the activities within the PRNS account that are targeted for reductions are:

- Mental Health Transformation State Incentive Grants (SIGs)—The budget proposes no future SIG grants, a \$26 million reduction,
- Mental Health System Transformation—A \$20.8 million program proposed for elimination,
- Garrett Lee Smith Suicide Prevention State Grants—The budget proposes an \$11.7 million reduction, from \$29.5 million, down to \$17.8 million,
- Homelessness Prevention and Service Demonstrations—Proposed for a an \$10.6 million cut, from \$13.6 million down to \$2.8 million,
- Seclusion and Restrain Technical Assistance—\$2.4 million proposed for elimination,
- Criminal Justice and Juvenile Justice Grants—A \$6.68 million activity for fiscal year 2008, proposed for a \$2.8 million reduction, and
- Older Adults—A \$4.8 million program proposed for elimination.

NAMI urges the subcommittee to restore these cuts to the CMHS PRNS program for fiscal year 2009. These targeted capacity expansion and service demonstration initiatives are critical for the agency to continue its role as a leader in promoting replication of effective services that reach children and adults with serious mental illness.

#### SUICIDE PREVENTION ACTIVITIES AT SAMHSA

NAMI is especially troubled by the President's proposal to cut funding for suicide prevention activities under the Garrett Lee Smith Act. Each year, over 31,000 Americans die by suicide and over 1.4 million make a suicide attempt. Suicide deaths consistently outnumber homicide deaths by a margin of three to two. The statistics are troubling for our Nation:

- In 2003, twice as many Americans died from suicide than from HIV/AIDS,
- Suicide is the third leading cause of death for those between the ages of 10 and 24 and the second leading cause of death for American college students,
- While the elderly comprise only 12 percent of the population, they account for about 18 percent of our Nation's suicides,
- Research has shown that more than 90 percent of people who die by suicide have a mental illness and/or substance abuse disorder.

Congress must continue to invest in effective suicide prevention strategies. NAMI urges this subcommittee to provide full funding for suicide prevention activities under the Garrett Lee Smith Act for fiscal year 2009—\$40 million.

#### CHRONIC HOMELESSNESS AND MENTAL ILLNESS

Together, Congress and the President have set a goal of ending chronic homelessness by 2012. Ninety States and local governments have responded to this challenge by creating plans to end homelessness, and 130 more States and local governments are in the process of developing similar plans. To address chronic homelessness, completed plans call for developing 80,000 new permanent supportive housing units. This will require creating 16,000 units of new permanent supportive housing for chronically homeless people in each of the next 5 years. Federal funding at the level of \$5,000 per unit will leverage other resources to provide the comprehensive services needed to help chronically homeless people achieve housing stability and pursue recovery from mental illness and substance abuse problems.

Over the course of a year, between 200,000 and 250,000 people experience long term or chronic homelessness. They are homeless for long periods of time or repeatedly, have one or more disabilities, and often cycle between homeless shelters, the streets, mental health facilities, emergency rooms, hospitals, and jails. The public cost for their care is extremely high, and their outcomes are very poor. The current

funding level of SAMHSA homeless programs is \$56 million. The President's fiscal year 2009 proposed budget recommended a \$20 million funding cut to this total. NAMI urges an increase of \$44 million for the Grants for the Benefit of Homeless Individuals (GBHI) and Treatment Systems for Homeless programs at SAMHSA, boosting funding to \$100 million for fiscal year 2009.

THE SOCIAL SECURITY DISABILITY CLAIMS AND APPEALS BACKLOG CRISIS MUST BE ADDRESSED

Mr. Chairman, people with mental illness and other severe disabilities have been bearing the brunt of the backlog crisis for disability claims and appeals at Social Security. Behind the numbers are individuals with disabilities whose lives have unraveled while waiting for decisions—families are torn apart; homes are lost; medical conditions deteriorate; once stable financial security crumbles; and many individuals die. NAMI congratulates this subcommittee on the progress made for fiscal year 2008 with the appropriation for SSA's Limitation on Administrative Expenses (LAE), boosting it to \$9.747 billion. This amount was \$148 million above the President's request and was the first time in years that the agency has received at least the President's request. While the fiscal year 2008 appropriation will allow the agency to hire some new staff and to reduce processing times, it will not be adequate to fully restore the agency's ability to carry out its mandated services.

The President's request for the SSA fiscal year 2009 LAE is encouraging, but does 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. In order for SSA to meet its responsibilities, it is projected that the agency needs a minimum of \$11.0 billion for its fiscal year 2009 administrative budget. This amount will allow the agency to not only significantly reduce the backlog, but also keep local offices open, provide adequate telephone services to the public, and maintain the integrity of its programs by performing more continuing disability reviews and SSI redeterminations.

PREPARED STATEMENT OF THE NATIONAL ALLIANCE OF STATE AND TERRITORIAL AIDS DIRECTORS

The National Alliance of State and Territorial AIDS Directors (NASTAD), whose members are responsible for administering state HIV/AIDS prevention and care programs nationwide, respectfully submits testimony for the record regarding federal funding for federal HIV/AIDS and adult hepatitis programs in the fiscal year 2009 Labor, HHS and Education Appropriations legislation. NASTAD appreciates the Committee's past support for these important public health programs.

As you craft the fiscal year 2009 Labor-HHS-Education Appropriations legislation, we urge you to consider the following critical funding needs of HIV/AIDS, STD and viral hepatitis programs:

- \$1.4 billion for the Ryan White Part B Program, including \$496.2 million for the Part B base and \$929 million for the AIDS Drug Assistance Program (ADAP);
- \$1.3 billion for CDC's HIV/AIDS Prevention Program, including an additional \$31 million to restore cuts to the state and local health department cooperative agreements since fiscal year 2003, an additional \$35 million to shore up state and local HIV/AIDS surveillance systems, and \$45 million for the continuation of CDC's HIV Testing Initiative targeting communities of color;
- \$50 million for CDC's Viral Hepatitis Prevention Program, including a doubling of resources for the Adult Viral Hepatitis Prevention Coordinator Program to \$10 million.
- \$20 million for hepatitis B vaccination for high-risk adults through the Section 317 Vaccine Program;
- \$167 million for CDC's STD Prevention Program for prevention, treatment and surveillance cooperative agreements with state and local health departments; and
- \$610 million for the Minority AIDS Initiative to enhance capacity in communities of color.

HIV/AIDS CARE AND TREATMENT PROGRAMS

NASTAD respectfully requests a minimum increase of \$230 million in fiscal year 2009 for state Ryan White Part B grants, including an increase of at least \$95 million for the Part B Base and at least \$135 million for AIDS Drug Assistance Programs (ADAPs). The President's budget cuts Part B programs \$6 million for fiscal year 2009. In fiscal year 2008, Base programs received a cut of \$5 million. These

funds provide care and support services across the United States and are necessary to ensure there are not large funding shifts resulting from formula changes in the reauthorized law.

While only one state currently has a waiting list to receive ADAP services, the present fiscal condition remains fragile and is not guaranteed beyond fiscal year 2007. The President's budget included an increase of \$20.2 million, which is insufficient to meet continuing demand for these programs. The elimination of waiting lists is largely due to state funding increases, \$39.4 million in fiscal year 2007 ADAP Supplemental grants, transfers of Part B Base funding into ADAP, and program savings from the Medicare Part D Prescription Drug Benefit. Shifts in funding as a result of reauthorization of the Ryan White Program and one-time additional funding to Part B in fiscal year 2007 render the fiscal future of ADAPs uncertain. Additionally, CDC estimates that their newly implemented HIV testing initiative will find 20,000 new infections over the next year. Two new therapies were approved in 2007 and at least one will be approved in 2008. ADAPs will be adding these to their formularies thus increasing costs.

#### HIV/AIDS PREVENTION AND SURVEILLANCE PROGRAMS

NASTAD respectfully requests a funding increase of \$608 million for total funding of \$1.3 billion for CDC's HIV prevention and surveillance programs. The President's budget cuts CDC's HIV prevention and surveillance programs by \$1 million. CDC is on the verge of releasing revised estimates of HIV incidence that will show that there have been more new infections each year than previously thought. Funding has not kept pace and has in fact been cut since fiscal year 2003. State and local HIV prevention cooperative agreements have been cut by \$26 million between fiscal year 2003 and fiscal year 2007. Due to the rescission, fiscal year 2008 cooperative agreements may receive further cuts of \$5.2 million. In fiscal year 2007, CDC awarded \$35 million to 18 states and 5 cities to support routine testing in clinical settings particularly targeted to settings that see a large number of African Americans. NASTAD requests the maintenance of these grants to continue the testing initiative. Additionally, core HIV/AIDS surveillance funding has eroded over the last decade, while the importance of this data has become paramount for targeting prevention efforts and directing Ryan White resources. \$35 million is needed to shore up state and local HIV/AIDS surveillance systems.

In addition, we urge you not to fund the Early Diagnosis Grant Program in Section 209 of the Ryan White Treatment Modernization Act of 2006. Funds should not be directed to fund this provision as it redirects scarce HIV prevention resources away from the ever shrinking state and local prevention cooperative agreements. At a minimum, the impact and scope of this provision should be reduced.

The Nation's prevention efforts must match our commitment to the care and treatment of infected individuals. State and local public health departments know what to do to prevent new infections, they just need the resources. First and foremost we must address the devastating impact on racial and ethnic minority communities. We must expand outreach and HIV testing efforts targeting high-risk populations including racial and ethnic minority communities, young gay men of color, substance users, women and youth. But, testing alone can never end the epidemic. All tools in the prevention arsenal must be supported. Additional resources must be directed to build capacity and provide technical assistance to enable community-based organizations and health care providers to implement evidence-based behavior change interventions, ensure fiscal responsibility and refer partners of HIV-positive individuals to counseling and testing services.

#### VIRAL HEPATITIS PREVENTION PROGRAMS

NASTAD respectfully requests an increase of \$36.4 million for a total of \$50 million in fiscal year 2009 for the CDC's Division of Viral Hepatitis (DVH) to enable state and local health departments to provide basic core public health services. DVH currently receives \$17.6 million to address chronic viral hepatitis B and C impacting 6.2 million Americans. This is \$7.4 million less than its peak funding of \$25 million in fiscal year 2001. The President's budget cuts DVH funding by \$80,000. Of the DVH funding, \$5.2 million is used to fund the Adult Viral Hepatitis Coordinator Program with an average award to states of \$90,000. The coordinator position receives precious little above personnel costs, leaving little to no money for the provision of public health services including public education, hepatitis counseling, testing, and hepatitis A and B vaccine. In addition, there are no funds for surveillance of chronic viral hepatitis, which would allow states to better target their limited resources. Given the recent hepatitis public health crises in Nevada and New York,

the government has a choice—invest in prevention now or wait until public systems are overwhelmed by a lack of infrastructure to address future outbreaks.

The greatest remaining challenge for hepatitis A and B prevention is the vaccination of high-risk adults. High-risk adults account for more than 75 percent of all new cases of hepatitis B infection each year and annually result in an estimated \$658 million in medical costs and lost wages. In fiscal year 2007, CDC allowed states to use \$20 million of 317 Vaccine funds to vaccinate high risk adults for hepatitis B. States are integrating vaccination into service programs for persons with risk factors for infection (e.g., STD clinics, HIV counseling and testing sites, correctional facilities and drug treatment clinics). By targeting high-risk adults, including those with hepatitis C, for vaccination, the gap between children and adults who have not benefited from routine childhood immunization programs can be bridged. NASTAD requests a continuation of the \$20 million in Section 317 Vaccine funds in fiscal year 2009 for hepatitis B vaccination for high-risk adults.

#### STD PREVENTION PROGRAMS

NASTAD supports a minimum increase of \$15 million for a total of \$167 million in fiscal year 2009 for STD prevention, treatment and surveillance activities undertaken by state and local health departments. The President's budget cut STD prevention program funding by \$680,000. STD prevention programs at CDC have been cut or flat-funded since fiscal year 2003 while the number of persons infected continues to climb. The United States has the unwanted distinction of having the highest rates of STDs of all industrial nations. In 2006 for the second consecutive year, the United States experienced record increases of the three leading STDs—Chlamydia (5.6 percent), Gonorrhea (5.5 percent), and Syphilis (13.8 percent).

#### MINORITY AIDS INITIATIVE

NASTAD also supports a \$218 million increase for a total of \$610 million for the Minority AIDS Initiative (MAI) in fiscal year 2009. The MAI was cut in fiscal year 2008. The President's budget flat funds these important programs. The MAI provides targeted resources to address the HIV/AIDS epidemic in hard-hit communities of color. The data from CDC on the disproportionate impact on African Americans continues to be alarming. Support for the MAI along with the traditional funding streams that serve these populations is essential.

As you craft the fiscal year 2009 Labor-HHS appropriations bill, we ask that you consider all of these critical funding needs. It is essential that the United States continue to demonstrate its commitment to fighting the ongoing domestic and global HIV/AIDS, viral hepatitis, and STD epidemics. The National Alliance of State and Territorial AIDS Directors thank the Chairman, Ranking Member and members of the Subcommittee, for their thoughtful consideration of our recommendations.

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#### PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COUNTY BEHAVIORAL HEALTH AND DEVELOPMENTAL DISABILITY DIRECTORS

Chairman Harkin, ranking member Specter, and members of the subcommittee, on behalf of the National Association of County Behavioral Health and Developmental Disability Directors (NACBHDD), we thank you for your leadership on issues related to mental illness, addictions and developmental disabilities. We are pleased to offer the following recommendations and highlight concerns regarding fiscal year 2009 funding.

The National Association of County Behavioral Health and Developmental Disability Directors (NACBHDD) is an organization based in Washington, D.C. active on a number of fronts, including policy development, advocacy and information dissemination on best practices to its members. As an affiliate of the National Association of Counties (NACo), NACBHDD members are a part of the health care safety net that contributes to local systems of care for millions of Americans. NACBHDD members include county and city governments and other local authorities with responsibility for assuring that essential mental health, developmental disabilities and substance use disorder services are provided to vulnerable and often disabled residents.

Recent financial changes at the Federal level regarding Medicaid are pressuring States and localities to cut other health and social services to cover the additional costs of essential services for which Federal reimbursement is no longer available. While Medicaid is an integral component to local systems of care and ensures that arrays of appropriate services are available to the right person at the right time; other Federal, State and local funds are essential to funding these public systems.

The coordination of these dollars assists in the delivery of effective community based services as well as transitioning individuals from institutional settings. Discretionary Federal funding is pivotal to the Federal-State-local partnerships that contribute to the financial foundation of vital local services. Without adequate funding, these activities will not be available to support some of our most vulnerable citizens.

NACBHDD recommendations and concerns regarding mental health, addictions and developmental disabilities funding priorities follow.

#### SUBSTANCE ABUSE PREVENTION AND TREATMENT (SAPT) BLOCK GRANT

NACBHDD recommends \$1,858.7 million for fiscal year 2009—an increase of \$100 million over fiscal year 2008 and \$80 million over the President's request. The SAPT Block Grant enables States and localities to address the unique needs of their communities. In addition, this block grant is crucial funding for public addictions systems and provides the capacity for the bulk of prevention and treatment services.

#### CENTER FOR SUBSTANCE ABUSE TREATMENT (CSAT)

NACBHDD is concerned with the proposed cut of \$63 million to CSAT programs and recommends \$420 million in fiscal year 2009. The President's request would eliminate programs that provide recovery services, State service improvements, program coordination and evaluation and strengthening treatment access and retention. In addition, programs that target pregnant and postpartum women and children and families with substance use disorders would no longer be available.

Other CSAT programs would be significantly reduced in the President's proposed budget. The Opioid Treatment Programs/Regulatory Activities, Targeted Capacity Expansion (TCE), Services Accountability, Addiction Technology Transfer Centers (ATTCs), Treatment Systems for the Homeless that include programs important to local substance abuse authorities would all be affected.

#### CENTER FOR SUBSTANCE ABUSE PREVENTION (CSAP)

NACBHDD recommends \$215 million in fiscal year 2009. This represents an increase of \$20.9 million compared to fiscal year 2008 and an increase of \$56.9 million over the President's request. The proposed budget would cut CSAP by \$36 million allowing a number of programs within this center to be significantly restricted. Of note, the Strategic Prevention Framework State Incentive Grant is proposed to be funded at \$95,389,000 a cut of \$9,318,000 from fiscal year 2008 level. In addition, the Centers for the Application of Prevention Technologies (CAPTs) are proposed to be funded at \$4,381,000, a cut of \$7,656,000 from fiscal year 2008 level. These two programs allow for much needed prevention programs at the local level. Other CSAP programs which are slated for elimination include the Sober Truth on Preventing Underage Drinking (STOP Act) and Evidence Based Practices. The Methamphetamine Prevention program and Program Coordination/Data Coordination and Consolidation Center would receive cuts in funding as well, hindering their effectiveness.

#### CENTER FOR MENTAL HEALTH SERVICES (CMHS)

##### *Community Mental Health Services Performance Partnership Block Grant*

NACBHDD recommends \$482.9 million for the fiscal year 2009 budget, an increase of \$61.9 million from the fiscal year 2008 budget and from the President's fiscal year 2009 request. The Community Mental Health Services Block Grant is an integral Federal funding source that supports community based mental health services.

##### *Childrens Mental Health and Homelessness Programs*

While the President's fiscal year 2009 budget did request increased funding for the Children's Mental Health Services Program and Projects for Assistance in Transition from Homelessness (PATH) Program, NACBHDD recommends \$117.3 million and \$61.1 million respectively for these programs. Adequate funding is essential to create systems of care focused on community based services for children and their families. Additionally, PATH programs allow for local solutions to assisting individuals who are homeless and have a mental illness and/or substance use disorder.

##### *Programs of Regional and National Significance (PRNS)*

NACBHDD recommends \$343.3 million for the fiscal year 2009 budget, an increase of \$44.0 million above the fiscal year 2008 budget. NACBHDD is concerned with the President's request for the drastic \$144 million decrease in funding to this program. Programs that prevent youth violence, suicide, and address post traumatic stress disorder would be severely restricted. Jail diversion grants are

also slated for reduced funding. These dollars are essential in assisting communities to provide support and organization to appropriately divert individuals with mental illness away from jails and prisons and ensure access to treatment and services in the community.

NACBHDD is particularly concerned that programs targeted for seniors, community technical assistance centers, consumer and family network grants would be eliminated. Additionally, the President's fiscal year 2009 request would terminate State incentive grants. These grants offer flexibility in planning and coordination among Federal, State, and local entities to create comprehensive plans and enhance existing resources to deliver quality, evidence based services in communities.

#### NATIONAL INSTITUTES OF HEALTH (NIH)

NACBHDD supports the furthering of research in the fields of mental health, substance use disorders and developmental disabilities. Our following recommendations for fiscal year 2009 appropriations:

- National Institute of Mental Health (NIMH)—\$1,498.6 million
- National Institute on Drug Abuse (NIDA)—\$1,067.7 million
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)—\$465.5 million
- National Institute of Child Health and Human Development (NICHD)—\$1,341 million

#### DEVELOPMENTAL DISABILITIES

NACBHDD supports the following recommendations for funding to ensure individuals with developmental disabilities receive services and supports in the communities in which they live. A number of departments and programs touch the lives of individuals with developmental disabilities and continued Federal financial participation is essential.

#### COMBATING AUTISM ACT

NACBHDD supports the President's funding request to expand research, screening, intervention and education activities by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) under the Combating Autism Act. This critical funding is important for research into the causes of Autism, diagnosis, early detection, prevention, services, supports, intervention and treatment of autism spectrum disorder.

#### DEVELOPMENTAL DISABILITIES ACT

While the President's fiscal year 2009 budget request essentially level funds these programs, increased funding for these activities will foster full integration and inclusion in the community for individuals with developmental disabilities. In particular, NACBHDD recommends funding Councils on DD at \$80 million, Protection and Advocacy Systems at \$45 million and University Centers for Excellence in DD at \$41 million.

#### THE DEPARTMENT OF LABOR

Programs under the Workforce Investment Act are essential to ensure individuals with developmental disabilities have access to employment training and opportunities. We are concerned that most of the programs have been requested to receive reduced funding in the President's fiscal year 2009 budget request. Each program assists local developmental disabilities authorities to ensure the individuals they serve have opportunities in the workforce. NACBHDD recommends the following:

- Adult Employment—\$987.9 million
- Pilots, Demonstration, Research—\$246 million
- Youth Activities—\$1.1 billion
- One Stop Career Centers—\$100 million
- Dislocated Worker Program—\$1.6 billion

Further, the following programs within the Department of Labor provide added support for job training and supports. NACBHDD recommends funding for fiscal year 2009:

- Office of Disability Employment Policy—\$47.5 million
- Community College Initiative/Community Based Job Training—\$150 million
- Work Incentives Grants—\$28 million
- Older Adult Community Service Employment Program (SCSEP)—\$572 million
- Veterans' Employment and Training Services (VETS) Program—\$233 million



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

NACBHDD recommends \$850 million for the Maternal & Child Health Block Grant. This program supports the health and welfare of mothers and children to provide access to services and care for vulnerable populations.

## REHABILITATIVE SERVICES ADMINISTRATION

Rehabilitative service programs are particularly important to assist local authorities to ensure individuals with developmental disabilities receive a range of services to reach vocational outcomes. Some programs received level funding requests while others were slated for elimination. Of note, the Supported Employment State Grant program would receive zero funding in the President's fiscal year 2009 budget. These important grants help develop collaborative local programs that offer supported employment services to individuals with developmental disabilities.

NACBHDD thanks the committee for its continued support of programs benefiting developmental disabilities, mental health and addictions systems. We look forward to working with you on our Association's priorities.

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PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS

## SUMMARY

The proposed cuts in the fiscal year 2009 budget for the Centers for Disease Control and Prevention (CDC) submitted by the President continue a pattern of reduced funding for public health that gravely worries the Nation's local health departments. The National Association of County and City Health Officials (NACCHO) is particularly concerned about two funding streams that directly benefit local health departments, although the range of reductions in CDC's budget threaten overall work in prevention that we fully support.

The President's budget requests \$609 million in fiscal year 2009 for State and local capacity building for public health preparedness in fiscal year 2009 and eliminates the Advanced Practice Center program. This represents a cut of 18 percent from fiscal year 2008. The Preventive Health and Health Services (PHHS) block grant program, the other major source of CDC funding to health departments, received funding of \$97 million in fiscal year 2008 and is eliminated in the President's budget. Taken together, these reductions will seriously compromise the ability of the Nation's governmental public health system to fulfill its mission of protecting and promoting health.

Local public health departments work every day on the front lines to combat threats to the health of their communities. They cannot afford substantial reductions in Federal support for their roles as first responders to natural disasters, acts of bioterrorism and other public health emergencies. Moreover, local public health departments receive about 40 percent of the PHHS funds. In States where local health departments rely exclusively on these funds to conduct prevention programs for which no other sources of funding are available, activities to reduce the burdens of preventable disease will cease. Prevention is critical to slowing the astronomical growth in chronic diseases like obesity and diabetes as well as protecting the public from hazards such as lead poisoning and infectious diseases like tuberculosis. An investment in prevention improves both length and quality of life.

At a time when the Nation is engaged in urgent work to protect the homeland from terrorists and natural disasters, as well as to stop the growth in chronic disease, it is profoundly counterproductive and irrational to reduce support for local programs that are the first line of defense against the greatest threats to the health of communities. NACCHO urges Congress to continue funding these two CDC programs at levels no less than those in fiscal year 2005. Those levels are \$919 million for State and local public health emergency preparedness and \$131 million for the Preventive Health and Health Services block grant. NACCHO urges Congress to continue funding for pandemic flu preparedness at \$350 million for fiscal year 2009. In addition, NACCHO advocates for new funding of \$10 million in fiscal year 2009 to inaugurate two new workforce programs within the National Health Service Corps in the Health Resources and Services Administration (HRSA) that would benefit local public health and address workforce shortages.

PROGRESS HAS BEEN MADE IN BOLSTERING THE READINESS OF LOCAL HEALTH  
DEPARTMENTS TO RESPOND TO EMERGENCIES

A report released by CDC on February 20, 2008, *Public Health Preparedness: Mobilizing State by State*, documents progress made by preparedness funding grantees. According to the report, preparedness funding has allowed State and local health departments to have a more focused and effective response to actual emergencies, not just to plan for a hypothetical future emergency. These real-life situations have provided an opportunity for local health departments to exercise their response plans and to learn where improvements can be made. Preparedness is not simply a matter of theoretical planning for a future catastrophe. Rather, it makes a difference in how well health departments can respond to public health problems daily.

CDC's report confirmed the findings of a 2007 NACCHO survey of LHDs, which found that three-quarters of local health departments (LHDs) reported that they had improvements in preparedness but that more improvement is needed. Virtually all local health departments had developed a plan for mass vaccination, as well as an all-hazards preparedness plan, had implemented the National Incident Management System (NIMS), trained their workforce in new emergency response skills, conducted public education campaigns, and improved their communication systems. The pandemic influenza funding has enabled exercising of the capabilities required for a pandemic response to take place regularly in localities across the Nation.

STRENGTHENING THE GOVERNMENTAL PUBLIC HEALTH SYSTEM TO PROTECT LOCAL  
COMMUNITIES REQUIRES SUSTAINED FUNDING

Since fiscal year 1999, Congress has provided funding to strengthen the Nation's capacity to respond to an act of bioterrorism or other public health emergency. After 9/11 and the anthrax attack in the fall of 2001, Congress increased this funding markedly and included \$940 million for building State and local capacities, of which about \$870 million was made available to States and localities. Federal funds for improving State and local public health preparedness have declined from \$919 million in fiscal year 2005 to \$746 million in fiscal year 2008. The President's budget would provide \$609 million for fiscal year 2009, and would cut the grant year to slightly more than nine months. In fiscal year 2010, a \$129.6 million increase in funding would be required to maintain level, full-year funding.

The downward slope in Federal preparedness funding has severely hampered LHDs in sustaining current activities and in building an experienced preparedness workforce. LHDs experienced an average 20 percent funding reduction in 2007 and further reductions are expected when HHS distributes fiscal year 2008 funds. Already, more than one-quarter of LHDs have reduced their preparedness activities, delayed completion of plans, and/or delayed acquisition of equipment and supplies as a result of reduced funding. Notwithstanding the Federal cuts, LHDs continue to contribute their share to this national effort. Nearly half of all LHDs make use of city or county funds to pay directly for preparedness activities. All contribute additional in-kind resources, principally staff time diverted from other activities.

The safety and well-being of America's communities is dependent on maintenance of the capacity of their health departments to respond in any emergency that threatens human health. Every community now has a public health emergency plan in place, but plans must be supported by public health responders who engage in continuous training and exercising. In its recent report, CDC listed challenges that remain with regard to public health emergency preparedness. Among them were the need for State and local health departments to sustain a system of all-hazards planning, training, exercising, and improving. In order to continue this essential cycle of continuous improvement, LHDs need consistent funding. The Nation cannot afford to backslide or lose its investment by failing to sustain Federal funding that helps health departments continue their progress and address new and emerging threats.

The President's budget eliminates the Advanced Practice Center (APC) program, which provides funds to eight local health departments to develop innovative field-tested tools and models to help other LHDs meet emergency preparedness goals. The products produced by the APCs are disseminated to other local health departments nationwide, saving them the expense and trouble of designing from scratch. A cost effective investment of \$5.4 million will allow this program to continue and to have a much greater impact than the numbers alone would suggest.

THE PHHS BLOCK GRANT IS A LINCHPIN FOR PREVENTION

Local public health departments receive approximately 40 percent of the Preventive Health and Health Services block grants nationally. The block grant funds en-

able States and localities to address critical unmet public health needs. The coexistence of other Federal categorical public health funds does not mean that sufficient funds are available to address all public health needs. They are not. Improving chronic disease prevention through screening programs and programs that promote healthy nutrition and physical activity are prime examples of activities to which many jurisdictions devote PHHS funds.

According to the National Association of Chronic Disease Directors, elimination of the PHHS block grant would cause a loss of \$40.8 million for chronic disease programs and \$11.2 million for infectious disease programs. In those States where local health departments receive a significant amount of PHHS funds from the State, local prevention efforts will diminish. As health care costs escalate, reducing the Nation's commitment to prevention by eliminating the PHHS block grant, weakening State and local public health departments, is unwise and uneconomic.

#### WORKFORCE SHORTAGES THREATEN THE STRENGTH OF LOCAL PUBLIC HEALTH

According to NACCHO's 2005 Profile of Local Health Departments, public health professionals in short supply include public health nurses, epidemiologists, environmental health scientists, and health educators. Nearly half of all LHDs experienced problems hiring public health nurses in 2005 and 60 percent expected to have trouble recruiting nurses in 2008. Staff attrition and retirement are the most frequently cited factors causing uncertainty and concern about future workforce capacity.

NACCHO advocates new funding of \$10 million in fiscal year 2009 to begin addressing public health workforce shortages. In 2006, the Pandemic and All-Hazards Preparedness Act created two new programs within the National Health Service Corps in the Health Resources and Services Administration (HRSA). One program would allow expansion of the National Health Service Corps on a trial basis to include loan repayment for individuals who complete their service in a State, local, or tribal health department that serves health professional shortage areas or areas at risk of a public health emergency. The second program establishes grants to States to create loan repayment programs. As the public health role has expanded to include greater involvement in emergency preparedness, in addition to the more traditional public health activities like immunization and chronic disease prevention, it is essential that there be a workforce trained to carry out these tasks.

The National Association of County and City Health Officials (NACCHO) is the organization representing the 2860 local public health departments in the United States.

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#### PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF FOSTER GRANDPARENT PROGRAM DIRECTORS

Mr. Chairman and members of the subcommittee, thank you for the opportunity to submit this testimony in support of fiscal year 2009 funding for the Foster Grandparent Program (FGP), the oldest and largest of the three programs known collectively as the National Senior Volunteer Corps, which are authorized by Title II of the Domestic Volunteer Service Act (DVSA) of 1973, as amended and administered by the Corporation for National and Community Service (CNS). The National Association of Foster Grandparent Program Directors (NAFGPD) is a membership-supported professional organization whose roster includes the majority of more than 350 directors, who administer Foster Grandparent Programs nationwide, as well as local sponsoring agencies and others who value and support the work of FGP.

Mr. Chairman, I would like to begin by thanking you and the distinguished members of the subcommittee for your steadfast support of the Foster Grandparent Program. No matter what the circumstances, this subcommittee has always been there to protect the integrity and mission of our programs. Our volunteers and the children they serve across the country are the beneficiaries of your commitment to FGP, and for that we thank you. I also want to acknowledge your outstanding staff for their tireless work and very difficult job they have to "make the numbers fit"—an increasingly difficult task in this budget environment.

#### ADMINISTRATION'S REQUEST FOR FGP

Although the number of older people in America eligible to serve as Foster Grandparent volunteers is increasing by leaps and bounds as the "Baby Boomer" cohort ages, we were extremely disappointed to learn that—instead of seeking an increase for FGP to enable FGP to engage more low-income seniors in service—the Administration has proposed slashing funding for FGP by \$40.825 million—a more than 37 percent cut.

## IMPACT OF THE ADMINISTRATION'S PROPOSED FUNDING CUT

FGP is the only program in existence today that actively seeks out, trains, enables, places and supports the elderly poor in contributing to their communities by changing the lives of children who desperately need one-on-one attention and assistance. This cut will take FGP back 12 years, to a funding level that is only slightly more than what was appropriated for the program in 1995.

If enacted, this request will have a devastating effect on FGP programs nationwide:

- Funding for FGP would be slashed \$40.825 million.
- 10,200 Foster Grandparent volunteers will be cut permanently, slashing the total number of Foster Grandparent volunteers from 30,550 to 20,350.
- Local communities will lose more than 10 million hours of volunteer service every year.
- FGP will permanently lose almost 10,200 Volunteer Service Years (VSY's, or volunteer "slots") if this budget is implemented. For each VSY that is cut from a Foster Grandparent Program, that program will lose approximately \$4,500 from its federal grant.
- 117,000 disadvantaged children/youth will lose their foster grandparent, an older adult they can count on!
- Low-income Baby Boomers will be excluded from serving as Foster Grandparents, because there will be no funds available to recruit and place new volunteers as they reach the age of 60. There are currently 6,000,000 low-income seniors eligible for FGP; in 20 years, there will be 13,000,000.

NAFGPD respectfully requests that the subcommittee:

(1) Provide \$115.937 million for the Foster Grandparent Program in fiscal year 2009, an increase of \$5,000 million over the fiscal year 2006 and fiscal year 2007 levels of funding (and the amount FGP would have received in fiscal year 2008 had there not been an across-the-board cut of 1.747 percent) for the program and an \$47.763 million increase over the Administration's fiscal year 2009 Budget Request for FGP. This critical funding will ensure the continued viability of the Foster Grandparent Program, and allow for important expansion of this unique program. Specifically, this proposal would fund a 3 percent cost of living increase for every Foster Grandparent Program as well as expansion grants to existing programs that would add 370 new low-income senior volunteers to serve 3,000 additional children;

(2) Maintain current appropriations statutory language that prohibits CNCS from using funds in the bill to pay non-taxable stipends to volunteers whose incomes exceed 125 percent of the national poverty level. Congress has repeatedly over the last seven years re-affirmed that the non-taxable stipend must be reserved for low-income volunteers. We ask that you again protect the mission of the Foster Grandparent Program to enable low-income older people to serve their communities—by maintaining this important statutory language.

## FGP: AN OVERVIEW

Established in 1965, the Foster Grandparent Program was the first federally funded, organized program to engage older volunteers in significant service to others. It remains today the only volunteer program in existence that enables seniors living on very low incomes to serve as community volunteers by providing a small non-taxable stipend that allows volunteers to serve at little or no cost to themselves. From the 20 original programs based totally in institutions for children with severe mental and physical disabilities, FGP now comprises nearly 350 programs in every state and the District of Columbia, Puerto Rico, and the Virgin Islands. These programs are now primarily in community-based child caring agencies or organizations—where most special needs children can be found today—and are administered locally through a non-profit organization or agency and Advisory Council comprised of community citizens dedicated to FGP and its mission. FGP represents the best in federal partnerships with local communities, with federal dollars flowing directly to local sponsoring agencies, which in turn determine how the funds are used. Through this partnership and the flexibility of the program, FGP is able to meet the immediate needs of the local communities. This was demonstrated by Foster Grandparent Programs in communities that were impacted by the influx of Hurricane Katrina evacuees. Foster Grandparents rallied to provide services to children in shelters, child care centers, and schools.

## FGP: THE VOLUNTEERS

There are currently 30,500 Foster Grandparent volunteers who give 31 million hours annually to more than 280,000 children, including almost 6,000 children of

prisoners through 10,200 local agencies. FGP is a versatile, dynamic, and uniquely multi-purpose program. The program gives Americans 60 years of age or older, who are living on incomes at or less than 125 percent of the poverty level, the opportunity to serve 15 to 40 hours every week and use the talents, skills and wisdom they have accumulated over a lifetime to give back to the communities which nurtured them throughout their lives. FGP provides intensive pre-service orientation and at least 48 hours of ongoing training every year to keep volunteers current and informed on how to work with children who have special needs.

FGP engages older people who are not usually asked to serve, those usually considered as needing services rather than being able to serve: 50 percent are between the ages of 61 and 74, 47 percent are 75+, and 50 percent are from various ethnic groups. FGP actively seeks out these low-income seniors. We dare to ask them to serve, and we help them to develop the additional skills they may need to function effectively in settings unfamiliar to them, like public schools, hospitals, childcare centers, and juvenile detention facilities. Through their service, our older volunteers say they feel and stay healthier, that they feel needed and productive. Most importantly, they leave to the next generation a legacy of skills, perspective and knowledge that has been learned the hard way—through experience.

#### FGP: THE CHILDREN

Through our volunteers, FGP also provides person-to-person service to children and youth under the age of 21 who have special or exceptional needs, many of whom face serious, often life-threatening challenges. With the changing dynamics in family life today, many children with disabilities and special needs lack a consistent, stable adult role model in their lives. The Foster Grandparent is very often the only person in a child's life who is there every day, who accepts the child, encourages him/her no matter how many mistakes the child makes, and focuses on the child's successes.

Special needs of children served by Foster Grandparents include AIDS or addiction to crack or other drugs; abuse or neglect; physical, mental, or learning disabilities; speech, or other sensory disabilities; incarceration and terminal illness. Of the children served, 7 percent are abused or neglected, 25 percent have learning disabilities, and 10 percent have developmental delays. FGP focuses its resources in areas where they will have the most impact: early intervention services and literacy activities. Nationally, 90 percent of the children served by Foster Grandparents are under the age of 12, with 39 percent of these children age 5 or under. Foster Grandparents work intensively with these very young children to address their problems at as early an age as possible, before they enter school. Nearly one-half of FGP volunteers serve nearly 12 million hours annually addressing literacy and emergent-literacy problems with special needs children.

Activities of the FGP volunteers with their assigned children include teaching parenting skills to teen parents; providing physical and emotional support to babies and toddlers at-risk; helping children with developmental delays, speech, or physical disabilities develop social and self-help skills; reinforcing reading and mathematics skills; and giving guidance and serving as mentors to incarcerated or other youth.

#### FGP: THE VOLUNTEER SITES

The Foster Grandparent Program provides child-caring agencies and organizations offering services to special-needs children with a consistent, reliable, invaluable extra pair of hands 15 to 40 hours every week to assist in providing these services. Seventy-one percent of FGP volunteers serve in public and private schools as well as sites that provide early childhood pre-literacy services to very young children, including Head Start.

#### FGP: COST-EFFECTIVE SERVICE

The Foster Grandparent Program serves local communities in a high quality, efficient and cost-effective manner, saving local communities money by helping our older volunteers stay independent and healthy and out of expensive in-home or institutional care. Using the Independent Sector's 2006 valuation for one hour of volunteer service (\$18.77/hour), the value of the service given by Foster Grandparents annually is over \$503 million, and represents a 4-fold return on the federal dollars invested in FGP.

The value local communities place on FGP and its multifaceted services is evidenced by the large amount of cash and in-kind donations contributed by communities to support FGP. For example, FGP's fiscal year 2007 federal allocation was matched with \$36.1 million in non-federal donations from states and local communities in which Foster Grandparents volunteer. This represents a non-federal match of 26 percent—well over the 10 percent local match required by law.

## CONCLUSION

The message is clear: (1) the population of low-income seniors available to volunteer 15 to 40 hours every week is increasing; (2) communities need and want more Foster Grandparent volunteers and more Foster Grandparent Programs. The Subcommittee's continued investment in FGP now will pay off in savings realized later, as more seniors stay healthy and independent through volunteer service, as communities save tax dollars, and as children with special needs are helped to become contributing members of society.

Mr. Chairman, in closing I would like to again thank you for the Subcommittee's support and leadership for Foster Grandparent Programs over the years. The National Association of Foster Grandparent Program Directors believes that you and your colleagues in Congress appreciate what our low-income senior volunteers accomplish every day in communities across the country.

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PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE ALCOHOL AND DRUG ABUSE DIRECTORS

Chairman Harkin, ranking member Specter, and members of the subcommittee, on behalf of the National Association of State Alcohol and Drug Abuse Directors (NASADAD), and our component organizations, the National Prevention Network (NPN), and the National Treatment Network (NTN), thank you for your leadership on issues related to addiction treatment, prevention, recovery services and research. We are pleased to offer recommendations on fiscal year 2009 funding.

*Substance Abuse Spending Represents Tiny Fraction of all Health Expenditures.*—It is estimated that substance abuse represented 1 percent (\$21 billion) of the expenditures for all healthcare (\$1,614 billion) in 2003. With over 22.6 million Americans suffering from substance abuse or dependency problems in 2006, we believe an increase in Federal investments for addiction services and research will save lives, families, and money.

Substance Abuse Prevention and Treatment (SAPT) Block Grant: NASADAD recommends \$1,858.7 million for the SAPT Block Grant in fiscal year 2009—an increase of \$100 million over fiscal year 2008 and \$80 million over the President's request. NASADAD supports such an increase in the SAPT Block Grant to enable all States the ability to expand capacity for much needed prevention and treatment services. The SAPT Block Grant, a program distributed by formula to all States and territories, represents the backbone of the nation's publicly funded addiction system.

Important Prevention Funding: Twenty percent of the SAPT Block Grant is dedicated to funding much needed substance abuse prevention programming. The prevention set-aside has helped produce demonstrable results. The Monitoring the Future (MTF) Survey found a 23 percent decline in any illicit drug use in the past month by 8th, 10th and 12th graders combined between 2001 and 2006. As a result, there were 840,000 fewer teens using drugs in 2006 compared to 2001. A strong commitment to the SAPT Block Grant will ensure a strong commitment to much needed prevention services for our youth.

SAPT Block Grant Funded Services Achieve Results: Through the National Outcome Measures (NOMs) initiative, States report excellent results from programs funded by the SAPT Block Grant—including the following examples:

Iowa's Division of Behavioral Health and Professional Licensure reported 42,700 admissions to treatment and provided prevention services to approximately 304,503 individuals in State fiscal year 2006. For State fiscal year 2006, the Iowa's Consortium for Substance Abuse Research and Evaluation found the following client outcomes comparing admission to 6 months after discharge: 87 percent of clients reported no arrests; 51.8 percent of clients were employed full time; and approximately 60 percent of clients were abstinent from illicit drugs.

Pennsylvania's Bureau of Drug and Alcohol Programs reported 92,224 admissions to treatment and provided prevention services to 111,145 individuals in State fiscal year 2005. In State fiscal year 2005, the Bureau reported the following client outcomes comparing admission to discharge: 77 percent of clients addicted to alcohol were abstinent; 71 percent of clients addicted to cocaine/crack were abstinent; 75 percent of clients addicted to marijuana were abstinent; and 65 percent of clients addicted to heroin were abstinent.

Rhode Island's Division of Behavioral Healthcare Services reported 8,170 admissions to treatment in 2006 and reported the following client outcomes: an 84.3 percent increase in the number of patients abstinent from alcohol; a 74.8 percent increase in the number of patients abstinent from other drugs; an 81.3 percent decrease in the number of patients arrested; and a 23 percent decrease in homelessness.

Illinois' Division of Alcoholism & Substance Abuse reported 77,386 admissions to treatment and provided services to 165,289 persons in State fiscal year (SFY) 2006. In fiscal year 2006, the Division reported the following client outcomes: 62 percent increase in the number of patients abstinent from alcohol; a 73 percent increase in the number of patients abstinent from illicit drug use; a 33 percent increase in the number of patients employed; and a 24 percent decrease in homelessness.

NASADAD wishes to recognize Dr. Terry Cline, SAMHSA Administrator, for his leadership, outreach and collaboration with States to improve service delivery.

Center for Substance Abuse Treatment (CSAT): NASADAD recommends \$420 million in fiscal year 2009—an increase of \$20.2 million compared to fiscal year 2008 and an increase of \$80 million compared to the President's request.

NASADAD is extremely concerned with the fiscal year 2009 proposed budget that would cut CSAT by \$63 million compared to fiscal year 2008. The proposed budget for CSAT would eliminate the following activities that are important to State substance abuse agencies:

- Recovery Community Services Program, a cut of \$5.2 million.
- State Service Improvement, with no funding fiscal year 2008 and \$907,000 in fiscal year 2007.
- Pregnant and Postpartum Women, a cut of \$11,790,000.
- Program Coordination and Evaluation, a cut of \$5,214,000. This initiative supports important initiatives such as Recovery Month.
- Strengthening Treatment Access & Retention, a cut of \$3.6 million.
- Children and Families, a cut of \$24,278,000.

The proposed budget for CSAT would significantly reduce funding for other programs that are important to State substance abuse agencies, including

- Opioid Treatment Programs/Regulatory Activities, a cut of \$2,886,000 compared to the fiscal year 2008 level of \$8,903,000.
- Targeted Capacity Expansion [TCE], a cut of \$11,191,000 compared to the fiscal year 2008 level of \$28,989,000.
- Services Accountability (supports CSAT data collection activities), a cut of \$13,617,000 compared to the fiscal year 2008 level of \$23,093,000.
- Addiction Technology Transfer Centers [ATTCs], a cut of \$478,000 compared to the fiscal year 2008 level of \$9,081,000.
- Treatment Systems for the Homeless, a cut of \$9,906,000 compared to the fiscal year 2008 level of \$42,5000,000.

NASADAD wishes to acknowledge Dr. H. Westley Clark, Director of CSAT, for his leadership and excellent partnership with NASADAD and States.

Center for Substance Abuse Prevention (CSAP): NASADAD recommends \$215 million—an increase of \$20.9 million compared to fiscal year 2008 and an increase of \$56.9 million compared to the President's proposal.

NASADAD is very concerned with the proposal to cut funding for CSAP by \$36 million compared to fiscal year 2008. The proposed budget for CSAP would negatively impact a number of activities that are important to State substance abuse agencies.

For example, NASADAD is concerned with a proposal to fund the Strategic Prevention Framework State Incentive Grant at \$95,389,000, representing a cut of \$9,318,000 compared to the fiscal year 2008 level of \$104,707,000. Presently, the proposed fiscal year 2009 budget does not identify whether SAMHSA would allocate future SPF-SIG awards at levels equal to previous years. NASADAD views resources for the SPF-SIG program as a top priority and recommends funding that would enable all States and jurisdictions to receive an award in an amount that is not less than the last cohort.

NASADAD is also concerned with the proposal to fund the Centers for the Application of Prevention Technologies [CAPTs] at \$4,381,000, representing a cut of \$7,656,000 compared to the fiscal year 2008 level of \$12,216,000. NASADAD remains concerned with any action that could threaten the continuation of the CAPTs in their present form and structure. NASADAD recommends funding at fiscal year 2008 levels for the CAPTs in order to enable these regional Centers to continue to improve the quality of each State's substance abuse prevention service system by translating the latest research into everyday practice.

Other concerns with the fiscal year 2009 proposed budget center on the following proposals:

- Sober Truth on Prevention Underage Drinking [STOP Act], which is proposed to be eliminated, representing a cut of \$5,404,000.
- Methamphetamine Prevention, a cut of \$2,386,000 compared to the fiscal year 2008 level of \$2,967,000.
- Program Coordination/Data Coordination and Consolidation Center, a cut of \$5,186,000 compared to the fiscal year 2008 level of \$6,016,000.

—Evidence Based Practices, which is proposed to remain at zero funding as it was in fiscal year 2008, while the program was funded at \$1,443,000 in fiscal year 2007.

NASADAD wishes to acknowledge the work of Dr. Anna Marsh, Acting Director of CSAP, for her work and dedication on prevention issues.

Safe and Drug Free Schools and Communities—State Grants: NASADAD recommends \$346.5 million, representing a \$51.8 million increase over fiscal year 2008 and \$246.5 million increase over the President's request. The SDFSC State Grants program is an effective initiative that represents a core component of each State's substance abuse prevention system. Certain Governors choose NASADAD members as the designee to manage these funds. This designation allows for a more comprehensive and coordinated approach to planning and implementing an effective State-wide system of care.

National Institute on Drug Abuse (NIDA): NASADAD recommends \$1,067.8 million, representing an increase of \$67.1 million over fiscal year 2008 and an increase of \$66.2 million over the President's request. NASADAD wishes to thank Dr. Nora Volkow, Director of NIDA, for her collaboration with State substance abuse agencies through its "Blending Initiative." This work improves the translation of research into everyday practice.

National Institute on Alcohol Abuse and Alcoholism (NIAAA): NASADAD recommends \$465.5 million, for an increase of \$29.2 million over fiscal year 2008 and an increase of \$28.9 million over the President's request.

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#### PREPARED STATEMENT OF THE NATIONAL ASSOCIATION FOR STATE COMMUNITY SERVICES PROGRAMS

Over the past several years and once again this year, the President has zeroed out the Community Services Block Grant (CSBG) program in his budget. However, recognizing the importance of the numerous self-sufficiency services provided by the CSBG Network, Congress has continued to support the program in word and in action by providing the CSBG program with funding. The National Association for State Community Services Programs (NASCSPP), the national association representing State administrators of the Department of Health and Human Services' Community Services Block Grant (CSBG) and State directors of the Department of Energy's Low-Income Weatherization Assistance Program, would like to thank Congress for its continued support of the Community Services Block Grant (CSBG) and requests an appropriation of \$700 million for the State grant portion of the CSBG. We are requesting \$700 million in CSBG funding this year in order for the CSBG Network to continue addressing the long-term needs of those families affected by Hurricanes Katrina and Rita and those families transitioning from welfare to work, and to assist low-income workers in remaining at work through supportive services such as transportation and child care. It is essential that the CSBG funding be increased for fiscal year 2009. The across the board cuts to the CSBG funding over the past several years have decreased the ability of the CSBG Network to provide essential services to low-income Americans.

#### BACKGROUND

The States believe the CSBG is a unique block grant that has successfully transferred decision-making to the local level. Federally funded with oversight at the State level, the CSBG has maintained a local network of nearly 1,100 agencies which operate in 99 percent of counties in the Nation. This network serves nearly 15 million low-income individuals, members of more than 7 million low-income families, CSBG eligible entities, largely local Community Action Agencies (CAAs), provide States with a stable and guaranteed network of designated entities which are mandated to change the conditions that perpetuate poverty for individuals, families, and communities. There is no other program in the United States mandated by Federal statute to respond to poverty. To fulfill that mandate, CAAs provide services based on the characteristics of poverty in their communities. For one community, this might mean providing job placement and retention services; for another, developing affordable housing. In rural areas, it might mean providing access to health services or developing a rural transportation system.

Since its inception, the CSBG has shown how partnerships between States and local agencies benefit citizens in each State. We believe it should be viewed as a model of how the Federal Government can best promote self-sufficiency for low-income persons in a flexible, decentralized, non-bureaucratic and accountable way.

Long before the creation of the Temporary Assistance for Needy Families (TANF) block grant, the CSBG set the standard for private-public partnerships that work



to revitalize local communities and address the needs of low-income residents. Family oriented, while promoting economic development and individual self-sufficiency, the CSBG relies on an existing and experienced community-based service delivery system of CAAs and other non-profit organizations to produce results for its clients.

#### WHAT DO LOCAL CSBG AGENCIES DO?

Since CAAs operate in rural areas as well as in urban areas, it is difficult to describe a typical Community Action Agency. However, one thing that is common to all is the goal of self-sufficiency for all of their clients. Reaching this goal may mean providing day care for a struggling single mother as she completes her General Equivalency Diploma (GED) certificate, moves through a community college course and finally is on her own supporting her family without Federal assistance. Many CAAs administer the Head Start Program which helps meet the educational needs of low-income families. It may mean assisting a recovering substance abuser as he seeks employment. Many of the Community Action Agencies' clients are persons who are experiencing a one-time emergency. Others have lives of chaos brought about by many overlapping forces—a divorce, sudden death of a wage earner, illness, lack of a high school education, closing of a local factory or the loss of family farms.

CAAs provide access to a variety of opportunities for their clients. Although they are not identical, most will provide some, if not all, of the services listed below:

- a variety of crisis and emergency safety net services
- employment and training programs
- transportation and child care for low-income workers
- individual development accounts
- micro business development help for low-income entrepreneurs
- local community and economic development projects
- housing, transitional housing, and weatherization services
- Head Start
- energy assistance programs
- nutrition programs
- family development programs
- senior services

CSBG is the core funding which holds together a local delivery system able to respond effectively and efficiently, without a lot of red tape, to the needs of individual low-income households as well as to broader community needs. In addition, CSBG funds many of these services directly. Without the CSBG, local agencies would not have the capacity to work in their communities developing local funding, private donations and volunteer services and running programs of far greater size and value than the actual CSBG dollars they receive.

CAAs manage a host of other Federal, State, and local programs which makes it possible to provide a one-stop location for persons whose problems are usually multifaceted. Over half (52 percent) of the CAAs manage the Head Start program in their community. Using their unique position in the community, CAAs recruit additional volunteers, bring in local school district personnel, tap into faith-based organizations for additional help, coordinate child care and bring needed health care services to Head Start centers. In many States they also manage the Low Income Home Energy Assistance Program (LIHEAP), raising additional funds from utilities for this vital program. CAAs may also administer the Weatherization Assistance Program and are able to mobilize funds for additional work on residences not directly related to energy savings that, for example, may keep a low-income elderly couple in their home. CAAs also coordinate their programs with the Community Development Block Grant program to stretch Federal dollars and provide a greater return for tax dollars invested. They also administer the Women, Infants and Children (WIC) nutrition program, as well as job training programs, substance abuse programs, transportation programs, domestic violence and homeless shelters, and food pantries.

For every CSBG dollar they receive, CAAs leverage \$5.47 in non-Federal resources (State, local, and private) to coordinate efforts that improve the self-sufficiency of low-income persons and lead to the development of thriving communities.

#### WHO DOES THE CSBG SERVE?

National data compiled by NASCSP show that the CSBG serves a broad spectrum of low-income persons, particularly those who are not being reached by other programs and are not being served by welfare programs. Based on the most recently reported data, from fiscal year 2005 CSBG serves:

- More than 3 million families with incomes at or below the poverty level; of these customer families, 31 percent are severely poor as they have incomes at or below 50 percent of the poverty guideline.
- More than 1.3 million families headed by single mothers.
- More than 1.6 million “working poor” families with wages or unemployment benefits as income; collectively, they make up 45 percent of all program participants.
- More than 404,000 TANF participant families, 23 percent of all TANF families nationwide.
- About 4 million children.
- Almost 2.8 million people without health insurance.
- Almost 1.8 million adults who had not completed high school.

#### MAJOR CHARACTERISTICS OF THE CSBG NETWORK

Due to the unique structure of the CSBG, the CSBG Network has earned a reputation for its:

*Emergency Response.*—CAAs are utilized by Federal and State emergency personnel as a frontline resource to deal with emergency situations such as floods, hurricanes and economic downturns. They are also relied on by citizens in their community to deal with individual family hardships, such as house fires or other emergencies.

In fact, during and after Hurricanes Katrina and Rita, the State CSBG offices and local CAAs quickly mobilized to provide immediate and long-term assistance to over 355,000 evacuees. This immediate assistance included, but was not limited to, transportation, food, medical check-ups, housing, utility deposits, job placement, and clothing. State CSBG offices and CAAs across the country coordinated their relief efforts with other agencies providing disaster relief assistance such as FEMA, Red Cross, and other faith-based and community-based organizations.

State CSBG offices, through their local network of CAAs, continue to provide the long-term assistance evacuees will need as they re-establish themselves through self-sufficiency and family development programs. These programs offer comprehensive approaches to selecting and offering supportive services that promote, empower and nurture the individuals and families seeking economic self-sufficiency. At a minimum, these approaches include:

- A comprehensive assessment of the issues facing the family or family members and of the resources the family brings to address these issues;
- A written plan for becoming more financially independent and self-supporting;
- A comprehensive mix of services that are selected to help the participant implement the plan;
- Professional staff members who are flexible and can establish trusting, long-term relationships with program participants; and
- A formal methodology used to track and evaluate progress as well as to adjust the plan as needed.

*Leveraging Capacity.*—In fiscal year 2006, every CSBG dollar leveraged \$18.73 from all other sources. Of those leveraged funds, \$5.47 came from non-Federal resources (State, local, and private) to coordinate efforts that improve the self-sufficiency of low-income persons and lead to the development of thriving communities.

*Volunteer Mobilization.*—CAAs mobilize volunteers in large numbers. In fiscal year 2006, the most recent year for which data are available, the CAAs elicited more than 44 million hours of volunteer efforts, the equivalent of almost 21,187 full-time employees. Using just the minimum wage, these volunteer hours are valued at nearly \$227 million.

*Adaptability.*—CAAs provide a flexible local presence that governors have mobilized to deal with emerging poverty issues.

Moreover, the CSBG Network has also earned a reputation for its:

*Accountability.*—The Federal Office of Community Services, State CSBG offices, and CAAs have worked closely to develop a results-oriented management and accountability (ROMA) system. Through this system, individual agencies determine local priorities within six common national goals for CSBG and report on the outcomes that they achieved in their communities.

*Local Direction and Oversight.*—Tri-partite boards of directors guide CAAs. These boards consist of one-third elected officials, one-third representatives from the private sector, and not less than one-third of the members are representative of the low-income persons in the neighborhoods served by the CAA. The boards are responsible for establishing policy and approving business plans of the local agencies. Since these boards represent a cross-section of the local community, they guarantee that CAAs will be responsive to the needs of their community.

The statutory goal of the CSBG is to ameliorate the effects of poverty. The primary goal of every CAA is self-sufficiency for its clients. Helping families become self-sufficient is a long-term process that requires multiple resources. This is why the partnership of Federal, State, local and private enterprise has been so vital to the successes of the CAAs.

#### EXAMPLES OF CSBG AT WORK

Since 1994, CSBG has implemented a Results-Oriented Management and Accountability (ROMA) system. Through ROMA, the effectiveness of programs is captured through the use of goals and outcomes measures. Below you will find the network's nationally aggregated outcomes achieved by individuals, families and communities as a result of their participation in innovative CSBG programs during fiscal year 2006:

- 104,792 participants gained employment with the help of community action
- 34,115 participants obtained “living wage” employment with benefits
- 82,981 low-income participants obtained safe and affordable housing in support of employment stability
- 715,870 low-income households achieved an increase in non-employment financial assets, including tax credits, child support payments, and utility savings, as a result of community action (\$288 million in aggregated savings)
- 1,301 families achieved home ownership as a result of accumulated savings from IDA savings accounts
- 157,061 low-income people obtained pre-employment skills and received training program certificates or diplomas, completed Adult Basic Education or GED coursework and received certificates or diplomas, and/or completed post-secondary education and obtained a certificate or diploma
- 4,498,366 new community opportunities and resources were created for low-income families as a result of community action work or advocacy, including “living wage” jobs, affordable and expanded public and private transportation, medical care, child care and development, new community centers, youth programs, increased business opportunity, food, and retail shopping in low-income neighborhoods

At the end of the day, the CSBG Network represents our abiding national commitment to care for the less fortunate and in recognition that we are stronger when we do so. The CSBG and CSBG Network, in addition to other non-profit faith-based and community-based organizations, are a critical complement to the public sector's efforts towards helping to lift low-income Americans and their communities out of poverty and into self-sufficiency.

In fiscal year 2006, the CSBG Network assisted approximately 22 percent of the persons in poverty that year and almost 15 million low-income individuals who are members of more than 7 million low-income families. Renewed funding for the CSBG Network is one of the best ways to ensure that America has an experienced, guaranteed and trusted network to assist its most vulnerable families in achieving and maintaining self-sufficiency. As such, NASCSP requests \$700 million in CSBG funding for fiscal year 2009.

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#### PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE HEAD INJURY ADMINISTRATORS

Mr. Chairman, on behalf of the National Association of State Head Injury Administrators (NASHIA), I am submitting this testimony in support of funding the Federal Traumatic Brain Injury (TBI) Grant Program at \$15 million for fiscal year 2009. The members of NASHIA also thank you for your support of the reauthorization of the TBI Act, which is expected to be signed into law within the next few days.

This year marks the eleventh year that grants have been available to States to develop and expand service delivery systems to better serve those with TBI and their families. Congress originally authorized the Federal TBI Program under the TBI Act of 1996, and the most recent reauthorization bill is currently awaiting the President's signature. The Act authorizes funding to the Department of Health and Human Services, Health Resources and Services Administration (HRSA) for grants to States, the District of Columbia and Territories to improve access and increase service delivery for individuals with TBI and their families. The Act also authorizes funding to HRSA for Protection & Advocacy Services (P&A) for individuals with TBI and their families and to the Centers for Disease Control and Prevention (CDC) for injury surveillance, prevention and public education.

The HRSA Federal TBI State Grant Program began as a very small program, yet it remains the only source of Federal funding that spurs States to develop, expand and improve service delivery for individuals with TBI and their families. For the past 4 years, the administration has zeroed out funding for the program as a result of a poor PART score by the Office of Management and Budget (OMB). This was unfortunate for persons with TBI and their families because the PART evaluation was flawed as it measured health outcomes for individuals and this program was not designed nor intended to provide direct health services.

In order to better evaluate the program, the Institute of Medicine (IOM) conducted a study and issued a report on its findings in 2006. The report commended state activities, particularly in leveraging other resources, but was less complimentary of program management due to lack of staff (there has been only one staff person) and agency commitment. IOM recommended that an advisory board be established as soon as possible to assist HRSA in setting a national agenda, coordinating with sister federal agencies and to develop evaluation procedures for the program.

The IOM found that the "Federal Program has demonstrated beneficial change in State organizational infrastructure and increased the visibility of TBI—both essential conditions for improving TBI service systems." Further, the IOM noted that "States are now at a critical stage and will need continued Federal support if they are to build an effective, durable service system for meeting the needs of individuals with TBI and their families." Federal funding, however, has declined.

To address IOM's recommendations and the emerging issues, such as returning troops with misdiagnosed or undiagnosed TBIs, we respectfully request \$15 million for the HRSA Federal TBI State Grant Program. This would allow each State to be funded in the amount of \$250,000, which is closer to the amount initially awarded to States in 1997 for Implementation Grants. Over time, HRSA lowered the grant award amounts to \$100,000 in an effort to bring more States into the program, with the Territories receiving \$70,000. While this approach may have helped to bring attention to TBI in more States, fewer dollars to each State made it more difficult to make important systems change and to sustain efforts.

As the result of the large number of returning troops from Iraq and Afghanistan who have TBI and related conditions, States are facing an increased demand for information, community resources, assistance and family supports. Almost half of the States legislatures, Governors and/or department directors have initiated State agency coordination among TBI, mental health, State Veteran's Commissions and National Guard or have elected to only focus on either TBI or Post Traumatic Stress Disorder (PTSD) in some capacity to address these concerns. This puts more pressure on TBI systems that are already woefully underfunded.

Given that the origin of these TBIs is a result of service to our country, this has resulted in a federal action that ultimately imposes an additional burden on the States. A \$100,000 grant is inadequate for States to develop and sustain efforts previously initiated, let alone increase service delivery each year to meet the growing number of individuals with TBI and their families, including returning servicemembers.

NASHIA also supports \$9 million for CDC data surveillance, prevention and public education programs, and \$6 million for the HRSA P&A Services Grant Program to expand their client advocacy to include individuals with TBI. These programs augment States' abilities to better plan for service delivery, as the result of CDC data, and the P&A grants help individuals to access these often confusing and complicated systems.

Families are the primary caretakers of individuals with TBI, and these families are aging as well. The CDC has just released its informational packet, "Help Seniors Live Better, Longer: Prevent Brain Injury Initiative" as the result of its finding that people ages 75 and older have the highest rates of TBI-related hospitalizations and death—another emerging issue. States have limited resources to provide the long-term care and supports needed for those who may not have families any longer to protect and support them. They are faced with decreased State revenue, cut backs in Medicaid and other Federal resources.

Despite all these challenges, States have been able to leverage and maximize other resources to address unmet needs. Some of these examples include:

#### VETERANS AND RETURNING TROOPS

The beauty of the HRSA Federal TBI Grant program is that it directs States to develop necessary infrastructure for service delivery, and promotes coordination of State programs and policies through the advisory boards and by the lead TBI agency. As such, those States that have had strong leadership and commitment for TBI services, are poised to help their sister State agencies and returning troops to access

services. A few States (MA, VT and NY) have already been at the forefront of collaborating with other State and local agencies to better coordinate public education, outreach, information & referral and resources to returning troops with TBI or for those who may be misdiagnosed and undiagnosed.

#### CHILDREN

The CDC estimates that 37,000 children and youth receive brain injuries severe enough to require hospitalization each year. According to the most recent U.S. Department of Education numbers, the total number of students served in special education under the TBI category is 14,844. This discrepancy in numbers illustrates that the majority of students with traumatic brain injury are either misclassified or not identified at all as having a brain injury and will not receive needed services.

As the result of these findings, States (OR, TN, AL, PA, HI, OH) have used their Federal grant funding to screen children for TBI in public educational settings to improve identification; developed resources for educators to help with developing Individual Education Programs (IEPs) and appropriate educational and behavioral strategies to improve learning; and/or resource teams to provide consultative services.

#### UNSERVED/UNDERSERVED

Several States have used their Federal funds to provide outreach to Native Americans (MT, OH, ND, AZ) and other cultures, such as African Americans, Hispanics and Asians (MA, NJ, IL, CT, FL, MN), to access TBI, needed services and supports to live and work in the community.

#### TBI TECHNICAL ASSISTANCE CENTER (TAC)

Another important component of the HRSA Federal TBI Program is the TBI TAC which is administered by NASHIA in order to help State grantees and non-grantees to:

- Develop Service delivery infrastructure
- Develop effective programs that improve access to health and other TBI services
- Develop plans for sustainability after federal funding ends
- Develop plan, implement and evaluate TBI related initiatives
- Identify resources, develop strategies, and implement programs for children and youth and ensure that activities are appropriately family centered and culturally competent.
- Develop and submit grantee proposal applications

The TBI TAC also develops and conducts the annual Federal TBI Program Grantee Meetings, offers peer mentoring to encourage the transfer of knowledge among the States and Territories, and disseminates materials and resources.

#### RESPONDING TO NATIONAL NEEDS

The TBI TAC responds to emerging issues through webcast trainings and informational packets on state and community initiatives. These educational packets include information on returning troops with TBI; TBI trust funds to support rehabilitation services and supports; educational services for children, screening tools, and training programs for direct support personnel and other professionals. Webcasts have been conducted on a variety of issues including services provided by the Veterans Administration, housing, substance abuse, employment, TBI trust funds, domestic violence, children's services, educational services and neurobehavioral health.

The TBI TAC also maintains a data base known as the Traumatic Brain Injury Collaboration Space (TBICS). The TBICS is a clearinghouse of all products and materials available for improving state service delivery. The TBI TAC also operates a listserv for approximately 1,000 subscribers to disseminate information and for subscribers to submit questions and share "best practices."

#### STILL WORK TO DO

While the IOM acknowledged these and other State efforts, it still noted that the quality and coordination of post-acute TBI service systems remains inadequate. Individuals with TBI, their families, caregivers and others report substantial problems in getting basic services, including housing, vocational services, neurobehavioral services, transportation and respite for caregivers. Service coordination, which is offered in some States, is not uniformly offered in all States to all age groups. Families still report the need for information and assistance at the time of hospitalization, and help with resulting behavioral problems that often are too burdensome to the family. States report difficulty in finding and paying for qualified and experi-

enced providers, professionals and direct care workers. Training and education are needed across the board for individuals, families, professionals, providers and policy makers to understand the complexity of the disability and resulting problems.

In conclusion, while the Federal TBI Act Programs have impacted State and local service delivery significantly, it is the only Federal funding available to help States develop, improve and expand service delivery to meet the growing, yet differing needs of individuals of all ages, all cultures and regardless of cause of injury—motor vehicle, falls, sporting, or occupational, including war-related injuries. This burden on the States is significant, complex and requires additional funding resources. For States to continue their efforts, let alone increase their capacity for the growing numbers of individuals with TBI needing community and long-term care and supports, will take significant federal support. We, therefore, urge you to increase funding for HRSA Federal TBI State Grant Program to \$15 million, as well as appropriate \$9 million to CDC and \$6 million to the HRSA TBI P&A Grant Programs.

Thank you for your continued support for the millions of individuals with TBI and those who serve them.

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PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE MENTAL HEALTH  
PROGRAM DIRECTORS

Chairman Harkin, ranking member Specter, and members of the subcommittee, on behalf of the National Association of State Mental Health Program Directors (NASMHPD), thank you for the opportunity to submit testimony on behalf of the \$29.5 billion public mental health service delivery systems serving 6.1 million people annually in all 50 States, four territories, and the District of Columbia. NASMHPD is the only national association to represent State mental health commissioners/directors and their agencies. In addition, NASMHPD has an affiliation with the approximately 220 State psychiatric hospitals. Our members administer and manage community-based systems of care for the millions of individuals with serious mental illness who at times require immediate access to a variety of inpatient facilities and psychiatric units in general hospitals but are often cared for successfully in the community.

An October 2006 report by NASMHPD illustrates how dire the need is for people with mental illness. This report States that persons with serious mental illness die, on average, 25 years earlier than the general population. In addition, according to the Substance Abuse and Mental Health Services Administration (SAMHSA), an estimated 17 million adults ages 18 and older (8.0 percent of the adult population) reported experiencing at least one major depressive episode during the past year. Finally, in the RAND Corporation's 2008 report, "Invisible Wounds of War: Psychological and Cognitive Injuries, Their Consequences, and Services to Assist Recovery," researchers concluded that there needs to be a nationwide effort to expand and improve the capacity of the mental health system to provide adequate care to members of the military and veterans. RAND further reported that this effort must involve the public mental health system, as well as the military and veteran health care systems.

*The Community Mental Health Services Block Grant (Block Grant).*—NASMHPD recommends providing \$482.9 million for the Block Grant, which represents a \$61.9 million increase over both the fiscal year 2008 budget and the President's fiscal year 2009 request.

The Block Grant is the principal Federal discretionary program supporting community-based mental health services for adults and children. States use Block Grant funding to provide a range of critical services for adults with serious mental illnesses and children with serious emotional disturbances, including employment and housing assistance, case management, school-based support services, family and parenting education, and peer support.

The Block Grant is vital because it gives each State the flexibility to: fund services that are tailored to meet the unique needs and priorities of consumers of the public mental health system in that State; hold providers accountable for access to, and quality of services provided; and coordinate services to help finance medical and social services that individuals with mental illnesses need to live safely and effectively in the community. The following are recent examples of how States used the Block Grant in the past to provide vital services:

*Iowa.*—Community mental health centers (CMHCs) that receive Block Grant funding use the funding to develop and implement evidence based practices for adults with serious mental illness and children with serious emotional disturbance. Block Grant funding has been used to provide training to CMHC about evidence based practices, how to evaluate programs for effectiveness, and how to transition

from non-evidence based practices. In addition, the Block Grant funds technical assistance to individual CMHCs regarding the implementation of evidence based practices.

*Pennsylvania.*—Pennsylvania allocated the majority of its fiscal year 2006 Block Grant funds to County Mental Health Programs, which expanded funds for services and supports to adults and older adults with serious mental illness and children with serious emotional disturbance. Block Grant funds may be spent in any service center except Psychiatric Inpatient services. These service areas include: community services; crisis intervention services; adult developmental training; community employment services; facility-based vocational rehabilitation; social rehabilitation services; family support services; community residential services; children's psychosocial rehabilitation services; community treatment teams; intensive case management; outpatient mental health; day treatment (partial hospitalization); family based mental health; resource coordination; administrative management; and emergency services such as housing support services.

*Wisconsin.*—Wisconsin's Block Grant funding has helped one or more of the following priorities: Certified Community Support Program development and service delivery; supported housing program development and service delivery; initiatives to divert persons from jails to mental health services; development and expansion of mobile crisis intervention programs; consumer peer support and self-help activities; coordinated, comprehensive services for children with serious emotional disturbance; development of strategies and services for persons with co-occurring mental health/substance use disorders, or mental health outcome data system improvement.

#### PROGRAMS OF REGIONAL AND NATIONAL SIGNIFICANCE (PRNS)

NASMHPD recommends providing \$343.3 million for PRNS, which represents a \$44 million increase over fiscal year 2008 and a \$188 million increase over the President's fiscal year 2009 request.

The Center for Mental Health Services (CMHS) addresses priority mental health care needs of regional and national significance by developing and applying best practices, providing training and technical assistance, building targeted capacity expansion, and changing the service delivery system through family, client-oriented and consumer-run activities. Several important programs that will be positively affected by an increase in PRNS funding include, but are not limited to:

#### *Suicide Prevention for Children and Adolescents.—\$55.7 million*

In 2004, 32,439 individuals died by suicide in the United States. Of these suicides, more than 4,500 were young people between the ages of 10–24. Nationally, suicide is the third leading cause of death among children aged 10–14 and among adolescents and young adults aged 15–24. According to the final report of President Bush's New Freedom Commission on Mental Health (2003), "our Nation's failure to prioritize mental health is a national tragedy . . . No loss is more devastating than suicide. Over 30,000 lives are lost annually to this largely preventable public health problem . . . Many have not had the care in the months before their death that would help them to affirm life. The families left behind live with shame and guilt . . ."

CMHS funds two specific suicide prevention initiatives. The first initiative is the National Suicide Prevention Lifeline (1-800-273-TALK), a network of more than 120 crisis centers across the country that respond, 24 hours a day, to individuals in emotional distress or suicidal crisis. In 2007, SAMHSA and the Department of Veterans' Affairs partnered to expand the reach of the Lifeline to provide for specialized veteran services. The second initiative is the Suicide Prevention Resource Center, which provides prevention support, training, and materials to strengthen suicide prevention efforts.

#### *Mental Health Transformation State Incentive Grants.—\$29.8 million*

The Mental Health Transformation State Incentive Grants (T-SIGs) support States' efforts to create comprehensive mental health plans and enhance the use of existing resources to serve persons with mental disorders. SAMHSA awarded seven T-SIGs in fiscal year 2005; two additional T-SIGs were awarded in fiscal year 2006. Grant funds can only be used for infrastructure changes, such as planning, collaborating, blended funding or developing service concepts, and policies and procedures that support a transformation agenda. Funding of direct mental health services must come from other sources. Grantees work closely with other agencies, such as criminal justice, housing, child welfare, Medicaid and education.

Federal funding for the State Incentive Grants supports States' efforts to develop more comprehensive State mental health plans. These plans facilitate the coordina-

tion of Federal, State, and local resources to support effective and dynamic State infrastructure to best serve persons with mental disorders.

*Alternatives to Seclusion and Restraint State Infrastructure Grants.—\$2.5 million*

Deaths due to seclusion and restraint in mental health and substance abuse care are estimated at approximately 150 per year across the United States. In addition to the risk of death and injury, individuals who have experienced previous physical or sexual abuse can suffer further traumatization when subjected to these practices.

The Alternatives to Seclusion and Restraint State Infrastructure Grant Project (S/R-SIG) provides training, technical assistance and other support to States, providers, facilities, and consumers and families in order to reduce and eliminate seclusion and restraint practices. SAMHSA awarded eight S/R-SIGs in fiscal year 2007. Most of these States are implementing best practices alternatives in multiple settings and with a variety of consumers.

*National Center for Trauma-Informed Care.—\$38 million*

The psychological effects of violence and trauma in our society are pervasive, highly disabling, yet largely ignored. Recent research indicates that interpersonal violence and trauma, including sexual and/or physical abuse, are widespread and have a major impact on a wide range of social problems which are costly if not addressed.

The National Center for Trauma-Informed Care provides technical assistance and training to publicly-funded agencies, programs, and services in order to encourage an environment that supports and empowers trauma survivors.

PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS (PATH)

NASMHPD recommends providing \$61.1 million for PATH, which represents a \$7.8 million increase over fiscal year 2008 and a \$1.4 million increase over the President's fiscal year 2009 request.

The PATH formula grant program provides funding to States, localities and non-profit organizations to support individuals who are homeless (or are at risk of homelessness) and have a serious mental illness and/or a co-occurring substance abuse disorder. PATH is designed to encourage the development of local solutions to the problem of homelessness and mental illness through strategies such as aggressive community outreach, case management and housing assistance. Other important core services include referral for primary care, job training and education. Surveys indicate that, in 2005, 463 PATH-funded local agencies enrolled more than 82,000 individuals of diverse racial and ethnic background with the most disabling mental illness. The most common diagnoses were schizophrenia, psychotic disorders and affective disorders. More than half of homeless consumers at first contact had been homeless for more than 30 days.

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

NASMHPD recommends providing \$1,498.6 million for NIMH, which represents a \$94.1 million increase over fiscal year 2008 and a \$91.6 million increase over the President's fiscal year 2009 request.

The mission of NIMH is to reduce the burden of mental and behavioral disorders through research on mind, brain, and behavior. Mental illnesses are fundamentally brain disorders that affect children, adolescents, and adults. Each year, more than 54 million people experience significant symptoms caused by mental disorders. This equates to one in every 20 adults who experience a disabling mental disorder. Of the ten leading causes of disability in the United States and internationally for individuals aged 15–44, four are mental disorders: major depression, bipolar disorder, schizophrenia, and obsessive-compulsive disorder. Left untreated, a mental disorder can lead to more severe and more difficult to treat illnesses, and to the development of co-occurring mental disorders.

NIMH is currently developing a Strategic Plan to: promote discovery in the brain and behavioral sciences to fuel research on the causes of mental disorders; determine when, where and how to intervene; develop new and better interventions that incorporate the diverse needs of people with mental disorders; and strengthen the public health impact of NIMH-supported research. NIMH must achieve the fundamental understanding of how mental disorders begin and progress, to discover new treatments, and eventually prevent and cure them.

OTHER IMPORTANT FUNDING RECOMMENDATIONS

—Substance Abuse Prevention and Treatment Block Grant for \$1,858.7 million



- Center for Substance Abuse Prevention Programs of Regional and National Significance for \$215.06 million
- Center for Substance Abuse Treatment Programs of Regional and National Significance for \$420 million
- SAMHSA Integrated Treatment for Co-Occurring Serious Mental Illness and Substance Abuse Disorders for \$4.14 million
- National Institute on Alcohol Abuse and Alcoholism (NIAAA) for \$465.5 million
- National Institute on Drug Abuse (NIDA) for \$1,067.7 million

#### CONCLUSION

Thank you for your continued support for mental health initiatives. If you have any questions, please do not hesitate to contact Elizabeth Prewitt, NASMHPD's Director of Government Relations, 66 Canal Center Plaza, Suite 302, Alexandria, VA, Fax: 703-548-9517, Phone: 703-682-5196, [elizabeth.prewitt@nasmhpd.org](mailto:elizabeth.prewitt@nasmhpd.org).

#### PREPARED STATEMENT OF THE NATIONAL COALITION FOR HOMELESS VETERANS

##### INTRODUCTION

The National Coalition for Homeless Veterans (NCHV) appreciates the opportunity to submit testimony to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education & Related Agencies regarding the Homeless Veteran Reintegration (HVRP) and Veteran Workforce Investment Programs (VWIP), administered by the U.S. Department of Labor (DOL) Veterans' Employment and Training Service (VETS).

Established in 1990, NCHV is a not for profit organization with the mission of ending homelessness among veterans by shaping public policy, promoting collaboration, and building the capacity of service providers. NCHV is the only national organization wholly dedicated to helping end homelessness among America's veterans.

In the years since its founding, NCHV's membership has grown to over 280 organizations in 46 states, the District of Columbia, Guam and Puerto Rico. As a network, NCHV members provide the full continuum of care to homeless veterans and their families, including emergency shelter, food and clothing, primary health care, addiction and mental health services, employment supports, educational assistance, legal aid and transitional housing.

##### HOMELESSNESS AMONG VETERANS

The homeless veteran assistance movement NCHV represents began in earnest in 1990, but like a locomotive it took time to build the momentum that has turned the battle in our favor. In partnership with the Departments of Veterans Affairs (VA), DOL, and Housing and Urban Development (HUD)—supported by the funding measures this committee has championed—our community veteran service providers have helped reduce the number of homeless veterans on any given night in America by 38 percent in the last 6 years.

This assessment is not based on the biases of advocates and service providers, but by the federal agencies charged with identifying and addressing the needs of the nation's most vulnerable citizens. To its credit, the VA has presented to Congress an annual estimate of the number of homeless veterans every year since 1994. It is called the CHALENG project, which stands for Community Homelessness Assessment, and Local Education Networking Groups. In 2003 the VA CHALENG report estimate of the number of homeless veterans on any given day stood at more than 314,000; in 2006 that number had dropped to about 194,000. We have been advised the estimate in the soon-to-be published 2007 CHALENG Report shows a continued decline, to about 154,000.

Part of that reduction can be attributed to better data collection and efforts to avoid multiple counts of homeless clients who receive assistance from more than one service provider in a given service area. But in testimony before the House Committee on Veterans Affairs in the summer of 2005, VA officials affirmed the number of homeless veterans was on the decline, and credited the agency's partnership with community-based and faith-based organizations for making that downturn possible.

Though estimates are not as reliable as comprehensive "point-in-time" counts, the positive trends noted in the CHALENG reports since 2003 are impressive. The number of contacts reporting data included in the assessments is increasing, while the number of identified and estimated homeless veterans is decreasing.

Other federal assessments of veteran homelessness that support our testimony are found in HUD's 2007 Annual Homelessness Assessment Report—which reported 18 percent of clients in HUD-funded homeless assistance programs are veterans—

and the 2000 U.S. Census, which reported about 1.5 million veteran families are living below the Federal poverty level. Earlier this year, the National Alliance to End Homelessness published a report, based on information from these resources, that estimated approximately 46,000 veterans meet the criteria to be considered as “chronically homeless.”

Despite the reduction in the “point-in-time” counts, the VA reports the number of veterans experiencing homeless at sometime during the year remains around 400,000. The VA serves about 25 percent or 100,000 of this population annually and NCHV member community-based organizations (CBOs) serve 150,000 or 35 percent each year. Consequently, almost 40 percent of the nation’s homeless veterans still do not receive the help they need. It is likely some of these veterans are receiving assistance from other community resources, but there is no way to determine how many or the nature of services being provided.

#### HOMELESS VETERANS REINTEGRATION PROGRAM APPROPRIATIONS

There are only two non-government veteran-specific homeless assistance programs serving the men and women who represent nearly a quarter of the nation’s homeless population. The over-representation of veterans among the homeless that is well documented and continues to this day is the result of several influences, most notably limited resources in communities with a heavy demand for assistance by single parents and families with dependent children, the elderly and the disabled.

The DOL HVRP and the VA Homeless Providers Grant and Per Diem were created in the late 1980s to provide access to services for veterans who were unable to access local, federally funded, “mainstream” homeless assistance programs. These programs are largely responsible for the downturn in veteran homelessness reported during the last six years, and must be advanced as essential components in any national strategy to prevent future veteran homelessness. This testimony will focus solely on the HVRP.

Administered by DOL–VETS, HVRP is a grant program that awards funding to government agencies, private service agencies and community-based nonprofits that provide employment preparation and placement assistance to homeless veterans. As the only federal employment assistance program targeted to this population, HVRP serves those who may be shunned by other programs and services because of problems such as severe post-traumatic stress disorder, long histories of substance abuse, serious psychosocial problems, legal issues, and those who are HIV-positive. These veterans require more time-consuming, specialized, intensive assessment, referrals and counseling than is possible in other programs that work with veterans seeking employment.

The employment focus of HVRP distinguishes it from most other programs for the homeless, which concentrate on more immediate needs such as emergency shelter, food and substance abuse treatment. While these are critical components of any homeless program, and grantees are required to demonstrate that their clients’ needs in those areas are met, the objective of HVRP programs is to enable homeless veterans to secure and keep jobs that will allow them to re-enter mainstream society as productive citizens.

The grants are competitive, which means applicants must qualify for funding based on their proven record of success at helping clients with significant barriers to employment to enter the work force and to remain employed. In September 2007 this program was judged by the Government Accountability Office as one of the most successful and efficient programs in the DOL portfolio.

HVRP is unique and so highly successful because it doesn’t fund employment services per se, rather it rewards organizations that guarantee job placement. DOL estimates HVRP will serve approximately 17,066 homeless veterans (\$1,500 average cost per participant) and approximately 10,240 homeless veterans will be placed into employment (\$2,500 average cost per placement) at the fiscal year 2009 budgeted level of \$25.62 million. These costs represent a tiny investment for moving a veteran out of homelessness, and off of dependency on public programs. For Program Year 2006 (the most recent data available), the program’s entered employment rate was 65.3 percent and the 90-day retained employment rate was 79.1 percent of the 65.3 percent who entered employment. Those numbers meet or exceed the results produced by most other DOL programs.

*Recommendation.*—HVRP is authorized at \$50 million through fiscal year 2009, yet the annual appropriation has been less than half that amount. For fiscal year 2009, the proposed funding level of \$25.6 million would fund only eleven percent of the overall homeless veteran population. Based on the program’s success and effectiveness in terms of employment outcomes for one of the most difficult populations to serve and its cost effectiveness as compared to other employment placement pro-

grams, NCHV believes in fiscal year 2009 the program should be funded at its full \$50 million authorization level. We believe the proven outcomes and efficiency of HVRP warrants this consideration, and that DOL-VETS has the administrative capacity, will and desire to expand the program. Employment is the key to transition from homelessness to self sufficiency—this program is critical to the campaign to end and prevent veteran homelessness.

#### INCARCERATED VETERANS TRANSITION PROGRAM

Between fiscal year 2004 and fiscal year 2007, HVRP was used to fund the Incarcerated Veterans' Transition Program (IVTP), a joint DOL and VA initiative authorized by Congress to assist veterans incarcerated in their reentry to the community. IVTP was successful in getting many veterans connected to health care, benefits, employment, reunification with families and reducing the return to prison. During the three years of operation 4,094 incarcerated veterans were assessed by the seven pilot programs. Of those assessed, 2,191 veterans were enrolled as participants, and of those enrolled (54 percent) successfully entered employment earning an average of \$10.00 an hour, at an average cost per placement of \$4,500.

*Recommendation.*—The success of the IVTP warrants both immediate reauthorization and expansion of the pilot projects. Once authorized, funds should be appropriated separately from HVRP to continue the work of those who provide these beneficial and much needed services.

#### VETERANS WORKFORCE INVESTMENT PROGRAM APPROPRIATIONS

The Veterans Workforce Investment Program (VWIP) within DOL-VETS provides grants to states and community-based, faith-based, and local public organizations to offer workforce services targeted to veterans with service connected disabilities, with active duty experience in a war or campaign, recently separated from the service, or facing significant barriers to employment (including homelessness). At least 80 percent of total VWIP funds are distributed via competition. VETS may reserve 20 percent of total VWIP funds for discretionary grants. VETS use these discretionary funds for studies, demonstration projects, and additional funding to supplement competitive grants. The fiscal year 2009 Budget recommendation for VWIP is \$7.351 million with plans to target 3,990 participants. This amount represents a 0 percent change in funding for the program.

The agencies receiving VWIP funds and those hoping to apply for this program face the problem of resource scarcity. Due to funding limitations, agencies and organizations in less than one-third of states receive VWIP funds. The need for the type of targeted assistance that VWIP offers is clearly needed by veterans in all states. Additionally, caps on the size of grant awards make it difficult for existing grantees to recruit and retain staff, which limits program effectiveness and the collaborative process.

*Recommendation.*—A funding request of only \$7.351 million for a program that can help our nation's veterans become more economically independent is a disgrace. NCHV asks Congress to fund this program at a much higher level.

#### CONCLUSION

NCHV appreciates the opportunity to submit recommendations to Congress regarding the DOL programs that assist homeless veterans. We look forward to continuing to work with the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies to ensure our federal government does what is necessary to prevent and end homelessness among our nation's veterans.

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#### PREPARED STATEMENT OF THE NATIONAL CONGRESS OF AMERICAN INDIANS

On behalf of the tribal nations of the National Congress of American Indians (NCAI), we are pleased to present testimony to the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies for the fiscal year 2009 Budget.

At the recent State of Indian Nations address, NCAI President Joe Garcia spoke about the special place of honor children hold in American Indian and Alaska Native cultures. He discussed the community's sacred obligation to instill in them the traditional knowledge of past generations so their innocence and laughter may develop into wisdom as they become the leaders of the future. He stressed our belief that every Indian child should have the right to community-based, culturally appropriate services that help them grow up safe, healthy, and spiritually strong—free

from abuse, neglect, and poverty. Unfortunately, all too often Native children are born into circumstances that may be rich in culture and love, but fail to meet their basic needs of health, shelter, safety, and education. Our communities have a vision of a restored, safer, healthier Indian Country for our children, but President Bush's budget request fails to move us in the direction of that vision and will leave Indian children in poverty and at risk.

This NCAI fiscal year 2009 testimony highlights key aspects of the vision tribal leaders have expressed to create a safe, healthy Indian Country for our children. In developing these recommendations we recognize that chipping away at the years of under-funding and backlogs that plague Indian Country can only be accomplished over time. The requests that follow do not reflect the full need in Indian Country, but rather are achievable first steps that we believe Congress and the President should be able to support this year.

#### EDUCATION

One of the President's major focuses of the fiscal year 2009 Education budget was closing the achievement gap. However, the numerous decreases proposed for programs that support Indian children's education government-wide does not support this claim. A standard argument of the current administration for eliminating tribal education programs is that they are duplicative, claiming that our students are eligible for funding through both the Department of Education and the Bureau of Indian Education. However, each of these offices provide different and essential services to ensure that our students are able to achieve the same challenging academic standards as other students.

Funding levels for Indian education under the Office of Indian Education remained stagnant at fiscal year 2008 levels. Of major concern is the elimination of discretionary funding for Strengthening Tribally Controlled Colleges and Universities (TCUs) and Strengthening Alaska Native and Native Hawaiian Serving Institutions. One of the primary arguments for their elimination was the substantial increase in mandatory funding from 2007. However, this increase is a result of funds made available from the College Cost Reduction and Access Act and were meant to supplement not supplant TCU funding. This decision was not made in consultation with the Tribes.

The administration proposed eliminating five tribal-specific programs at the Department of Education: Education for Native-Hawaiians (\$33.3 million), Alaska Native Education Equity Assistance (\$33.3 million), Strengthening Alaska Native, Native Hawaiian Serving Institutions (\$11.6 million), Strengthening Tribal Colleges (\$23.2 million), and Tribally Controlled Postsecondary Institutions (\$7.4 million).

- Restore the 5 Indian specific programs eliminated by the DOE in the fiscal year 2009 budget.
- Strengthening Tribal Colleges (\$23.2 million)
- Tribally Controlled Postsecondary Institutions (\$7.4 million)
- Education for Native-Hawaiians (\$33.3 million)
- Alaska Native Education Equity Assistance (\$33.3 million)
- Strengthening Alaska Native, Native Hawaiian Serving Institutions (\$11.6 million)
- Increase funding 10 percent for 2 programs that remained stagnant in DOE fiscal year 2009 budget.
- Impact Aid (\$1,365)
- Indian Education Act, Title VII (\$132 million)

#### HEALTH AND HUMAN SERVICES

##### *Administration on Aging*

The aging of our Nation's population will challenge Federal programs such as those in the Older Americans Act. The tribal service delivery systems, with social service programs and delivery systems already stretched beyond capacity, face an impending human and financial crisis. The crisis is exacerbated by inadequate funding, remoteness of the areas, inadequate healthcare funding, increased training needs for program staff, and lack of resources. According to the National Indian Council on Aging, inadequate funding has made it impossible for many Tribes to meet the five days a week home-delivered meal requirement and has forced them to provide congregate meals only 2 or 3 days a week.

- Increase Older Americans Act, Title VI funding to \$50 million to help older American Indian elders to remain independent in their homes and communities.
- Provide funding support of not less than \$10 million to the Older Americans Act, Title VI Native American aging programs to support one-on-one counseling and enrollment assistance regarding Medicare and Medicaid services.

—Provide funding support of \$10 million for the Older Americans Act, Title VII, Subtitle B “Native American Provision for Prevention of Elder Abuse and Neglect” and the “Allotment for Vulnerable Elder Rights Protection Activities” to protect elder rights and implement elder rights activities in tribal communities.

*Administration for Children and Families*

*Head Start.*—Indian Head Start programs are vital to many Native communities, providing support to needy families, strengthening revitalization efforts for tribal culture and language, and contributing greatly to community-based healthcare strategies. Of the approximately 562 federally recognized tribes, only 188 have Head Start programs. That means 374 tribes do not have Head Start available for their children. Indian Head Start has been receiving a declining percentage of Head Start funds, now currently at about 2.7 percent. As funding for Head Start over the last seven years has failed to keep pace with inflation we continue to support efforts to increase funding for Head Start by \$1.072 billion in the coming year.

—To meet the expansion commitment made to the Indian Head Start program in the reauthorization bill, increase Head Start funding by no less than \$155 million in fiscal year 2009.

*Administration for Native Americans*

*Native Languages.*—Throughout Indian Country tribes are combating the loss of traditional languages by advocating for and instituting language programs within their communities. Created to reverse centuries of Federal policies meant to destroy Native languages, Native language programs prevent the loss of tribal traditions and cultures while assisting students in their academic endeavors. The tribal students in immersion programs perform substantially better academically, including on national tests, than Native students who have not gone through such programs.

—Maintain or increase the \$2 million provided for the Esther Martinez Native American Languages program in the Administration for Native Americans.

*Substance Abuse and Mental Health Services Administration (SAMHSA)*

Tribal youth between the ages of 15 and 24 commit suicide at a rate more than three times the national average. In Alaska, Native youth ages 19 and younger make up 19 percent of the population but comprise 60 percent of the suicides in that age group for the entire State. More than half of those who committed suicide in Indian country had never been seen by a mental health provider, yet 90 percent of all teens who die by suicide suffer from a diagnosable mental illness at the time of death.

*American Indian and Alaska Native Grant Program.*—The American Indian and Alaskan Native specific grant program within SAMHSA was authorized to award grants to Indian health programs to provide the following services: prevention or treatment of drug use or alcohol abuse, mental health promotion, or treatment services for mental illness in the amount of \$15 million. To date, these funds have never been appropriated.

—Fully fund the American Indian and Alaska Native specific grant program at \$15 million.

*Circles of Care.*—Circles of Care is the only grant program in SAMSHA where tribes do not need to compete with the States to receive funding. This grant program was designed specifically to respond to the inequity that tribes experience in trying to access Federal behavioral health services funding compared to States and the lack of programming that is specifically designed to respond to tribal communities and their service delivery system realities.

—Fund Circles of Care at \$5 million.

LABOR

The unemployment rate among American Indians is twice that for the total U.S. population at 8.6 percent according to the U.S. Census Bureau. On some reservations, the rate is drastically high. For example, according to the Bureau of Indian Affairs, the Blackfeet Tribe face a 69 percent unemployment rate and the San Carlos Apache Tribe struggle with 81 percent of their population being unemployed.

*Denali Commission.*—The Employment and Training Administration (ETA) provides tribes with grants to offer these valuable services to their members. The purpose of the Denali Commission is to provide critical utilities, infrastructure and economic support to distressed rural communities in Alaska. This funding stream is being terminated in the President’s budget.

—Restore funding to Denali Commission \$6,755 million.

*Native American Programs.*—One of the ETA’s priorities for the Native American Section 166 program in fiscal year 2009 will be to integrate the program with the

One-Stop Career Center system. The One-Stop Career Center System does not allow flexibility for cultural barriers and disability barriers to employment.

—Fully fund Native American Programs at \$53 million.

#### CONCLUSION

NCAI realizes Congress must make difficult budget choices this year. As elected officials, tribal leaders certainly understand the competing priorities that you must weigh over the coming months. However, the Federal Government's constitutional and treaty responsibility to address the serious needs facing Indian Country are unique. These responsibilities remain unchanged, whatever the economic climate and competing priorities may be. We at NCAI urge you to make a strong, across-the-board commitment to meeting the Federal trust obligation by fully funding those programs that are vital to the creation of vibrant Indian Nations. Such a commitment, coupled with continued efforts to strengthen tribal governments and to clarify the government-to-government relationship, truly will make a difference in helping us to create stable, diversified, and healthy economies in Indian Country.

#### PREPARED STATEMENT OF THE NATIONAL CONSUMER LAW <sup>1</sup>

The Federal Low Income Home Energy Assistance Program (LIHEAP)<sup>2</sup> is the cornerstone of government efforts to help needy seniors and families avoid hypothermia in the winter and heat stress (even death) in the summer. We are in a sustained period of much higher household energy prices and expenditures and the demand for this program is growing as increases in energy prices far outstrip the ability of low-income households to pay. 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 2009 and that advance funding of \$5.1 billion be provided for the program in fiscal year 2010.

#### THE COST OF HOME ENERGY REMAINS AT RECORD HIGH LEVELS

Residential heating expenditures remain at record high levels. The average residential heating expenditures are projected to be 95 percent higher for heating oil, 28 percent higher for natural gas, 66 percent higher for propane, and 18.5 percent higher for electricity than the averaged expenditures for 2001–2006. The current U.S. Department of Energy short-term forecast of residential heating expenditures predicts that, on average, residential bills are still among the highest on record. The cost of electricity, used for both heating and cooling, has been increasing rapidly due, in part, to increases in the price of natural gas used to generate electricity in many power plants and the lifting of price caps in States that restructured their electric markets. In a brief span of time, energy bills have walloped low-income households. The effect of these continually rising prices on low-income households is devastating.

#### STATES' DATA ON ELECTRIC AND NATURAL GAS DISCONNECTIONS AND ARREARAGES SHOW THAT MORE HOUSEHOLDS ARE FALLING BEHIND

The steady and dramatic rise in residential energy costs has resulted in increases in electric and natural gas arrearages and disconnections. For example, in Rhode Island there were over 30,000 residential service disconnections in 2007, over 5,000 more than in any previous year. Of those 30,000 shutoffs, over 5,200 were not restored. Similarly, the gap between service disconnections and reconnections has been increasing over time, suggesting increased durations of service loss and greater numbers of households that do not regain access to service under their own accounts as demonstrated by data from Iowa.<sup>3</sup>

Although there are winter utility shut-off moratoria in place in many States, not every home is protected against energy shut-offs in the middle of winter. As we approach the lifting of winter shut-off moratoria, we expect to see a wave of disconnections as households are unable to afford the cost of the energy bills. The chart illustrating Iowa's shut-off and reconnection data shows the typical sharp increase in disconnections in the spring once the winter moratorium ends in a State. Low-in-

<sup>1</sup>Pennsylvania Utility Law Project (PULP) on behalf of its low-income clients, Esparanza Community Housing Corporation (CA), Community Housing Development Corporation of North Richmond (CA).

<sup>2</sup>42 U.S.C. §§ 8621 et seq.

<sup>3</sup>Chart provided by the Iowa Bureau of Energy Assistance.

come families are falling further behind as we endure year after year of rising home energy prices. We expect the disconnection peaks to grow and the gap between disconnections and reconnections to also grow.

*Iowa.*—While the basic LIHEAP block grant for Iowa is at last year's levels, this winter has been colder than in the past several years and natural gas prices remain high and propane prices are around a third higher this year than the same point last year. In February 2008, the number of low-income households with past due energy accounts and the total amount of the low-income arrears were the second highest on record for this time of year since these data have been tracked. As an indication of the effect of long term effect of rising home energy prices, the total number of LIHEAP households in arrears in February 2008 was 67 percent higher than 5 years ago at this point in time and 159 percent higher than in February 1999. The total amount of arrearages of LIHEAP households has also grown sharply due to the increase in prices. By February 2008, the total amount of LIHEAP household arrears had increased 58 percent from the same period 5 years ago and 176 percent compared to arrears in February 1999. The total number of LIHEAP households served in fiscal year 2009 is expected to exceed the number of households served last year.<sup>4</sup>

*Ohio.*—Ohio has experienced a steady and dramatic demand for low-income energy assistance. The number of households entering into the State's low-income energy affordability program, the Percentage of Income Payment Program (PIPP), increased 7 percent from January 2007 to January 2008. The increase is an even more dramatic 75 percent between January 2002 and January 2008. The total dollar amount owed (arrearage) by low-income PIPP customers increased 14 percent from January 2007 to January 2008 and 84 percent when comparing PIPP customer arrears from January 2002 to January 2008. The growing demand is also apparent from the frontlines. One community action agency in Ohio reports that: "We have been busy with HEAP this winter . . . as always . . . but this year even busier than last. There are still many people in the lobby every day seeking this assistance, and many we have never seen before. It is an indication of how serious the struggle is for Ohioans this year." Ohio has experienced an increase in enrollment for the regular LIHEAP block grant program (HEAP) from 2005 to 2007 with 262,561 total households in 2005; 354,371 in 2006; 360,656 in 2007 and expects to see an increase in enrollment by the end of this program year as well."<sup>5</sup>

*Pennsylvania.*—Utilities in Pennsylvania that are regulated by the Pennsylvania Public Utility Commission (PA PUC) have established universal service programs that assist utility customers in paying bills and reducing energy usage. Even with these programs, electric and natural gas utility customers find it difficult to keep pace with their energy burdens. The PA PUC estimates that more than 16,857 households entered the current heating season without heat-related utility service—this number includes about 3,095 households who are heating with potentially unsafe heating sources such as kerosene or electric space heaters and kitchen ovens. In mid-December 2007, an additional 11,468 residences where electric service was previously terminated were vacant and over 5,826 residences where natural gas service was terminated were vacant. In 2007, the number of terminations increased 44 percent compared with terminations in 2004. As of December 2007, 19.2 percent of residential electric customers and 16.9 percent of natural gas customers were overdue on their energy bills.<sup>6</sup>

#### LIHEAP IS A CRITICAL SAFETY NET PROGRAM FOR THE ELDERLY, THE DISABLED AND HOUSEHOLDS WITH YOUNG CHILDREN

Preliminary estimates by the National Energy Assistance Directors' Association are that fiscal year 2008 participation rates will remain near the same levels as in fiscal year 2007, reaching an estimated 5.5 million households.<sup>7</sup> Yet, energy prices have been on a continued upward climb, eroding LIHEAP's purchasing power. LIHEAP is vital to poor seniors: Poor seniors who cut back on energy usage, jeopardize their health and safety. In general, elder households use less total household energy than non-elderly households, which is attributable primarily to the smaller dwelling units. However, poor elderly households use markedly less energy than non-poor elderly households. The disparity in usage between the poor elderly and

<sup>4</sup>Conversations with the Director of the Iowa Bureau of Energy Assistance (March 19, 2008).

<sup>5</sup>Public Utilities Commission of Ohio and correspondence with staff at the Ohio Community Development Division (March 11, 2008).

<sup>6</sup>Pennsylvania Public Utility Commission Bureau of Consumer Services.

<sup>7</sup>National Energy Assistance Directors' Association, Testimony of the National Energy Assistance Directors' Association on the Low Income Home Energy Assistance Program Before the Subcommittee on Health, Education, Labor and Pensions, U.S. Senate (March 5, 2008).

the non-poor elderly is present in each of the Census regions: with the poor elderly using 37 percent less in the Northeast Census Region, 40 percent less in the Midwest Census Region, 20 percent less in the South Census Region and 54 percent less in the West Census region. Even worse, poor elderly households, on average, consume 12 percent more energy per square foot of living space (this measurement is also referred to as energy intensity) than non-poor elderly households. This disparity is attributable to the poorly weatherized living spaces and the use of old, inefficient heating equipment and appliances.<sup>8</sup> In the summer, the inability to keep the home cool can be lethal, especially to seniors. According to the CDC, in 2001 300 deaths were caused by excessive heat exposure, and seniors and young children are particularly vulnerable to heat stress.<sup>9</sup> The CDC also notes that air-conditioning is the number one protective factor against heat-related illness and death.<sup>10</sup> LIHEAP assistance helps these vulnerable seniors keep their homes at safe temperatures during the winter and summer and also funds low-income weatherization work to make homes more energy efficient.

*Dire Choices and Dire Consequences.*—Recent national studies have documented the dire choices low-income households are faced with when energy bills are unaffordable. Low-income households faced with unaffordable energy bills cut back on necessities such as food, medicine and medical care.<sup>11</sup> The U.S. Department of Agriculture recently 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 when energy bills are high.<sup>12</sup> The U.S. Conference of Mayors' December 2007 Status Report on Hunger and Homelessness in America's Cities cites utility assistance programs as one of the most common ways to reduce hunger.<sup>13</sup> A pediatric study in Boston documented an increase in the number of extremely low weight children, age 6 to 24 months, in the three months following the coldest months, when compared to the rest of the year.<sup>14</sup> Clearly, families are going without food during the winter to pay their heating bills, and their children fail to thrive and grow. When people are unable to afford paying their home energy bills, dangerous and even fatal results occur. Families resort to using unsafe heating sources, such as space heaters, ovens and burners, all of which are fire hazards.<sup>15</sup> In the summer, the inability to afford cooling bills can result in heat-related deaths and illness.

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 2009 in light of the steady increase in home energy costs and the increased need for assistance to protect the health and safety of low-income families by making their energy bills more affordable. In addition, fiscal year 2010 advance funding would facilitate the efficient administration of the State LIHEAP programs. Advanced funding provided certainty of funding levels to States to set income guidelines and benefit levels before the start of the heating season. States can also plan the components of their program year (e.g., amounts set aside for heating, cooling and emergency assistance, weatherization, self-sufficiency and leveraging activities).

<sup>8</sup>NCLC analysis of U.S. Energy Information Administration, 2001 Residential Energy Consumption Survey data on elderly energy consumption and expenditures.

<sup>9</sup>CDC, "Extreme Heat: A Prevention Guide to Promote Your Personal Health and Safety" available at [www.bt.cdc.gov/disasters/extremeheat/heat\\_guide.asp](http://www.bt.cdc.gov/disasters/extremeheat/heat_guide.asp).

<sup>10</sup>Id.

<sup>11</sup>See e.g., National Energy Assistance Directors' Association, 2005 National Energy Assistance Survey, Tables in section IV,G (September 2005) To pay their energy bills, 20 percent of LIHEAP recipients went without food, 35 percent went without medical or dental care, 32 percent did not fill or took less than the full dose of a prescribed medicine). Available at [http://www.neada.org/comm/surveys/NEADA\\_2005\\_National\\_Energy\\_Assistance\\_Survey.pdf](http://www.neada.org/comm/surveys/NEADA_2005_National_Energy_Assistance_Survey.pdf).

<sup>12</sup>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.

<sup>13</sup>Exhibit 1.4 shows 60 percent of cities in the study cited utility assistance programs as a way to reduce hunger.

<sup>14</sup>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).

<sup>15</sup>John R. Hall, Jr., Home Fires Involving Heating Equipment: Space Heaters (In 2005 there were an estimated 19,700 home fires involving space heaters resulting in 490 deaths, 980 injuries and \$518 million in property damage) National Fire Protection Association (Nov. 2007).



## PREPARED STATEMENT OF THE NATIONAL COUNCIL ON AGING

## SECTION I—BASIC PROGRAMS IN THE OLDER AMERICANS ACT

The Older Americans (OAA) is the backbone of services to America's aging population. First enacted in 1965, the OAA helps seniors to stay independent and healthy through a wide range of services and programs, including: home-delivered meals, congregate meals, senior center services, transportation, support for family caregivers, home and community services, health promotion, disease prevention, nursing home ombudsmen, grants for Native Americans, community service employment for low-income older workers, and numerous program innovations. With strong support from the National Council on Aging (NCOA) and many other aging-related organizations, Congress reauthorized the OAA in the fall of 2006, strengthening it in many ways and adding important new initiatives.

These are the major components of the OAA, receiving more than 92 percent of the annual appropriations:

- Supportive Services (Title III-B)*.—Services that enable older persons to remain in their own homes and age in place, rather than enter institutions. The most frequently provided services are home health, personal care and transportation.
- Nutrition Services (Title III-C)*.—Congregate and home-delivered meals, increasing the health, functionality and quality-of-life for millions of seniors. Approximately 40 percent of home-delivered meal providers have waiting lists.
- National Family Caregiver Support Program (Title III-E)*.—Services to help ease the burdens of caregivers, including respite care, counseling and supplemental services.
- Senior Community Service Employment Program (Title V, known as SCSEP)*.—Part-time employment and training for low-income workers, helping to lift them out of poverty and restore a sense of self-worth. SCSEP strengthens communities through community service job placements.

All OAA programs are under the Administration on Aging of the Department of Health and Human Services, except for the SCSEP, which is under the Department of Labor (DoL). Total appropriations for all of OAA in fiscal year 2008 come to \$1.935 billion—\$1.413 billion to the Administration on Aging (AoA) and \$522 million to DoL for SCSEP.

OAA funding was virtually frozen (with very small increases) from fiscal year 2002 to fiscal year 2005, and then cut in fiscal year 2006. This frozen funding eroded many services because of rising prices, and simultaneously diminished the ability of OAA programs to reach the growing population of seniors in need. In fiscal year 2007 Congress increased OAA funding by a small amount, adding \$20 million in nutrition services and \$51.3 million for SCSEP to cover the increase in the Federal minimum wage. The fiscal year 2008 increases were similar to fiscal year 2007: a modest \$30.4 million increase for nutrition and some other AoA programs, plus \$38.0 million for SCSEP's minimum wage increase. Though the SCSEP increases of the past two cycles sound significant, they have not expanded the program nor helped it to keep up with inflation, but have only provided sufficient funds to pay the same number of enrollees at the higher minimum wage level.

If OAA funding since fiscal year 2002 had simply kept pace with inflation and the growing number of seniors, it would be \$380 million higher in fiscal year 2008 than it actually is. Looked at another way, the total increase in appropriations from fiscal year 2002 to fiscal year 2008 for all OAA programs was less than 8 percent. However, the mandated minimum wage expansion for SCSEP enrollees consumed about two-thirds of the total funding increase; if the minimum wage dollars are not included in the calculation, all OAA programs combined received total increases of less than 3 percent in six years, far less than the rise in inflation in that period.

The OAA urgently needs a significant boost in funding, for the following reasons:

- OAA programs help to preserve the health and independence of our Nation's seniors, enabling them to remain in their own homes longer.
- Spending money on OAA programs saves taxpayers' dollars in the long run, by reducing premature nursing home placements, averting malnutrition and controlling chronic health conditions.
- With flat funding, service providers are constantly faced with difficult choices about which services to cut. Rising food and gas prices hit nutrition programs hard.
- Strengthening the OAA was the top priority of the delegates to the once-per-decade 2005 White House Conference on Aging, and Congress responded with the 2006 reauthorization. Congress needs to take the next step and provide substantial increases in funding for the #1 priority of those bipartisan delegates.

In view of the above, the National Council on Aging urges Congress to increase funding for all existing OAA programs by 9 percent in fiscal year 2009. An increase of 9 percent over fiscal year 2008 would be \$174 million—\$127 million for AoA and \$47 million for the SCSEP in DoL.

#### SECTION II—RECENTLY-ADDED PROGRAMS IN THE OLDER AMERICANS ACT

The reauthorization of the OAA, signed into law in October of 2006, added three valuable new initiatives that deserve significant funding:

(1) The bill authorized a National Center on Senior Benefits Outreach and Enrollment under section 202(20)(B) that will marshal person-centered, cost effective techniques to enroll low-income seniors in a range of benefits programs for which they are eligible. Participation rates in current needs-based programs are unacceptably low:

- Up to 4.2 million low-income beneficiaries eligible for Medicare prescription drug Low-Income Subsidy are still not receiving it. An August 2007 survey found that almost half of low-income Medicare beneficiaries still are not aware of the program.

- Enrollment in the Specified Low-Income Medicare Beneficiary (SLMB) program, which pays for increasing Medicare Part B premiums, is estimated to be only 13 percent.

- After more than 40 years, participation rates by eligible seniors in the Food Stamps program have been estimated at only about 30 percent.

Enrolling in these programs for which they are eligible could help poor, vulnerable seniors to afford basic needs and emerge from deep and chronic poverty. Last year, the National Center received initial, start-up funding of \$1.97 million. NCOA urges that funding of \$4 million be provided to the National Center in fiscal year 2009, which will work with experienced community based organizations to conduct one-on-one counseling, provide training and technical assistance, maintain web-based decision support tools, and develop a clearinghouse on best practices.

(2) The OAA amendments authorized expansion of evidence-based health promotion and disease prevention activities under AoA's Choices for Independence initiative, establishing a national technical assistance program and directing the aging network to develop evidence-based educational and behavioral change programs to reduce the risk of injury, disease, and disability. Evidence-based programs help older people better manage their chronic conditions, improve their physical and mental health, and reduce their risk of falls. The Stanford Chronic Disease Self-Management Program (CDSMP), has provided ample evidence that such initiatives produce significant Medicare and Medicaid savings for the Federal Government.

The Choices initiative also funds Aging and Disability Resource Centers (ADRCs) to make it easier for people to access health and long-term care services and make informed decisions about options that best meet their needs, and consumer-directed Nursing Home Diversion programs to enable older people at risk of institutionalization to receive flexible services that will sustain community living and reduce the potential for depleting their resources and relying on Medicaid for supports. NCOA believes that the Choices for Independence program should be funded for at least \$28 million in fiscal year 2009. We strongly oppose the proposal to limit the program to five States.

(3) The OAA amendments under section 417 authorized AoA to conduct demonstration projects that provide opportunities for older adults to participate in multigenerational and civic engagement activities designed to meet critical community needs, including support for grandparents raising children and for volunteers working with families who have a child with a disability or chronic illness. NCOA strongly supported these initiatives when they were passed, because they will bring significant benefits to youth, older adults and communities. For example:

- Youth involved in intergenerational mentoring programs demonstrated improved grades, significant decreases in school absences, and suspensions from school, as well as decreases in drug and alcohol abuse.

- Older adults who volunteer live longer and with greater functional ability and better physical and mental health than their non-volunteering counterparts.

- Investments in civic engagement projects contribute to a community's economy by mobilizing volunteers. Volunteer time is estimated at \$18.77/hour.

- Healthy adults living longer provide talent and resources to the health and aging networks, enabling them to increase services and the quality of care to vulnerable elders.

- Interacting with older adults enables youth to develop social networks, a sense of community service, communication skills, problem solving abilities, and positive attitudes on aging.

The demonstration projects currently receive about \$1 million in funding. We urge that this be increased to \$9 million. In addition, \$1 million should be provided to develop a national blueprint for civic engagement for older adults, as described in Section 202(c) of the OAA.

Summarizing the three initiatives above, the National Council on Aging urges Congress to appropriate sufficient funding in fiscal year 2009 for these new programs in the 2006 reauthorization:

- \$4 million for the National Center on Senior Benefits Outreach and Enrollment;
- At least \$28 million for the Choices for Independence initiative; and
- \$10 million for multigenerational and civic engagement activities.

#### SECTION III—FALLS PREVENTION AND REDUCTION AMONG OLDER AMERICANS

Each year, one in three Americans aged 65 and older falls; about 30 percent of those who fall require medical treatment. In 2005, approximately 1.8 million older adults were treated in emergency departments for nonfatal injuries from falls, more than 433,000 were hospitalized, and nearly 16,000 died. Falls are the leading cause of both fatal and nonfatal injuries for those 65 and over. According to the Centers for Disease Control and Prevention (CDC), the mortality rate from falls among older Americans increased 39 percent from 1999 to 2005.

The costs of these falls are enormous. CDC reports that \$19 billion annually is spent on treating the elderly for the effects of falls: \$12 billion for hospitalization, \$4 billion for emergency department visits, and \$3 billion for outpatient care. Most of these expenses are paid for through Medicare. If we cannot stem the current rate of increase in senior falls, it is projected that the direct treatment costs will reach \$43.8 billion annually in 2020.

Many of the falls that seniors suffer are preventable, and the results of recent pilot programs offer some promising directions for cost-effective interventions, such as: comprehensive clinical assessments, exercise programs to improve balance and strength, management of medications, correction of vision, and reduction of home hazards.

CDC is the lead Federal agency for injury prevention and control through its National Center for Injury Prevention and Control (NCIPC). Currently the Federal Government allocates only \$1 million per year to NCIPC to address a problem that costs us more than \$19 billion a year.

Thanks to the leadership of Senators Enzi and Mikulski, S. 845, the Safety of Seniors Act, passed the Senate and House and is awaiting the President's signature. The Act encourages the Secretary to conduct demonstration projects, public education and research on falls prevention.

The National Council on Aging urges Congress to appropriate an additional \$20.7 million in the fiscal year 2009 Labor-HHS-Education bill for CDC's NCIPC to carry out falls prevention and reduction activities. Thirty national organizations support this request, including AARP, the Home Safety Council, the National Safety Council, the American Physical Therapy Association, the American Occupational Therapy Association, the American Association of Homes and Services for the Aging, Easter Seals, the National Association for Hospice and Home Care, the National Association of Social Workers, and the National Committee to Preserve Social Security and Medicare.

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#### PREPARED STATEMENT OF THE NATIONAL FEDERATION OF COMMUNITY BROADCASTERS

Thank you for the opportunity to submit testimony to this subcommittee regarding the appropriation for the Corporation for Public Broadcasting (CPB). As the President and CEO of the National Federation of Community Broadcasters (NFCB), I speak on behalf of 250 community radio stations and related individuals and organizations across the country. Nearly half our members are rural stations and half are controlled by people of color. In addition, our members include many of the new Low Power FM stations that are putting new local voices on the airwaves. NFCB is the sole national organization representing this group of stations which provide independent, local service in the smallest communities of this country as well as the largest metropolitan areas.

In summary, the points we wish to make to this Subcommittee are that NFCB:

- Requests \$483 million in funding for CPB for fiscal year 2011;
- Requests \$40 million in fiscal year 2009 for conversion of public radio and television to digital broadcasting;
- Requests \$27 million in fiscal year 2009 for replacement of the radio interconnection system;

- Requests that advance funding for CPB is maintained to preserve journalistic integrity and facilitate planning and local fundraising by public broadcasters;
- Rejects the Administration's proposal to rescind \$200 million of already-appropriated 2009 CPB funds and \$220 million from 2010 funds;
- Supports CPB activities in facilitating programming and services to Native American, African American and Latino radio stations;
- Supports CPB's efforts to help public radio stations utilize new distribution technologies and requests that the Subcommittee ensure that these technologies are available to all public radio services and not just the ones with the greatest resources.

*Community Radio fully supports the appropriation of \$483 million in Federal funding for the Corporation for Public Broadcasting in fiscal year 2011.*—Federal support distributed through CPB is an essential resource for rural stations and for those serving communities of color. These stations provide critical, life-saving information to their listeners and are often in communities with very small populations and limited economic bases, thus the community is unable to financially support the station without Federal funds.

In larger towns and cities, sustaining grants from CPB enable Community Radio stations to provide a reliable source of noncommercial programming about the communities themselves. Local programming is an increasingly rare commodity in a Nation that is dominated by national program services and concentrated ownership of the media. Federal funding allows an alternative to exist in these larger markets.

For over 30 years, CPB appropriations have been enacted 2 years in advance. This insulation has allowed public broadcasting to grow into a respected, independent, national resource that leverages its Federal support with significant local funds. Knowing what funding will be available in advance has allowed local stations to plan for programming and community service and to explore additional non-governmental support to augment the Federal funds. Most importantly, the insulation that advance funding provides "go[es] a long way toward eliminating both the risk of and the appearance of undue interference with and control of public broadcasting." (House Report 94-245.)

For the past few years, CPB has increased support to rural stations and committed resources to help public radio take advantage of new technologies such as the internet, satellite radio and digital broadcasting. We advocate for these activities which we feel better serve the American people but want to ensure that smaller stations with more limited resources are not left behind in this technological transition. We ask that the subcommittee include language in the appropriation that will make certain funds available to help the entire public radio system, particularly rural and minority stations, utilize the new technologies.

NFCB commends CPB for the leadership it has shown in supporting and fostering programming services to Latino stations and Native American stations. For example, *Satélite Radio Bilingüe* provides 24 hours of programming to stations across the United States and Puerto Rico addressing issues of particular interest to the Latino population in Spanish and English. At the same time, *Native Voice One (NV1)* is distributing politically and culturally relevant programming to Native American stations. There are now over 33 stations in the United States controlled by and serving Native Americans.

Two years ago, CPB funded the establishment of the Center for Native American Public Radio (CNAPR). After 3 years in operation, CNAPR has assisted with the renewal of licenses and expansion of the interconnection system to all Native stations and has advanced the opportunity for Native Nations to own their own, locally controlled station. In the process of this work, it was recognized that radio would not be available to all Native Nations and broadband and other new technologies would be necessary. CNAPR has been repositioned as Native Public Media (NPM) and is working hard to double the number of Native stations within the next three years. These stations are critical in serving local, isolated communities (all but one are on Indian Reservations) and in preserving cultures that are in danger of being lost. CPB's 2003 assessment recognized that "... Native Radio faces enormous challenges and operates in very difficult environments." CPB funding is critical to these rural, minority stations. The funding of the Intertribal Native Radio Summit by CPB in 2001 helped to gather these isolated stations together into a system of stations that can support one another. The CPB assessment goes on to say "Nevertheless, the Native Radio system is relatively new, fragile and still needs help building its capacity at this time in its development." NPM promises to leverage additional new funding to ensure that these stations continue providing essential services to their communities.

CPB also funded a Summit for Latino Public Radio which took place in September 2002 in Rohnert Park, California, home of the first Latino public radio station. This

year, CPB has provided funding to the Latino Public Radio Consortium to develop a Strategic Plan and Business Model to expand the service of public radio to the Latino population.

CPB plays an extremely important role in the public and Community Radio system: They convene discussions on critical issues facing us as a system. They support research so that we have a better understanding of how we are serving listeners. And, they provide funding for programming, new ventures, expansion to new audiences, and projects that improve the efficiency of the system. (This is particularly important at a time when there are so many changes in the radio and media environment with media consolidation and new distribution technologies.)

*Community Radio supports \$40 million in fiscal year 2009 for the conversion to digital broadcasting by public radio and television.*—While public television's digital conversion needs are mandated by the FCC, public radio is converting to digital to provide more public service and to keep up with commercial radio. The Federal Communications Commission has approved a standard for digital radio transmission and to allow multicasting. CPB has provided funding for 615 radio transmitters to convert to digital. Of those, 365 have completed their conversion and 117 are multicasting 153 streams. The development of second and third audio channels will potentially double or triple the service that public radio can provide listeners, particularly in unserved and underserved communities. However, this initial funding still leaves nearly 200 radio transmitters that must ultimately convert to digital or become obsolete.

Federal funds distributed by the CPB should be available to all public radio stations eligible for Federal equipment support through the Public Telecommunications Facilities Program (PTFP) of the National Telecommunications and Information Agency in the Department of Commerce. In previous years, Federal support for public radio has been distributed through the PTFP grant program. The PTFP criteria for funding are exacting, but allow for wider participation among public stations. Stations eligible for PTFP funding and not for CPB funding include small-budget, rural, and minority-controlled stations and the new Low Power FM service.

Community Radio strongly supports \$27 million in fiscal year 2009 for the public radio interconnection system. Public radio pioneered the use of satellite technology to distribute programming. The Public Radio Satellite System's recently-launched ContentDepot continues this tradition of cutting edge technology. Satellite capacity supporting it must be renewed and upgrades are necessary at the station and network operations levels. Interconnection is vital to the delivery of the high-quality programming that public broadcasting provides to the American people. This is the second year of a 3-year request for \$73 million for the complete project.

We are in a period of tremendous change. The digital movement is transforming the way we do things; new distribution avenues like digital satellite broadcasting and the internet are changing how we define our business; and, the concentration of ownership in commercial radio makes public radio in general, and Community Radio in particular, more important as a local voice than we have ever been. New Low Power FM stations are providing local voices in their communities an avenue of expression, and many new community stations will be going on the air within the next few years. Community Radio is providing essential local emergency information, programming about the local impact of major global events taking place, and culturally-relevant information and entertainment in native languages, as well as helping to preserve cultures that are in danger of dying out. During the natural disasters of recent years, radio proved once again that it is the most dependable and available medium for getting emergency information to the public.

During these challenging times, the role of CPB as a convener of the system becomes even more important. The funding that it provides will allow smaller stations to participate alongside larger stations that have more resources as we move into a new era of communications.

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 sole organization representing leaders in nursing education and nurse faculty across all the types of nursing programs in the United States. With more than 1,200 nursing schools and health care agencies, some 25,000 individual members comprising nurses, educators, administrators, public members, and 18 constituent leagues, the National League for Nursing is the premier organization—established 115 years ago—dedicated to excellence in nursing education that prepares the nursing workforce to meet the needs of our diverse populations in an ever-changing health care environment. The NLN appre-

ciates the opportunity to discuss the status of nursing education and the damage that could ensue to patients and our Nation's health care by the ill-considered cuts aimed at the Nursing Workforce Development Programs, authorized under Title VIII of the Public Health Service Act.

The NLN endorses the Subcommittee's past policy strategies for health care capacity-building via nursing education. We likewise respect your recognition of the requisite role nurses play in the delivery of cost-efficient health care services and the generation of quality health outcomes.

The National League for Nursing is disturbed, however, that the tenth-year and counting nursing shortage is outpacing the level of Federal resources and investments that have been expended to help alleviate the nationwide nursing scarcity. The NLN is gravely concerned that the Administration's proposed fiscal year 2009 appropriations for nursing education are inconsistent with the health care reality facing our Nation. The President's budget proposes a funding decrease of \$46.193 million (or 29.6 percent) for the Health Resources and Services Administration's (HRSA) Nursing Workforce Development Programs. This budget cut will diminish education and development, a shortsighted and hazardous course of action that potentially further jeopardizes the delivery of health care for the people in the United States. Thirty-five years ago in 1973, during another less serious nursing shortage, Congress appropriated nearly \$161 million for nurse education programs. In today's dollars, that amount would be worth more than \$742.8 million—4.76 times the amount the Federal Government currently is spending on Title VIII programs.

The NLN contends that the Federal strategy should be to broaden, not curtail, Title VIII initiatives by increasing investments to be consistent with national demand. We urge the Subcommittee to fund the Title VIII programs at a minimum level of \$200 million for fiscal year 2009. The NLN also advocates that Sec. 811 of Title VIII—Advanced Education Nursing Program—be restored and funded at an augmented level equal to the other Title VIII programs.

#### NURSE SHORTAGE AFFECTED BY FACULTY SHORTAGE

The Subcommittee is well aware that today's nursing shortage is real and unique from any experienced in the past with an aging workforce and too few people entering the profession at the rate necessary to meet growing health care requirements. In its biennial 10-year employment projections for 2006–2016, the U.S. Department of Labor's Bureau of Labor Statistics (BLS) reported that during that 10-year period, the system is projected to generate 587,000 new registered nurses (RN) jobs, with hundreds of thousands of job openings resulting from the need to replace experienced nurses who will leave the occupation. BLS's model-based findings estimate that employment of RNs is expected to grow 23 percent from 2006 to 2016, a much faster rate than the average for all occupations. The NLN research provides evidence of a strong correlation between the inability of nursing programs to keep pace with the demand for new RNs and the shortage of nurse faculty. Without faculty to educate our future nurses, the shortage cannot be resolved.

The NLN's Nursing Data Review 2005–2006: Baccalaureate, Associate Degree, and Diploma Program revealed that applications to RN programs fell a notable 8.7 percent during 2005–06, down from a peak in applications a year earlier. The drop is suspected to be the result of "applicant discouragement" defined by the NLN as widespread awareness of the difficulty of gaining entry to nursing school, fueled by the continuing crippling shortage of nurse educators.

Despite the reduced number of applications, many factors indicate that opportunities to obtain a nursing education are still in short supply. Eighty-eight thousand (88,000) qualified applications—or one out of every three qualified applications submitted to nursing education programs this year—were denied due to lack of capacity. Baccalaureate degree programs turned away 20 percent of their applications, while associate degree programs turned away 32.7 percent.

On a positive front, the NLN's data show a marked increase in the percentage of graduating pre-licensure students who are members of racial or ethnic minority groups, with the increase distributed across all racial and ethnic categories: Asians, African Americans, Hispanics, and American Indians. After three consecutive years in which the proportion of minorities entering the RN workforce stagnated at approximately 20 percent, the fraction of minority graduates jumped to 24.5 percent in 2006. Research increasingly links minority health disparities to a lack of cultural competence on the part of health care providers, who often differ from their patients with respect to racial-ethnic background. This concern has been particularly acute within the RN workforce where the percentage of minorities has been slow to increase, and only exceeded 10 percent in the last decade. Additionally, the percentage of men graduating from basic RN programs has exhibited a small but steady growth

trend over the past 3 years, with men reaching just over 12.1 percent of graduates in 2006.

#### TRENDS STRESSING FACULTY SHORTAGE

The NLN's research, reported in its *Nurse Educators 2006: A Report of the Faculty Census Survey of RN and Graduate Programs*, indicated that the nurse faculty vacancies in the United States continued to grow even as the numbers of full- and part-time educators increased. The estimated number of budgeted, unfilled, full-time positions countrywide in 2006 was 1,390. This number represents a 7.9 percent vacancy rate in baccalaureate and higher degree programs, which is an increase of 32 percent since 2002; and a 5.6 percent vacancy rate in associate degree programs, which translates to a 10 percent rise in the same period. It is not surprising that the problem of nurse faculty vacancies often is described as acute and as exacerbating the national nurse-workforce shortfall.

The present nurse faculty staffing deficit is expected to intensify as the existing nurse educator workforce reaches retirement age. A 2006 NLN/Carnegie Foundation Preparation for the Professions Program national survey of nurse educators found that fully one half of today's nurse faculty say they expect to retire within the next 10 years, while just over one in five (21 percent) expect to retire within the next 5 years. The NLN/Carnegie data also distinguished the nurse faculty cohort from the rest of the academic workforce by age: Where 48 percent of nurse educators are age 55 and over, only 35 percent of U.S. academics and only 29 percent of health science faculty are over the age of 54.

Salaries are a significant issue for recruitment and retention of nurse educators. The NLN/Carnegie study found that nurse faculty earn only 76 percent of the salary that faculty in other academic disciplines earn. Colleges and universities also are reporting that the nurse educator's compensation is not competitive with that of nurses in clinical settings. The NLN notes that although few data are available on salaries of nurses with doctorates, the U.S. Department of Health and Human Services Preliminary Findings: 2004 National Sample Survey of Registered Nurses (NSS-RN) data on salaries of master's-prepared nurses can be used to compare the competitiveness of nurse faculty salaries. The NLN/Carnegie study reports "nurse faculty salaries (annualized to a 12-month calendar) rank only eighth among the 11 positions evaluated by the NSS-RN study. Not only are master's-prepared nurse faculty paid 33 percent less than nurse anesthetists, but they are also paid 17 percent less than head nurses and nurse midwives, and approximately 12 percent less than nurse practitioners and clinical nurse specialists with the same educational credentials."

Workload is another factor distinguishing nurse faculty from their peers. According to the NLN/Carnegie research, 90 percent of the nurse educators, responding to the survey, work full-time, many adding administrative duties to teaching responsibilities, resulting in a 56-hour average work week. In addition to their work inside their primary academic institutions (PAI), more than 62 percent of nurse faculty picked up work outside their PAI, averaging an additional day each week (7–10 hours). With 45 percent of nurse faculty reporting dissatisfaction with their current workload, "over one in four nurse educators who said they were likely to leave their current job cited the desire for reduced workload as a motivating factor."

Data also indicate that in large part the nurse faculty workforce is not reflective of the Nation's population or of the nursing student population. The NLN/Carnegie study affirmed that 96 percent of the nurse faculty are female, contrasting with the three-fifths of the U.S. postsecondary faculty who are males. The 2006 NLN/Carnegie study reports that nursing also lags significantly behind the remainder of academia with respect to diversity. Seven percent of nurse educators are minorities while 16 percent of U.S. faculty belong to a racial minority group.

The homogeneity of the nurse faculty plays out as a unique capacity constraint, limiting nursing schools' ability to provide culturally appropriate health care education toward developing a health care system that understands and addresses the needs of the Nation's rapidly diversifying population. Factors such as biases and stereotyping, communication barriers, cultural sensitivity/competence, and system and organizational determinants contribute to health care disparities, generating a compelling need for workforce diversity.

#### THE FEDERAL FUNDING REALITY

Today's undersized supply of appropriately prepared nurses and nursing faculty does not bode well for our Nation, where the shortages are deepening health disparities, inflated costs, and poor quality health care outcomes. Congress moved in the right policy direction in passing the Nurse Reinvestment Act in 2002. That act

helped develop Title VIII programs into a more comprehensive system of capacity-building strategies to develop nurses by providing schools of nursing with grants to strengthen activities, such as 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. Yet, as the HRSA Title VIII data show, it is abundantly clear that Congress must step up in providing critical attention and significantly more funding to this ongoing systemic problem.

*Nursing Education Loan Repayment Program.*—In fiscal year 2007, with 4,845 applicants to the Title VIII Nursing Education Loan Repayment Program, 586 awards were made, or 12 percent of applicants received awards. Whereas in fiscal year 2006, of the 4,222 applicants to this program, 615 awards were made—translating to 14.6 percent of applicants receiving awards.

*Nursing Scholarship Program.*—In fiscal year 2007, only 173 students were awarded scholarships due to the program's funding capacity; versus a total of 218 awards in fiscal year 2006.

*Advanced Education Nursing (AEN) Program.*—This program supports the graduate education that is the foundation to professional development of advanced practice nurses, whether with clinical specialties or with a specialty in teaching. In fiscal year 2007, AEN supported 16,092 graduate nursing students across the various specialties. The President's proposed fiscal year 2009 budget eliminates this program, which is fundamental to appropriately preparing future nursing faculty, the engine of the workforce pipeline. AEN must be restored and fully funded in order to prevent the Nation from losing ground in the effort to remedy the nurse and nurse faculty shortages.

As the only organization that collects data across all levels of the nursing education infrastructure, the NLN can state with authority that the nursing shortage in this country will not be reversed until the concurrent shortage of qualified nurse educators is addressed. Without adequate faculty, there are simply too few spots in nursing education programs to train all the qualified applicants out there. This challenge requires millions of dollars of increased funding for the professional development of nurses. The NLN urges Congress to strengthen existing Title VIII nurse education programs by funding them at a minimum level of \$200 million for fiscal year 2009; and to restore the Advanced Education Nursing program (Sec. 811) and fund it at an increased level equivalent to the other Title VIII Nursing Workforce Development Programs' proposed increase for fiscal year 2009.

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 in this country who will need our care.

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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 strong support for the National Institutes of Health (NIH).

The NPRCs are a national network of eight primate research centers supported by the NIH National Center for Research Resources (NCRR). The centers comprise the National Primate Research Program (NPRP), which was created by Congress in 1960. The program seeks to address human health problems through scientific research using the animal models that most closely resemble humans in their genetics, physiology, and disease processes—nonhuman primates. NPRC investigators and resources support research projects sponsored by nearly every institute at NIH. For example, NPRCs conduct research to help understand and treat conditions such as heart disease, hypertension, cancer, diabetes, hepatitis, AIDS, kidney disease, Alzheimer's disease, and Parkinson's disease. We also conduct research on emerging infectious diseases and support many aspects of biodefense. Each NPRC makes its facilities and resources available to over 2,000 external NIH-funded investigators from around the country. Our centers create collaborative research environments that allow scientists to combine their individual expertise beyond the scope of established disciplinary research projects.

NPRCs are integral partners in new science partnerships that will transform America's health and healthcare in the 21st century. NIH has responded to the rapidly changing world by strategically framing the next generation of biomedical research through cross-cutting, interdisciplinary initiatives such as those supported in



the NIH Roadmap, the NIH Neuroscience Blueprint, the Clinical and Translational Science Award program and the Genes, Environment and Health Initiative. NPRCs are poised to continue research and resource partnerships that will nurture the collaborative environment necessary to successfully and efficiently conduct research within these evolving NIH frameworks.

In 2007, NPRCs endorsed the fiscal year 2008 Ad Hoc Group for Medical Research proposal to increase the NIH budget by 6.7 percent over each of the next three fiscal years, fiscal year 2008-fiscal year 2010. At the time, we recognized that competing budget priorities put pressure on Congress to face difficult funding trade-offs yet we asked the Subcommittee to adopt long-term commitment to NIH. As you are aware, the final fiscal year 2008 appropriation for NIH was a disappointment to many. For the fifth straight year, NIH funding failed to match even the pace of biomedical inflation.

Unfortunately, the President's fiscal year 2009 budget request for NIH continues this flat funding trend for the agency for the sixth straight year. If the President's fiscal year 2009 request is enacted, the agency will have lost over 13.4 percent of its purchasing power during this time period when taking into account the anticipated 3.5 percent biomedical inflation rate for this year. As such, the NPRCs join with their colleagues in the biomedical community in calling for a \$1.9 billion (6.6 percent) increase in NIH's total discretionary budget for fiscal year 2009.

As a result of years of expanded investment and advancement in NIH biomedical research during the doubling years, the demand for NPRC resources has increased. To accommodate the increased focus of NIH on translational science and other research demands placed on NPRCs, NCRR should increase NPRCs P51 base grant (the mechanism that funds each NPRC) so that all appropriate areas of research can benefit from primate resources without delay. The ability of NIH-funded researchers to conduct future projects with primate models will depend on the enhancement of three key areas: (1) the nationwide availability of primates; (2) the quality and capacity of primate housing and breeding facilities, as well as the availability of related state-of-the-art diagnostic and clinical support equipment at NPRCs; and (3) the number of personnel trained in primate care and management at NPRCs. It is unacceptable that NPRCs budgets were held relatively flat by NCRR while the NIH budget doubled.

To illustrate the value of NPRC resources and expertise, below are examples of cutting edge research activities conducted with nonhuman primates:

*Heart Disease and Stroke.*—To date, advances against heart disease have cut deaths due to heart attack and stroke by more than 50 percent and save our economy more than half a trillion dollars annually in healthcare expenses and worker productivity. Nonhuman primates are used to investigate how genes interact with dietary factors to influence an individual's risk of developing atherosclerosis or hypertension. It is not possible to conduct this research with human subjects because it requires long-term feeding of defined diets, specialized pedigrees and the ability to frequently monitor multiple aspects of physiology. Establishment of the pedigreed baboon as a model in which to study risk factors for atherosclerosis has led to improvements in methods used to search the genome for genes regulating these risk factors. Increased funding for NIH and support for NPRCs will allow investigators to build on this research and apply significant findings to human health.

*Alzheimer's Disease.*—A new report from the Alzheimer's Association shows that there are more than 5 million people in the United States living with Alzheimer's disease today—10 percent more than a previous estimate 5 years ago. Medicare expenditures for beneficiaries with Alzheimer's and other dementias is projected to increase to \$160 billion by 2010 and \$189 billion by 2015. NPRCs are using rhesus monkeys to establish better models for studying the basic mechanisms of Alzheimer's disease, and for testing new diagnostic and therapeutic methods. Two distinct and cutting edge approaches are being developed to express in rhesus monkeys the human mutant genes that cause Alzheimer's disease. Further NIH-funded investigation and NPRCs support could lead us to early interventions for Alzheimer's that would decrease the healthcare cost burden and safeguard the health of millions of Americans.

*Mental Health Disorders.*—The National Institute of Mental Health points out that the annual economic cost of mental illness in the United States is estimated at well over \$150 million, including direct and indirect costs. Further, according to statistics from the Centers for Medicare and Medicaid Services, the direct costs of mental health care represent 6.2 percent of overall healthcare costs which totaled 14.5 percent of the gross domestic product in 2001. Just one example of NPRCs contribution to this category of diseases and disorders is a project in which research conducted with non-human primates produced a strong link between significant stress early in life and the increased incidence of mental health problems during

adolescence. The research strengthens the case for proactive treatment or counseling of children who undergo a significant early-life stress. Non-human primates provide unique insight into a variety of mental health disorders in ways that cannot be achieved in controlled studies in humans. Increased NIH funding and NPRCs support will allow researchers across the Nation and at NPRCs to continue work toward developing reliable diagnostic tools and therapies so that the quality of life will be enhanced for the millions of Americans burdened by mental health disorders.

*Cancer.*—According to NIH data, the 5-year survival rates 30 years ago for the five most common cancers were: breast, 75 percent; prostate 68 percent; colon, 50 percent; rectum, 49 percent; and lung, 13 percent. However, due in large part to NIH-funded research advances, data as of 2001 (the latest year for which NIH has statistics) shows the 5-year survival rates for the most common cancers have increased to: prostate, 100 percent; breast, 90 percent; colon, 65 percent; rectum, 65 percent; and lung, 16 percent. It is known that approximately 20 percent of cancers have a viral etiology. As such, a project taken on by NPRCs uses non-human primate models of viral-induced cancer to help scientists to understand fundamental mechanisms through which normal cells are transformed into cancerous cells. Increased and steady NIH funding and NPRC support will allow researchers to build on past progress in treating, curing and reducing the burden of cancer—this will lead to both a decline in the projected rise of U.S. healthcare expenditures and result in an American workforce with more healthy, productive years.

As mentioned previously, NPRCs research projects span the disease foci at NIH institutes and centers, and also play important roles in the various NIH initiatives, such as the NIH Roadmap, the NCRR Strategic Plan, and the Clinical and Translational Science Award program, among others. In the 1950's, primate research produced the first vaccine for one of the world's worst childhood killers, the Polio virus, reducing the number of cases in the United States from 58,000 to one or two per year. More recently, primate research enabled the development of a safe and effective vaccine for hepatitis B. Every school child in the country is now vaccinated against hepatitis B. Primates have also served as the best model for various types of HIV research, and their availability for use has resulted in at least 14 licensed anti-viral drugs for treatment of HIV infection. Primate models will continue to be necessary to defend the world against possible future epidemics such as SARS, West Nile Virus, and avian flu. In addition to deadly viral epidemics, primate research has enabled the discovery of better treatments and therapies for diseases and occurrences such as stroke, cataracts, depression and other psychiatric illnesses.

Not only do primates have the potential to provide answers for long-standing research questions, primate research provides an unparalleled opportunity to address more recently defined research priorities, such as those relating to genomics. The specific availability of information in the primate genome, which is quite similar to the human genome, makes primates essential in studies that require an integrated understanding of a whole biological system. Recent reports suggest that extensive analysis of genome structure and function in nonhuman primates could make immediate and significant contributions to the overall mission of NIH by accelerating progress in understanding many human diseases. Also, primates serve as critical animal models in biodefense research projects for which, in some cases, it would be inappropriate to conduct early clinical trials in humans. Primates are recognized as vital research resources within Federal strategic plans regarding biodefense research, including: the National Institute of Allergy and Infectious Diseases (NIAID) Strategic Plan for Biodefense Research; the NIAID Research Agenda for Category A Agents; and the NIAID Research Agenda for Category B and C Priority Pathogens. Also, NPRCs are partners in NIAID-funded Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases as well as with NIAID-funded National and Regional Biocontainment Laboratories.

As NIH and the national biomedical research agenda evolve, NPRCs adjust to meet the resource needs of the research community and also to maintain research programs that are on the cutting-edge of science. The reservoirs of knowledge residing within the NPRCs create new opportunities for research partnerships with investigators at host academic institutions and in the biomedical research community at large. Never have the research questions been so profound, or the implications for human health so critical. NPRCs are poised to bridge the gap between knowledge already gleaned from simple cellular and animal models and knowledge that is needed to promote human health, and to translate that knowledge into vaccines, therapeutic drugs, and other strategies to prevent or treat human diseases.

Thank you for the opportunity to submit this written testimony concerning funding for NIH in the fiscal year 2009 appropriations bill and for your attention to the critical need for primate research and enhancement of the NPRCs P51 base grant.

Please do not hesitate to contact any one of the eight NPRC Directors should you have any questions.

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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 testimony for the record regarding Federal funding for psoriasis and psoriatic arthritis research for fiscal year 2009. The Foundation serves as the Nation's largest patient-driven non-profit voluntary association committed to improving the quality of life for the millions of people affected by psoriasis and psoriatic arthritis.

As part of our mission, we educate health professionals, the public and policymakers to increase public awareness and understanding of the challenges faced by people with psoriasis and psoriatic arthritis. Moreover, the Foundation maintains a strong commitment to securing public policies and programs that support its focus of education, advocacy and research toward better treatments and a cure. The Foundation specifically seeks to advance public and private efforts to improve treatment of these diseases, identify a cure and ensure that all people with psoriasis and psoriatic arthritis have access to the medical care and treatment options they need to live the highest quality of life possible.

The Foundation 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 psoriasis and psoriatic arthritis. Specifically, the Foundation advocates that the National Institutes of Health (NIH) be given additional resources to 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, as well as studies to understand co-morbidities such as obesity, depression, and heart disease that may be associated with inflammation in the skin and joints. Specifically, we respectfully call upon Congress to boost psoriasis and psoriatic arthritis research efforts by allocating a 6.6 percent increase in fiscal year 2009 (to \$31.1 billion) to NIH and its institutes and centers that play an integral role in psoriasis and psoriatic arthritis research:

- The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS);
- The National Institute of Allergy and Infectious Diseases (NIAID);
- The National Human Genome Research Institute (NHGRI);
- The National Institute for Environmental Health Systems (NIEHS);
- The National Institute of Mental Health (NIMH);
- The National Center for Complementary and Alternative Medicine (NCCAM);
- and
- The National Center for Research Resources (NCRR).

In addition, the Foundation urges the Subcommittee to encourage the Centers for Disease Control and Prevention (CDC) to strengthen patient data collection on psoriasis to improve the knowledge base of the longitudinal impact of these diseases on the individuals they affect. The Foundation believes that a greater investment in NIH, NIAMS, NIAID, NHGRI, NIEHS, NIMH, NCCAM, NCRR, and CDC will lead to the development of new, safe, effective and long-lasting treatments and a cure for psoriasis and psoriatic arthritis.

THE IMPACT OF PSORIASIS AND PSORIATIC ARTHRITIS

According to the NIH, as many as 7.5 million Americans have psoriasis—an immune-mediated genetic, chronic, inflammatory, painful, disfiguring, and life-altering disease that requires life-long sophisticated medical intervention and care, and imposes serious adverse effects on the individuals and families affected. On average, 17,000 people with psoriasis live in each Congressional District.

Psoriasis most often first strikes between the ages of 15 and 25 and lasts a lifetime. Unfortunately, psoriasis often is overlooked or dismissed because it typically does not cause death. It is commonly and incorrectly considered by insurers, employers, policymakers, and the public as a mere annoyance—a superficial problem, mistakenly thought to be contagious and/or due to poor hygiene. Yet, together psoriasis and psoriatic arthritis impose significant economic costs on individuals and society. Each year, Americans with psoriasis lose approximately 56 million hours of work and spend \$2 billion to \$3 billion to treat the disease.

There is mounting evidence that people with psoriasis are at elevated risk for myriad other serious, chronic and life-threatening conditions. Although data are still

emerging on the relationship of psoriasis to other diseases and their ensuing costs to the medical system, it is clear that psoriasis goes hand-in-hand with comorbidities such as Crohn's disease, diabetes, metabolic syndrome, obesity, hypertension, heart attack, cardiovascular disease, liver disease and psoriatic arthritis—which occurs in up to 30 percent of people with psoriasis. Of serious concern is that studies have shown that psoriasis causes as much disability as other major chronic diseases and individuals with psoriasis are twice as likely to have thoughts of suicide as people without psoriasis or with other chronic conditions.

Despite some recent breakthroughs, many people with psoriasis and psoriatic arthritis remain in need of improved quality of life and effective, safe, and affordable therapies, which could be delivered through an increased Federal commitment to genetic, clinical and basic research. Research holds the key to improved treatment of these diseases, better diagnosis of psoriatic arthritis and eventually a cure for both conditions.

#### FEDERAL PSORIASIS AND PSORIATIC ARTHRITIS RESEARCH

While our Nation has benefited from past Federal investment in the NIH, unfortunately psoriasis and psoriatic arthritis research progress has not keep pace with other chronic conditions. An analysis of longitudinal Federal funding data shows that, on average over the past decade, NIAMS has spent less than \$1 per person with psoriasis per year. At the historical and current rate of psoriasis funding, NIH funding is not keeping pace with research needs.

Meetings and correspondence with NIAMS and other Institutes and Centers at NIH indicates that the three principal agencies involved in psoriasis and psoriatic arthritis research are NIAMS, NCCR and NHGRI, the Foundation knows from meetings at NIH that other Federal research agencies—such as NIAID, NIEHS, NIMH, and NCCAM—have important roles to play in psoriasis and psoriatic arthritis and understanding their health and psychosocial impact on affected individuals. The Foundation has joined with the broader health community in advocating \$31.1 billion for the NIH in fiscal year 2009. This level of investment will allow NIH to sustain and build on its research progress resulting from the recent NIH budget doubling effort while avoiding the severe disruption to that progress that would result from a minimal increase. More than ever, a greater investment today in psoriasis and psoriatic arthritis will go farther faster and help the Nation turn the corner on finding a cure for these two life-altering, disfiguring diseases.

We hope that the subcommittee will provide all seven of the aforementioned institutes and centers with increased fiscal year 2009 funding specifically, we urge the subcommittee to provide NIH and the aforementioned institutes and centers with a 6.6 percent increase in fiscal year 2009 funding and encourage them to undertake and/or expand psoriasis and psoriatic arthritis research so they can undertake the following:

- Make efforts to understand the reasons for the co-morbidities associated with psoriasis and psoriatic arthritis such as obesity, depression, heart disease and heart attack and the interplay between inflammation and such co-morbidities found disproportionately among individuals with psoriasis. Individuals with psoriasis are at elevated risk for other chronic and debilitating health conditions, such as heart attacks and diabetes and the risk of mortality is 50 percent higher for people with severe psoriasis.
- Conduct research within the Institutes and Centers associated with these co-morbidities with particular focus on biomarkers for psoriasis and psoriatic arthritis and shared molecular pathways with comorbid conditions.
- Support NIAMS in its interest in a strong follow-up study to the Genetic Association Information Network grant. Research is beginning to identify the immune cells involved in psoriasis; this knowledge will help scientists understand which cells or molecular processes should be targeted for more effective treatments and eventually a cure.
- Undertake research relating to genetics, immunology, and animal models relating to psoriasis and psoriatic arthritis.
- Expand basic research including how genetic variation gives rise to differences in treatment responses and mechanisms that link skin and joint inflammation.
- Study the immune cells and inflammatory process as it relates to the pathogenesis of psoriasis.
- Conduct research to better the understanding between psoriasis and mental health, including identifying any underlying biologic reason for mental health issues associated with psoriasis, as well how negative social and psychological effects impact psoriasis. It is estimated as many as 52 percent of psoriasis patients report clinically significant psychiatric symptoms (such as depression)

- and that individuals with psoriasis are twice as likely to have thoughts of suicide as people without psoriasis or with other chronic conditions.
- Study how environmental triggers interact with different genetic susceptibility factors to better understand psoriasis disease development and response to treatment to provide insight in psoriasis and prevention of psoriasis and psoriatic arthritis.
- Evaluate of the effectiveness of complementary and alternative therapies for the treatment of psoriasis and/or psoriatic arthritis.

#### THE ROLE OF CDC IN PSORIASIS AND PSORIATIC ARTHRITIS RESEARCH

The Foundation is concerned that there have been very few efforts to collect epidemiological and other related data on individuals with psoriasis and psoriatic arthritis. Researchers and clinicians continue to be limited in their longitudinal understanding of these conditions and their effects on individual patients. The Foundation hopes that the Subcommittee will encourage the CDC to add psoriasis and psoriatic arthritis specific epidemiological studies where appropriate as part of its research plan. In addition, we ask that the Subcommittee encourage the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) within the CDC to examine and develop options and recommendations for the creation of a National Psoriasis and Psoriatic Arthritis Patient Registry in fiscal year 2009. A national patient registry that collects longitudinal patient data will help researchers to learn about key attributes such as response to treatment, substantiating the waxing and waning of psoriasis, understanding associated manifestations like nail disease and arthritis, and the relationship of psoriasis to other public health concerns.

#### CONCLUSION

On behalf of the Foundation's Board of Trustees and the millions of individuals with psoriasis and psoriatic arthritis who we represent, thank you for this opportunity to submit written testimony regarding the fiscal year 2009 funding levels necessary to ensure that our Nation adequately addresses psoriasis and psoriatic arthritis and to make gains in improving therapies and eventually attaining a cure. We thank you in advance for encouraging the CDC and the NCCDPHP to become more engaged in psoriasis and psoriatic arthritis data collection. We believe that additional research undertaken at the NIH coupled with epidemiologic efforts at the CDC together will help advance the Nation's efforts to improve treatments and identify a cure for psoriasis and psoriatic arthritis. 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 our requests.

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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 country who support respite. Twenty-five State respite coalitions, including two of the most active, the Iowa Respite and Crisis Care Coalition and the Pennsylvania Respite Coalition, are also affiliated with the NRC. This statement is presented on behalf of these organizations, as well as the members of the Lifespan Respite Task Force, a coalition of over 80 national and more than 100 State and local groups who support funding for the Lifespan Respite Care Act (Public Law 109-442). We are requesting that the Subcommittee include funding for the newly enacted Lifespan Respite Care Act in the fiscal year 2009 Labor, HHS and Education Appropriations bill at its modest authorized level of \$53.3 million for fiscal year 2009. Many Members of Congress already support funding for Lifespan Respite. In fact, the Senate Budget Resolution reserves \$53 million in the Department of Health and Human Services Account for Lifespan Respite.

*Who Needs Respite?*—A national survey found that 44 million family caregivers are providing care to individuals over age 18 with disabilities or chronic conditions (National Alliance for Caregiving (NAC) and AARP, 2004). In 2006, the last year Federal data were collected, 13.9 percent of U.S. children (approximately 10 million) had special health care needs and 21 percent of households with children included at least one child with a special health care need. These rates represent a modest increase since the last survey conducted in 2001. (National Survey of Children with Special Health Care Needs, U.S. Health Resources and Services Administration, 2008). These surveys suggest that a conservative estimate of the Nation's family caregivers probably exceeds 50 million.

Compound this picture with the growing number of caregivers known as the “sandwich generation” caring for young children as well as an aging family member. An estimated 20 to 40 percent of caregivers have children under the age of 18 to care for in addition to a parent or other relative with a disability. And in the US, 6.7 million children, with and without disabilities, are in the primary custody of an aging grandparent or other relative other than their parents.

Together, these family caregivers are providing about 80 percent of all long-term care in the United States. It has been estimated that these family caregivers provide \$350 billion in uncompensated care, an amount comparable to Medicare spending (\$342 billion in 2005) and more than total spending for Medicaid, including both Federal and State contributions and both medical and long-term care (\$300 billion in 2005). (AARP, 2007).

*What is Respite Need?*—State and local surveys have shown respite to be the most frequently requested service of the Nation’s family caregivers, including a recent study by Evercare (Evercare and NAC, 2006). Yet respite is unused, in short supply, inaccessible, or unaffordable to a majority of the Nation’s family caregivers. The 2004 NAC/AARP survey of caregivers found that despite the fact that the most frequently reported unmet needs were “finding time for myself,” (35 percent), “managing emotional and physical stress” (29 percent), and “balancing work and family responsibilities” (29 percent), only 5 percent of family caregivers were receiving respite (NAC and AARP, 2004). In rural areas, the percentage of family caregivers able to make use of respite was only 4 percent (Easter Seals and NAC, 2006).

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.

Twenty of 35 State-sponsored respite programs surveyed in 1991 reported that they were unable to meet the demand for respite services. In the last 15 years, we suspect that not too much has changed. A study conducted by the Family Caregiver Alliance identified 150 family caregiver support programs in all 50 states and Washington, DC funded with state-only or State/Federal dollars. Most of the funding comes through the Federal National Family Caregiver Support Program. As a result, programs are administered by local area agencies on aging and primarily serve the elderly. And again, some programs provide only limited respite, if at all. Only about one-third of these 150 identified programs serve caregivers who provide care to adults age 18–60 who must meet stringent eligibility criteria. As the report concluded, “State program administrators see the lack of resources to meet caregiver needs in general and limited respite care options as the top unmet needs of family caregivers in the States.” The 25 State respite coalitions and other National Respite Network members confirm that long waiting lists or turning away of clients because of lack of resources is still the norm.

While most families take great joy in helping their family members to live at home, it has been well documented that family caregivers experience physical and emotional problems directly related to their caregiving responsibilities. Three-fifths of family caregivers age 19–64 surveyed recently by the Commonwealth Fund reported fair or poor health, one or more chronic conditions, or a disability, compared with only one-third of non-caregivers (Ho, Collins, Davis and Doty, 2005). A study of elderly spousal caregivers (aged 66–96) found that caregivers who experience caregiving-related stress have a 63 percent higher mortality rate than noncaregivers of the same age (Schulz and Beach, December 1999).

Supports that would ease their burden, most importantly respite care, 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. One Massachusetts mother of a seriously ill child spoke to the demands of constant caregiving: “I recall begging for some type of in-home support . . . I fell asleep twice while driving on the Massachusetts Turnpike on the way to appointments at Children’s Hospital. The lack of respite . . . put our lives and the lives of everyone driving near me at risk.”

Restrictive eligibility criteria also preclude many families from receiving services or continuing to receive services they once were eligible for. A mother of a 12-year-old with autism was denied additional respite by her State Developmental Disability agency because she was not a single mother, was not at poverty level, wasn’t exhibiting any emotional or physical conditions herself, and had only one child with a disability. She said, “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. An Alabama mom of a 19-year-old-daughter with multiple disabilities who requires constant care recently told us about her fears at a respite summit in Alabama, "My daughter Casey has cerebral palsy, she does not communicate, she is incontinent she eats a pureed diet, she utilizes a wheelchair, she is unable to bathe or dress herself. At 5 feet 5 inches and 87 pounds I carry her from her bedroom to the bathroom to bathe her, and back again to dress her. . . . Without respite services, I do not think I could continue to provide the necessary long-term care that is required for my daughter. . . . As I age, I do wonder how much longer I will be able to maintain my daily ritual as my daughter's primary caregiver." Even with recent changes to the National Family Caregiver Support Program, this mom would not qualify for respite.

Disparate and inadequate funding streams exist for respite in many States. But even under the Medicaid program, respite is allowable only through State waivers for home and community-based care. Under these waivers, respite services are capped and limited to narrow eligibility categories. Long waiting lists are the norm.

Respite may not exist at all in some States for 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. She went for years providing constant care to her mom with almost no support. Now 31, she wrote, "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, we've developed a small pool of people and friends that will also come and stand in. And it has made all the difference."

*Respite Benefits Families and is Cost Saving.*—Respite has been shown to be effective in improving 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 recent report from the U.S. Dept. of Health and Human Services 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, especially in the policy arena. Delaying a nursing home placement for just one individual with Alzheimer's or other chronic condition for several months can save government long-term care programs 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. They also found that the lack of available respite care 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 most recent study by 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. Offering respite to working family caregivers could help improve job performance and employers could potentially save billions (MetLife and National Alliance for Caregiving, 2006).

*Lifespan Respite Care Program Will Help.*—The Lifespan Respite Care Act is based on the success of statewide Lifespan Respite programs in four States: Oregon, Nebraska, Wisconsin and Oklahoma. A new Arizona State Lifespan Respite program is now up and running. Michigan passed State Lifespan Respite legislation in 2004 but has not had funding, and new State Lifespan Respite legislation is currently pending in Kansas in preparation for the Federal funds.

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 State agency or community-based organization being forced to constantly 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 the savings used to fund new respite services for families who may not qualify for any existing Federal or State program.

The State Lifespan Respite programs provide best practices on which to build a national respite policy. The programs have been recognized by prominent policy organizations, including the National Conference of State Legislatures, which recommended the Nebraska program as a model for State solutions to community-based long-term care. The National Governors Association and the President's Committee for People with Intellectual Disabilities also have highlighted lifespan respite systems as viable solutions. And most recently, the White House Conference on Aging recommended enactment of the Lifespan Respite Care Act to Congress.

The purpose of the new law is to expand and enhance respite services, improve coordination, and improve respite access and quality. Under a competitive grant program, 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. 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.

The Federal Lifespan Respite program would be administered by the U.S. Department of Health and Human Services (HHS), which would provide competitive grants to State agencies through Aging and Disability Resource Centers working in collaboration with State respite coalitions or other State respite organizations. The program is authorized at \$53.3 million in fiscal year 2009 rising to \$95 million in fiscal year 2011. The program has received no Congressional funding to date.

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 \$53.3 million in the fiscal year 2009 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 SLEEP FOUNDATION

Mr. Chairman and members of the subcommittee, thank you for allowing me to submit testimony on behalf of the National Sleep Foundation (NSF). I am Dr. Meir Kryger, Chairman of the NSF Board of Directors and Director of Sleep Medicine Research and Education, Gaylord Hospital, Wallingford, Connecticut. NSF is an independent, non-profit organization that is dedicated to improving public health and safety by achieving understanding of sleep and sleep disorders, and by supporting sleep-related education, research, and advocacy. We work with sleep medicine and other health care professionals, researchers, patients and drowsy driving victims throughout the country as well as collaborate with many government, public and private organizations with the goal of preventing health and safety problems related to sleep deprivation and untreated sleep disorders.

Sleep problems, whether in the form of medical disorders or related to work schedules and a 24/7 lifestyle, are ubiquitous in our society. It is estimated that sleep-related problems affect 50 to 70 million Americans of all ages and socioeconomic classes. Sleep disorders are common in both men and women; however, important disparities in prevalence and severity of certain sleep disorders have been identified in minorities and underserved populations. Despite the high prevalence of sleep disorders, the overwhelming majority of sufferers remain undiagnosed and untreated, creating unnecessary public health and safety problems, as well as increased health care expenses. Surveys conducted by NSF show that more than 60 percent of adults have never been asked about the quality of their sleep by a physician, and fewer than 20 percent have ever initiated such a discussion.

Additionally, Americans are chronically sleep deprived as a result of demanding lifestyles and a lack of education about the impact of sleep loss. Sleepiness affects vigilance, reaction times, learning abilities, alertness, mood, hand-eye coordination, and the accuracy of short-term memory. Sleepiness, as a result of untreated dis-



orders or sleep deprivation, has been identified as the cause of a growing number of on-the-job accidents and automobile crashes.

According to the National Highway Traffic Safety Administration's 2002 National Survey of Distracted and Drowsy Driving Attitudes and Behaviors, an estimated 1.35 million drivers have been involved in a drowsy driving crash in the past 5 years. According to NSF's 2008 Sleep in America poll, 64 percent of respondents report that they have driven drowsy at least once in the past year. In fact, 32 percent say they drive drowsy once a month or more! A large number of academic studies have linked work accidents, absenteeism, and poor school performance to sleep deprivation and circadian effects.

The 2006 Institute of Medicine (IOM) report, *Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem*, found the cumulative effects of sleep loss and sleep disorders represent an under-recognized public health problem and have been associated with a wide range of negative health consequences, including hypertension, diabetes, depression, heart attack, stroke, and at-risk behaviors such as alcohol and drug abuse—all of which represent long-term targets of the Department of Health and Human Services (HHS) and other public health agencies. Moreover, the personal and national economic impact is staggering. The IOM estimates that the direct and indirect costs associated with sleep disorders and sleep deprivation total hundreds of billions of dollars annually.

Sleep science and government reports have clearly demonstrated the importance of sleep to health, safety, productivity and well-being, yet studies continue to show that millions of Americans are at risk for serious health and safety consequences of untreated sleep disorders and inadequate sleep. Unfortunately, despite recommendations in numerous Federal reports, there are no on-going national educational programs regarding sleep and fatigue issues aimed at the general public, health care professional, underserved communities or at-risk groups.

NSF believes that every American needs to understand that good health includes healthy sleep, just as it includes regular exercise and balanced nutrition. We must elevate sleep to the top of the national health agenda. We need your help to make this happen.

Our biggest challenge is bridging the gap between the outstanding scientific advances we have seen in recent years and the level of knowledge about sleep held by health care practitioners, educators, employers, and the general public. Because resources are limited and the challenges great, we think creative and new partnerships are needed to fully develop sleep awareness, education, and training initiatives. Consequently, the NSF is spearheading two important initiatives to raise public and physician awareness of the importance of sleep to the health, safety and well-being of the Nation.

First, for the last 4 years, Congress has recommended that the CDC support activities related to sleep and sleep disorders. As a result, CDC's National Center for Chronic Disease Prevention and Health Promotion has been collaborating with more than twenty voluntary organizations and Federal agencies to form the National Sleep Awareness Roundtable (NSART), which was officially launched in March of 2007. NSART is currently working to develop a National Action Plan. This document will address what is required to organize a successful collaboration to implement effective public and professional awareness and education initiatives to improve sleep literacy and healthy sleep behaviors. NSART is seeking to expand its membership by reaching out to new organizations and State and Federal agencies that are interested in raising awareness of sleep issues and implementing NSART's National Action Plan.

In fiscal year 2008, Congress provided \$818,000 for activities related to sleep and sleep disorders, including CDC's participation in NSART and incorporating questions on sleep and sleep-related disturbances into established CDC surveillance systems. The President's fiscal year 2009 budget request currently includes \$818,000 for these programs.

With fiscal year 2008 funding, CDC plans to provide grants to at least 15 States to include several sleep questions in their data collection through the Behavioral Risk Factor Surveillance System. CDC also plans to include one core sleep question in its national data collection efforts. This new data will provide important information on the prevalence of sleep disorders and enable researchers to better address the complex interrelationship between sleep loss and comorbid conditions such as obesity, diabetes, depression, hypertension, and drug and alcohol abuse.

CDC also plans to provide support for the goals and activities of the National Sleep Awareness Roundtable.

Although the CDC has taken initial steps to begin to consider how sleep affects public health issues, the agency needs additional resources to take appropriate actions, as recommended by the IOM and other governmental reports.

Expanded funding for sleep and sleep disorder-related activities would allow the Center to create education and training materials for current and future health professionals; build and test public health interventions; expand surveillance and epidemiological activities; create fellowships and research opportunities at State universities; and enhance public awareness and education on sleep and sleep disorders. The following are detailed scenarios for various funding levels.

*\$2 million*

—*Expand Surveillance on BRFSS.*—CDC could double the number of grants it provides to States to use the optional sleep module and include more core questions in the nationwide data collection through the Behavioral Risk Factor Surveillance System (BRFSS). CDC would also expand its participation in and funding of the goals and activities of the National Sleep Awareness Roundtable.

*\$5 million—All activities detailed in the \$2 million scenario, plus*

—*Public Education.*—CDC could support the development of public education and awareness initiatives that use targeted approaches for delivering sleep-related messages.

—*Training Materials.*—Tools could be developed for current and future health professionals to increase the diagnosis and treatment of sleep disorders. Today, most health care professionals receive no such training, which increases the Nation's health burden.

*\$11 million—All activities detailed in the \$5 million scenario, plus*

—*Initiate Surveillance on YRBSS.*—CDC could implement questions on the Youth Risk Behavior Surveillance System (YRBSS). This will further build the evidence base for the prevalence of sleep-related conditions that commonly afflict the American population, such as obstructive sleep apnea, in addition to increasing data collection on sleep-related practices and public awareness of their importance across the life stages.

—*Fellowship and Research Opportunities.*—Additional funding would also allow the CDC to support the development of targeted approaches for delivering sleep-related messages and increasing public education and awareness on this important issue. Fellowship opportunities could be increased to attract promising researchers into the field of sleep epidemiology.

NSF and members of the National Sleep Awareness Roundtable believe that a partnership with CDC is critical to address the public health impact of sleep and sleep disorders. We ask that the Committee encourage CDC to continue to take a leadership role in partnering with other Federal agencies and voluntary health organizations in the National Sleep Awareness Roundtable to create collaborative sleep education and public awareness initiatives. We hope that the Committee will provide funding of \$11,000,000 to the CDC to execute programs as outlined here and to financially support efforts developed by NSART through a cooperative agreement similar to other roundtables in which CDC participates.

Thank you again for the opportunity to present you with this testimony.

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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 2009 appropriation request for the National Technical Institute for the Deaf (NTID), one of eight colleges of RIT, in Rochester NY. Created by Congress, we have fulfilled our mission with distinction for 40 years. We currently provide university technical education to a total of 1,343 students including 1,185 deaf and hard-of-hearing students and 158 hearing students from almost every state.

BUDGET REQUEST

We respectfully request your support of our full appropriation request, plus additional funds. Since the submission of our fiscal year 2009 budget request, a number of unanticipated—and unavoidable—circumstances have affected NTID. The first table below details our original request and the second details an additional \$2,185,000 that we request.

In total we ask for \$64,212,000 (\$62,027,000 requested plus \$2,185,000 in added funds).

## NTID FISCAL YEAR 2009 ORIGINAL REQUEST AND PRESIDENT'S REQUEST

	Operations	Construction	Total
NTID Request .....	\$60,852,000	\$1,175,000	\$62,027,000
President's Request .....	58,020,000	1,175,000	59,195,000
Difference .....	2,832,000	.....	2,832,000

## NTID FISCAL YEAR 2009 ADDITIONAL UNANTICIPATED REQUESTED FUNDING (NOT INCLUDED ABOVE)

	Amount
Enrollment: We experienced significant growth in enrollment, up 93 students to 1,343, the second largest in our history. New applications are up another 8 percent. Scholarships costs will be \$350,000 above last year .....	\$350,000
Fair Labor Standards Act: RIT learned some non-exempt staff were improperly classified as exempt. Reclassification means about 140 NTID employees will receive an added \$650,000 overtime pay. Forty more are under review, potentially adding \$350,000 overtime fiscal year 2009 .....	1,000,000
Salary increases: Intense local competition for interpreters from video relay services means increased salaries are a must. A 10 percent increase is approximately \$550,000; more may be required to retain interpreters. Also NTID budgeted a 3.0 percent faculty/staff raise for fiscal year 2009; however, RIT allocated 4.5 percent for faculty costing an extra \$285,000. ....	835,000
Subtotal Additional Unanticipated Request .....	2,185,000
Total of Original and Unanticipated Requests .....	<sup>1</sup> 64,212,000

<sup>1</sup> Thus we ask that the \$2,832,000 cut by the President be restored and that an additional \$2,185,000 be added to our operations, bringing our total request to \$64,212,000.

Adding to our concerns for fiscal year 2009—and as included above—RIT learned it was not in compliance with some provisions of the Fair Labor Standards Act. This finding affected about 140 NTID employees, and others who worked for NTID in the last six years. Forty additional NTID positions are now being evaluated for reclassification, which we anticipate will result in added pay to these individuals for overtime in fiscal year 2009 and beyond.

The reclassification has already added \$800,000 to fiscal year 2008 overtime expenditures and is expected to grow to \$1,000,000 in fiscal year 2009 and beyond. We can not support this at our requested level much less at the amount recommended in the President's budget.

Unanticipated salary pressures also impact fiscal year 2009. We budgeted for a 3 percent salary increase; however, only two months ago RIT increased faculty salaries by 4.5 percent, a \$285,000 impact. We also face a necessary increase in interpreter salaries for fiscal year 2009 to compete with video relay service centers in Rochester; they have significantly increased local pay scales.

It is extremely unusual that NTID asks for funds above our original request. However, the added circumstances we face—all of which have developed since we submitted our fiscal year 2009 request, require us to ask for these additional funds. Recall that quite the opposite, we have consistently restrained requests. From fiscal year 2003 through fiscal year 2007 we documented \$6,200,000 of savings by reducing/reallocating headcounts and increasing revenues. These difficult savings controlled requests while improving programs and expanding in areas like speech-to-text services for deaf and hard-of-hearing students who benefit from this service.

We are proud of those accomplishments; however, they leave limited flexibility in what we respectfully submit is inadequate funding in the President's budget. Without the added funds we will need to reduce important programs and services. The following are not all inclusive but exemplify the actions we will be required to undertake if we are not funded as requested.

1. *Technology.*—Student curricula demand state-of-the-art technology. Students depend on technology updates to prepare for work. For deaf and hard-of-hearing students, instructional delivery technology is critical. We require \$1,000,000 per year to remain current.

2. *Endowment.*—The Education of the Deaf Act authorizes matching private gifts from appropriations, reducing dependence on federal funds. In fiscal year 2007 we matched over \$800,000; we expect to match over \$1,000,000 in fiscal year 2008. We need to continue matching to follow through on commitments made to donors.

3. *Outreach and Enrollment.*—Approximately \$500,000 supports programs that: attract junior/senior high school students; create a community college referral program to enhance college preparation and transferability; and revamp English programs to help students to improve their reading and writing skills. All increase future enrollment of deaf and hard-of-hearing students at the university level. Limited funding may impact these efforts.

4. *Open Positions.*—Current and future position openings will not be filled. The impact of a freeze depends on where vacancies appear. The position reduction we planned and implemented from fiscal year 2003 through fiscal year 2007 leaves few options today that will not directly impact services to students; this is especially true in light of the significant enrollment increases mentioned earlier.

Our fiscal year 2009 operations request represents costs driven by increases in salary, health benefits, and energy costs, as well as RIT service charges that have the same inflationary pressures. We do not ask for funds to address program modifications; we will reallocate to meet those needs. Our experience from fiscal year 2003 to fiscal year 2007 proves we can and will do this without additional appropriations.

Our fiscal year 2009 request was submitted in June 2007, a full 15 months before the fiscal year begins. NTID is a dynamic institution, and needs changed significantly in the interim; while this is not an unusual occurrence which we normally are able to accommodate, this year we are seriously concerned that the magnitude of the changes may overwhelm us.

But at the same time, we would like you to be aware that there is also a decrease in another part of our request; our original construction request for \$1,640,000 has been reduced by nearly 30 percent to \$1,175,000. We accomplished this by negotiating cost-sharing with RIT for two projects in the original submission.

NTID is committed to providing exemplary education for deaf and hard-of-hearing students in a cost-effective manner and has a long history of successful stewardship of federal funds.

#### ENROLLMENT

Total enrollment is at 1,343 for school year 2007–08 (fiscal year 2008), and was 1,250 students last year as we began fiscal year 2007. This dramatic increase of 93 students (7.4 percent) brings us to the second largest enrollment in our 40-year history, just 15 students below our peak 24 years ago. NTID anticipates maintaining or increasing enrollment for school year 2008–09 (fiscal year 2009). A five-year history of our enrollment numbers follows.

#### NTID ENROLLMENTS: 5-YEAR HISTORY

School year	Deaf and hard-of-hearing students				Hearing students			Grand Total
	Undergrad	Graduate		Subtotal	Interpreting program	MSSE	Sub-Total	
		RIT	MSSE					
2003–2004 .....	1,064	45	41	1,150	92	28	120	1,270
2004–2005 .....	1,055	42	49	1,146	100	35	135	1,281
2005–2006 .....	1,013	53	38	1,104	116	36	152	1,256
2006–2007 .....	1,017	47	31	1,095	130	25	155	1,250
2007–2008 .....	1,103	51	31	1,185	130	28	158	1,353

The number of students in our interpreting program has grown substantially in recent years. The number in our graduate secondary teacher preparation program (MSSE) has fluctuated (totaling both MSSE columns above), and the total of deaf and hard-of-hearing students increased dramatically from 1,095 in 2006–2007 to 1,185 in 2007–2008 an increase of 90 students (8.2 percent).

#### STUDENT ACCOMPLISHMENTS

Our placement rate for graduates is 95 percent placed in jobs commensurate with the level of their education (using the Bureau of Labor Statistics methodology). Over the last five years, 64 percent were employed in business and industry, 26 percent in education/non profits, and 10 percent in government.

In fiscal year 2005, NTID, the Social Security Administration, and Cornell University examined over 13,000 NTID applicants. We learned NTID graduation has significant economic benefits. By age 50, deaf and hard-of-hearing baccalaureate graduates earn on average \$6,021 more per year than those with associate degrees, who in turn earn \$3,996 more per year on average than those who withdraw. Stu-

dents who withdraw earn \$4,329 more than those who are not admitted. Students who withdraw also experience twice the rate of unemployment as graduates.

The same studies show 60 percent of students at NTID receive Supplemental Security Income benefits, but when they are age 50, less than 3 percent draw these benefits. Graduates also access Social Security Disability Insurance (an unemployment benefit), at far lesser rates than withdrawals; by age 50, withdrawals were twice as likely to be receiving these benefits as graduates. A large percentage of school leavers without a degree will continue to depend heavily on federal income support throughout their lives. But NTID graduates have significantly reduced dependence on welfare programs.

Considering the added taxes graduates pay as a result of their increased earnings and the savings derived from reduced dependency on the 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.

#### NTID BACKGROUND

**Academic Programs:** NTID offers high quality, career-focused, associate degree programs preparing students for specific well-paying technical careers. A cooperative education component ties closely to high demand employment opportunities. Expanding transfer associate degree programs better serve the higher achieving segment of our student population who seek bachelors and masters degrees in an increasingly demanding marketplace. These associate transfer programs provide seamless transition to baccalaureate studies. We also support students in RIT baccalaureate programs. One of NTID's greatest strengths is our outstanding track record of assisting high-potential students gain admission to and graduate from the other colleges of RIT at rates that are better than their hearing peers.

**Research:** The research program is guided and organized according to these general research areas: language and literacy, teaching and learning, socio-cultural influences, career development, technology integration, and institutional research. All benefit the deaf and hard-of-hearing population.

**Outreach:** Extended outreach activities to junior/senior high school students expand their horizons regarding a college education. We also serve other universities and post-college adults.

**Student Life:** The new CSD Student Development Center, funded by a \$2,000,000 private gift and a \$1,500,000 fiscal year 2005 federal appropriations, opened a year ago. Our activities conducted there foster student leadership and community service, and provide opportunities for students to explore other educational interests.

#### SUMMARY

It is extremely important that our funding be provided at the full level detailed in this testimony, particularly in light of the unanticipated impacts described above; even at this level, some service reductions may be necessary should we be unable to offset these costs.

We will continue our mission of preparing deaf and hard-of-hearing people to enter the workplace and society.

Our alumni have demonstrated that they can achieve independence, contribute to society, earn a living, and live a satisfying life as a result of NTID. Research shows that NTID graduates over their lifetimes are employed at a much higher rates, earn substantially more (therefore paying significantly more in taxes), and participate at a much lower rate in federal welfare programs than those who apply but do not attend NTID or who withdraw.

We are hopeful that the members of the Committee will agree that NTID, with its outstanding record of service to deaf and hard-of-hearing people, remains deserving of their support and confidence.

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#### PREPARED STATEMENT OF THE NEPHCURE FOUNDATION

##### ONE FAMILY'S STORY

Chairman Harkin and members of the subcommittee thank you for the opportunity to present testimony today, I am Dee Ryan and my husband is Lieutenant Colonel John Kevin Ryan, an Iraq war veteran. I would like to tell you about my 6 year old daughter Jenna's nephrotic syndrome (NS), a medical problem caused by rare diseases of the kidney filter. When affected, these filters leak protein from the blood into the urine and often cause kidney failure requiring dialysis or kidney transplantation. We have been told by our physician that Jenna has one of two filter diseases called Minimal Change Disease (MCD) or Focal and Segmental

Glomerulosclerosis (FSGS). According to a Harvard University report there are presently 73,000 people in the United States who have lost their kidneys as a result of FSGS. Unfortunately, the causes of FSGS and other filter diseases are very poorly understood.

In October 2007 my daughter began to experience general swelling of her body and intermittent abdominal pain, fatigue and general malaise. Jenna began to develop a cough and her stomach became dramatically distended. We rushed Jenna to the emergency room where her breathing became more and more labored and her pulse raced. She had symptoms of pulmonary edema, tachycardia, hypertension, and pneumonia. Her lab results showed a large amount of protein in the urine and a low concentration of the blood protein albumin, consistent with the diagnosis of FSGS. Jenna's condition did not begin to stabilize for several frightening days.

Following her release from the hospital we had to place Jenna on a strict diet which limited her consumption of sodium to no more than 1,000 mg per day. Additionally, Jenna was placed on a steroid regimen for the next 3 months. We were instructed to monitor her urine protein levels and to watch for swelling and signs of infection, in order to avoid common complications such as overwhelming infection or blood clots. Because of her disease and its treatment, which requires strong suppression of the immune system, Jenna did have a serious bacterial infection several months after she began treatment.

We are frightened by her doctor's warnings that NS and its treatment are associated with growth retardation and other medical complications including heart disease. As a result of NS, Jenna has developed hypercholesterolemia and we worry about the effects the steroids may have on her bones and development. This is a lot for a little girl in kindergarten to endure.

Jenna's prognosis is currently unknown because NS can reoccur. Even more concerning to us is that Jenna may eventually lose her kidneys entirely and need dialysis or a kidney transplant. While kidney transplantation might sound like a cure, in the case of FSGS, the disease commonly reappears after transplantation. And even with a transplant, end stage renal disease caused by FSGS dramatically shortens one's life span.

The NephCure Foundation has been very helpful to my family. They have provided us with educational information about NS, Minimal Change Disease, and FSGS and the organization works to provide grant funding to scientists for research into the cause and cure of NS.

Mr. Chairman, because the causes of Nephrotic Syndrome are poorly understood, and because we have a great deal to learn in order to be able to effectively treat NS, I am asking you to please significantly increase funding for the National Institutes of Health so that treatments can be found for other people like Jenna who suffer from NS. Also, please support the establishment of a collaborative research network that would allow scientists to create a pediatric patient registry and biobank for NS/FSGS, and that would allow coordinated studies of these deadly diseases for the first time. Finally, please urge the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) to continue to focus on FSGS/NS research in general, consistent with the recent program announcement entitled Grants for Basic Research in Glomerular Disease (R01) (PA-07-367).

Mr. Chairman, on behalf of the thousands of people suffering from NS and FSGS and the NephCure Foundation, thank you for this chance to speak before the Subcommittee and for your consideration of my request; Thank you.

#### MORE RESEARCH IS NEEDED

We are no closer to finding the cause or the cure of FSGS. Scientists tell us that much more research needs to be done on the basic science behind the disease.

NFC would also like to see the Office of Rare Disease (ORD) to establish a FSGS Clinical Research Network within the Rare Disease Clinical Research Consortia. The development of a Clinical Research Network would allow for further collaboration between researchers and an expansion of the clinical understanding and treatment of FSGS.

NCF is also grateful to the NIDDK for issuing of a program announcement (PAs) that serve to initiate grant proposals on glomerular disease. The PA, issued in March of 2006, is glomerular-disease specific. The announcement will utilize the R01 mechanism to award researchers funding.

We ask the Committee to encourage the ORD to establish a FSGS Clinical Research Network to expand FSGS research. We also ask the NIDDK to continue to issue glomerular disease program announcements.

## TOO LITTLE EDUCATION ABOUT A GROWING PROBLEM

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.

We also applaud the work of the NIDDK in establishing the National Kidney Disease Education Program (NKDEP), and we seek your support in urging the NIDDK to make sure that glomerular disease remains a focus of the NKDEP.

We ask the Committee to encourage the NIDDK to have glomerular disease receive high visibility in its education and outreach efforts, and to continue these efforts in conjunction with the NephCure Foundation's work. These efforts should be targeted towards both physicians and patients.

## GLOMERULAR DISEASE STRIKES MINORITY POPULATIONS

Nephrologists tell us that glomerular disease strikes a disproportionate number of African-Americans. No one knows why this is, but some studies have suggested that a genetic sensitivity to sodium may be partly responsible. DNA studies of African Americans who suffer from FSGS may lead to insights that would benefit the thousands of African Americans who suffer from kidney disease.

I ask that the NIH pay special attention to why this disease affects African-Americans to such a large degree. The NephCure Foundation wishes to work with the NIDDK and the National Center for Minority Health and Health Disparities (NCMHD) to encourage the creation of programs to study the high incidence of glomerular disease within the African American population.

There is also evidence to suggest that the incidence of glomerular disease is higher among Hispanic Americans than in the general population. An article in the February 2006 edition of the NIDDK publication *Recent Advances and Emerging Opportunities*, discussed the case of Frankie Cervantes, a 6 year old boy of Mexican and Panamanian descent. Frankie has FSGS received a transplanted kidney from his mother. We applaud the NIDDK for highlighting FSGS in their publication, and for translating the article about Frankie into both English and Spanish. Only through similar efforts at cross-cultural education can the African-American and Hispanic-American communities learn more about glomerular disease.

We ask the Committee to join with us in urging the NIDDK and the National Center for Minority Health and Health Disparities (NCMHD) to collaborate on research that studies the incidence and cause of this disease among minority populations. We also ask that the NIDDK and the NCMHD undertake culturally appropriate efforts aimed at educating minority populations about glomerular disease.

## PATIENT REGISTRY AND BIOBANK

Experts currently believe glomerular disease is increasing in frequency and it is often misdiagnosed or undetected and, as a result, is often unreported. Since many cases of glomerular disease are unreported, it is difficult to ascertain different aspects of the disease and to form more comprehensive data sets on the patient population.

It is also possible that the development of a biobank would be beneficial in understanding the genetic components of glomerular disease and their corresponding interactions with environmental factors.

We ask the Committee to support funding for the first-ever national database/registry for FSGS within NIDDK. Experts say that the incidence of FSGS is increasing and that the disease is often misdiagnosed, undetected or unrecorded. While databases and registries have helped defeat other diseases, one does not exist for FSGS. We also ask the Committee support the development of a biobank as a further means of understanding the causes of FSGS, both genetic and environmental.

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PREPARED STATEMENT OF THE NEUROFIBROMATOSIS, INC., NORTHEAST AND TEXAS  
NEUROFIBROMATOSIS FOUNDATION

## NATIONAL INSTITUTES OF HEALTH

Thank you for the opportunity to present 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 cancer, learning disabilities, heart disease, memory loss, brain tumors, and other disorders affecting

up to 175 million Americans in this generation alone. 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.

On behalf of Neurofibromatosis, Inc., Northeast and the Texas Neurofibromatosis Foundation, both participants in a national coalition of NF advocacy groups, we speak on behalf of the 100,000 Americans who suffer from NF as well as approximately 175 million Americans who suffer from diseases linked to NF such as cancer, brain tumors, heart disease, memory loss and learning disabilities.

#### 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/or 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 three times more common than Multiple Sclerosis (MS) and Cystic Fibrosis combined, but is not widely known because it has been poorly diagnosed for many years. Approximately 100,000 Americans have NF, and it appears in approximately one in every 3,000 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 two types of NF: NF1, which is more common, and NF2, which primarily involves tumors causing deafness and balance problems. In addition, advances in NF research stand to benefit over 175 million Americans in this generation alone because NF, the most common neurological disorder caused by a single gene, is directly linked to many of the most common diseases affecting the general population.

If a child was diagnosed with NF it would mean tumors could grow anytime, anywhere on his/her nervous system, from the day he/she was born until the day he/she died with no way to predict when or how severely the tumors would 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 would then have a 50 percent chance to pass the gene to his/her children. That's 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.

*Cancer.*—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 affected 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. Leading researchers have already rescued learning deficits in both mice and fruit flies with NF1 with a number of drugs, and clinical trials have now been approved



by the FDA. This NF research 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.

*Autism.*—While there is no firm scientific evidence at this point, some published studies have shown, and leading researchers have stated, that there is reason to believe there is an implication between NF and Autism.

#### 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;
- Creation of a National Clinical Trials Consortia 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;
- Linking NF to vascular disorders such as congenital heart disease and hypertension, affecting more than 50 million Americans; and
- Conducting natural history studies to analyze the progression of the disease.

#### FUTURE DIRECTIONS

NF research has now advanced to the translational and clinical stages which hold incredible promise for NF patients, as well as for patients who suffer from many of the diseases linked to NF. This research is costly and will require an increased commitment on the federal level. Specifically, future investment in the following areas would continue to advance research on NF:

- Clinical trials;
- Funding of a clinical trials network to connect patients with experimental therapies;
- DNA Analysis of NF tissues;
- Development of NF Centers, tissue banks, and patient registries;
- Development of new drug and genetic therapies;
- Further development of advanced animal models;
- Expansion of biochemical research on the functions of the NF gene and discovery of new targets for drug therapy; and
- Natural history studies and identification of modifier genes—studies are already underway to provide a baseline for testing potential therapies and differentiate among different phenotypes of NF.

#### CONGRESSIONAL SUPPORT FOR NF RESEARCH

The enormous promise of NF research—and its potential to benefit over 175 million Americans in this generation alone—has gained increased recognition from Congress and the NIH. This is evidenced by the fact that six institutes at NIH are currently supporting NF research (NCI, NHLBI, NINDS, NIDCD, NHGRI, AND NCRR), and NIH's total research portfolio has increased from \$3 million in fiscal year 1990 to \$15 million in fiscal year 2008. However, we are concerned that the NF research portfolio at NIH has declined by several million dollars in recent years (fiscal year 2005 \$17.5 million, fiscal year 2006 \$16 million, fiscal year 2007 \$15.8 million, fiscal year 2008 \$15.4 million), despite appropriations report language recommending a greater investment. Given the potential offered by NF research for progress against a range of diseases, we are hopeful that NIH will substantially increase NF research funding.

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 again for the opportunity to tell you of the progress and potential of NF research.

PREPARED STATEMENT OF THE NEW ENGLAND ANTI-VIVISECTION SOCIETY PROJECT  
R&R: RELEASE AND RESTITUTION FOR CHIMPANZEES IN U.S. LABORATORIES

NEAVS/Project R&R requests that no Federal funding be appropriated for:

- breeding of chimpanzees or other great apes for research
- transfer of federally-owned chimpanzees to private ownership
- housing/maintenance/endowments for federally-owned chimpanzees in private facilities
- maintenance of surplus chimpanzees except in retirement in sanctuary
- research involving the use of chimpanzees

NEAVS/Project R&R requests that Federal funding be appropriated for:

- transfer of federally-owned chimpanzees into sanctuary
- housing/maintenance grants for federally-owned chimpanzees in sanctuary
- retirement of all “surplus” chimpanzees now held in laboratories
- reallocation of funding for chimpanzee research into funding non-animal research methods

SUBSTANTIATING INFORMATION

1. The National Center for Research Resources (NCRR) announced a permanent end to funding for the breeding of federally-owned and supported chimpanzees (including funding NIH projects requiring chimpanzee breeding). This NCRR decision recognizes the exorbitant costs of lifetime care of chimpanzees in laboratory settings and its consequent drain to limited and precious research dollars. No other Federal agency should threaten this fiscally, ethically, and scientifically sound NCRR decision by providing funding for breeding of federally-owned chimpanzees. To do so would perpetuate an animal model that has been of limited or no value, especially in relation to the costs they require for their care and maintenance. Chimpanzees live for decades and 71 percent of the American public, according to an independent public opinion survey, believe those in labs for 10 or more years should be retired. A current estimate of the U.S. population puts that figure at approximately 93 percent of the chimpanzees now held in labs.

2. The government is currently spending close to \$10 million each year to care for approximately 600 federally-owned or supported chimpanzees (nearly \$1.0 million per chimpanzee’s lifetime). Breeding perpetuates this fiscal burden on the Government. Further, grants to private companies, like Charles River Laboratory’s (CRL) Federal \$43 million 10 year grant could have gone further, covered more chimpanzees, and provided superior care had it been appropriated for sanctuary care and not the laboratory care provided by CRL at Alamogordo. This funding is an example of Federal subsidizing of private profits, not an example of sound research dollar priorities.

3. The United States is still managing the “surplus of chimpanzees” previously bred to be available to HIV research. Today their use in HIV/AIDS research has diminished to the point of hardly existent. They proved to be a poor, even dangerous model in not only AIDS research but in every area of major “killer diseases” for humans, including cancer, heart disease, stroke, etc. (An Assessment of the Role of Chimpanzees in AIDS Vaccine Research, Jarrod Bailey, Ph.D., 2008)

4. Studies have indicated that the majority of chimpanzee research published (in addition to research not accepted for publication) is never later cited in studies to do with human prophylactic, diagnostic, or therapeutic methods. This indicates that in general, the chimpanzee model has made limited contributions to human health and in many cases has actually led to dangerously erroneous applications to humans. (Chimpanzee Research: An Examination of Its Contribution to Biomedical Knowledge and Efficacy in Combating Human Diseases, Jarrod Bailey, Ph.D. and Jonathan Balcombe, Ph.D., 2007)

5. The transfer of government-owned and supported chimpanzees into private facilities with accompanying Federal endowments would perpetuate their financial burden on taxpayers, and only private facilities would profit from such an arrangement. The lifetime support of federally-owned chimpanzees is required by the CHIMP Act. The government can provide this care more efficiently and effectively through maintaining ownership and transferring all government-owned chimpanzees into the federally supported sanctuary system or private sanctuary that meets those standards. The government can share the cost of their lifetime care with private donations from the public, who would be assured that the chimpanzees are no longer available for research. Private laboratories interested in “maintaining” a chimpanzee population are a fiscally inefficient solution for the government. Such facilities do not provide the quality care that sanctuaries can provide. The private warehousing and/or lifetime use of chimpanzees in private research—supported with government taxpayer dollars—will lead to public outcry.

6. If private industry receives Federal support for breeding and using government owned, once owned or government endowed chimpanzees for their own private research, then private industry would be unfairly, and perhaps illegally, benefiting from federally-owned “resources” meant for the betterment of the American public, not for the profit of private industry.

7. To date, the private sector has not been fiscally responsible for the lifetime care of chimpanzees once their use to them for private profit is over. When their chimpanzees are retired, the private sector has not, to date, offered financial compensation for their chimpanzees’ lifetime care. Instead, on the few occasions where the chimpanzees were sent to sanctuary with some funding, the financial compensation falls far short of what is actually needed, leaving the burden of responsibility on the private facilities and their public donors.

8. If the Government: transfers all approximately 600 federally-owned chimpanzees to the national sanctuary system or to private sanctuary that meets or exceeds these standards; appropriates to those sanctuaries the funding currently being given to chimpanzee laboratories; and, prohibits breeding, there is an end to the financial burden that this misused and underproductive animal model has caused the government. The Government needs a solution, and the funding priority suggestions set forth herein would offer a major step toward such a solution.

9. Transferring all federally-owned chimpanzees to sanctuary will: (a) consolidate and decrease costs; (b) provide better care; and, (c) offer the public the humane solution they are asking for.

10. Scientific justification for maintaining the exorbitant costs associated with such a physically strong, intellectual curious, socially and emotionally complex species as a chimpanzee does not exist. A 2007 article, “The Endangered Lab Chimp” in *Science*, noted that “a huge number” of chimpanzees are not being used in active research protocols and are therefore “just sitting there.” If breeding ends and current mortality rates continue (as they are expected given the aging population of chimpanzees in U.S. labs), the government will have no—or a bare minimal—financial responsibility for the chimpanzees it owns within 20–30 years. No Federal funding for breeding will ensure that no breeding of federally-owned or supported chimpanzees for research will occur in fiscal year 2009 and be a major step to ending the government’s non-productive, high cost involvement in chimpanzee research. As years of a voluntary breeding moratorium showed, private industry is not willing to breed without government support. It understands the costs and refuses to adequately provide for the lifetime care of chimpanzees it already owns. If the use of chimpanzees was lucrative or necessary, then the private industry’s dollars and practices would reflect that. However, it is not. The Federal Government needs to follow suit in such “wise business” decisions.

11. The American and world (great ape research is banned or severely limited in eight scientifically advanced nations and a European Union wide ban is expected to pass soon) public are deeply concerned about the use of chimpanzees in research. Their close emotional, cognitive, and social similarities to humans have put them in a unique category of interspecies ethics. This moral reality has been acknowledged by the government (requirements for their care in the CHIMP Act that apply to no other animal species used in research) and scientists (several private laboratories that used chimpanzees have closed or stop using them), and the American public are clearly concerned about these issues. As the voice of the American public, our administrative offices should consider that: 90 percent of Americans believe it is unacceptable to confine chimpanzees individually in government-approved cages; 71 percent believe that chimpanzees who have been in the laboratory for over 10 years should be retired to sanctuary; 54 percent believe that it is unacceptable for chimpanzees to “undergo research which causes them to suffer for human benefit”; and, twice as many Americans support an outright ban on chimpanzee research as do those who oppose such a ban.

12. Therefore, we respectfully request the following committee report language: “The Committee directs that funds provided in this act not be used: to support the breeding of chimpanzees or other great apes for research; to support research that requires breeding of chimpanzees; to support the transfer of ownership of federally-owned chimpanzees to private entities (including endowments for their maintenance); to maintain surplus chimpanzees except in retirement in sanctuary; or to fund new research involving the use of chimpanzees.

The Committee directs that funds provided in this Act be used: to transfer federally-owned chimpanzees into sanctuary; to house and maintain federally-owned chimpanzees in sanctuary; to retire all “surplus” chimpanzees now held in laboratories; and to reallocate funding from chimpanzee research into non-animal research methods.”

## 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 2009 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.

This year more than 1,437,180 million Americans will be diagnosed with cancer, and more than 565,650 will lose their battle with this terrible disease. Overall, age is the number one risk factor for developing cancer. Approximately 77 percent of all cancers are diagnosed at age 55 and older.<sup>1</sup> 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 adverse impact in oncology physician 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. The Society 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 2009 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 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 will drop precipitously 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 health care, 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.<sup>2</sup> 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.

Further, 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

<sup>1</sup> American Cancer Society. *Cancer Facts and Figures 2008*. Atlanta: American Cancer Society: 2008.

<sup>2</sup> 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.

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 has joined with others in the nursing community in advocating \$200 million as the fiscal year 2009 funding level necessary to support implementation of the Nurse Reinvestment Act and the range of nursing workforce development programs housed at the U.S. Health Resources and Services Administration (HRSA). Enacted in 2002, the Nurse Reinvestment Act (Public Law 107-205) included new and expanded initiatives, including loan forgiveness, scholarships, career ladder opportunities, and public service announcements to advance nursing as a career. Despite the enactment of this critical measure, HRSA fails to have the resources necessary to meet the current and growing demands for our Nation's nursing workforce. For example, in fiscal year 2006 HRSA received 4,222 applications for the Nurse Education Loan Repayment Program, but only had the funds to award 615 of those applications.<sup>3</sup> Also, in fiscal year 2007 HRSA received 6,611 applications for the Nursing Scholarship Program, but only had funding to support 220 awards.<sup>4</sup>

While a number of years ago one of the biggest factors associated with the shortage was a lack of interested and qualified applicants, due to the efforts of the nursing community and other interested stakeholders, the number of applicants is growing. As such, now one of the greatest factors contributing to the shortage is that nursing programs are turning away qualified applicants to entry-level baccalaureate programs, due to a shortage of nursing faculty. According to the American Association of Colleges of Nursing (AACN), U.S. nursing schools turned away 42,866 qualified applicants from baccalaureate and graduate nursing programs in 2006, due to insufficient number of faculty.<sup>5</sup> The nurse faculty shortage is only expected to worsen with time, as half of the RN workforce is expected to reach retirement age with in the next 10 to 15 years.<sup>6</sup> At the same time, significant numbers of faculty are expected to retire in the coming years, with insufficient numbers of candidates in the pipeline to take their places. If funded sufficiently, the components and programs of the Nurse Reinvestment Act will help address the multiple factors contributing to the nursing shortage.

The nursing community opposes the President's fiscal year 2009 budget proposal that decreases nursing workforce funding by \$46 million—a cut which eliminates all funding for advanced nursing education programs. With additional funding in fiscal year 2009, these important programs will have much-needed resources to address the multiple factors contributing to the nationwide nursing shortage, including the shortage of faculty—a principal factor contributing to the current 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 a minimum of \$200 million in fiscal year 2009 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 non-profit organization comprised of 26 national organizations, is also advocating \$200 million for the Nurse Reinvestment Act in fiscal year 2009. 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 broad-

<sup>3</sup>U.S. Health Resources and Services Administration: Nurse Education Loan Repayment Program: <http://bhpr.hrsa.gov/nursing/loanrepay.htm>.

<sup>4</sup>U.S. Health Resources and Services Administration: Nursing Scholarship Program Statistics: <http://bhpr.hrsa.gov/nursing/scholarship/>.

<sup>5</sup>American Association of Colleges of Nursing, "2006–2007 Enrollment and Graduations in Baccalaureate and Graduate Programs in Nursing." <http://www.aacn.nche.edu/IDS/datarep.htm>, March 2007.

<sup>6</sup>Preliminary Results: "National Survey of Nurse Educators: Compensation, Workload, and Teaching Practices." National League of Nursing/Carnegie Foundation. (February 7, 2007) [http://www.nln.org/newsreleases/pres\\_budget2007.htm](http://www.nln.org/newsreleases/pres_budget2007.htm).

er health community in advocating a 6.6 percent increase (\$31.1 billion) for NIH in fiscal year 2009. This will allow NIH to sustain and build on its research progress, resulting from the recent doubling of its budget, while avoiding the severe disruption to that progress that would result from a minimal increase. Cancer research is producing extraordinary breakthroughs—leading to new therapies that translate into longer survival and improved quality of life for cancer patients. 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 \$5.26 billion to the National Cancer Institute (NCI) in fiscal year 2009 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 health care 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 in advocating a fiscal year 2009 allocation of \$150 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.<sup>7</sup> 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 2009 funding levels for the following CDC programs:

- \$250 million for the National Breast and Cervical Cancer Early Detection Program;
- \$65 million for the National Cancer Registries Program;
- \$25 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 Ovarian Cancer Control Initiative;
- \$5.5 million for the Geraldine Ferraro Blood Cancer Program;
- \$145 million for the National Tobacco Control Program; and
- \$65 million for the Nutrition, Physical Activity, and Obesity Program.

#### CONCLUSION

ONS maintains a strong commitment to working with Members of Congress, other nursing societies, 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 2009 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.

<sup>7</sup> American Cancer Society.

## PREPARED STATEMENT OF THE OVARIAN CANCER NATIONAL ALLIANCE

On behalf of the Ovarian Cancer National Alliance (the Alliance), thank you for this opportunity to submit comments for the record regarding the Alliance's fiscal year 2009 funding recommendations. We believe these recommendations are critical to ensure advances to help reduce and prevent suffering from ovarian cancer. For 11 years, the Alliance has worked to increase awareness of ovarian cancer and advocated for additional federal resources to support research that would lead to more effective diagnostics and treatments.

As an umbrella organization with 45 State and local organizations, the Alliance unites the efforts of survivors, grassroots activists, women's health advocates and health care professionals to bring national attention to ovarian cancer. Our sole mission is to conquer ovarian cancer.

According to the American Cancer Society, in 2008, more than 22,000 American women will be diagnosed with ovarian cancer and approximately 15,000 will lose 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 five years. While ovarian cancer has early symptoms, there is no 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.

In addition, 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 problems, 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 2009.

The Alliance also fully supports Congress in taking action on ovarian cancer through its recent passage of Johanna's Law: The Gynecologic Cancer Education and Awareness Act [Public Law 109-475]. The Alliance respectfully requests that Congress provide the remaining \$10 million to implement Johanna's Law in fiscal year 2009.

Further, the Alliance urges Congress to continue funding the Specialized Programs of Research Excellence (SPORs), including the four 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 a 9.5 percent increase to NCI in fiscal year 2009.

## 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.

Prompted by efforts from leaders of the Alliance and championed by Representative Rosa DeLauro—with bipartisan, bicameral support—Congress established the Ovarian Cancer Control Initiative at the CDC in November 1999. 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.

Through the OCCI, the National Comprehensive Cancer Control Program is helping states address issues related to ovarian cancer. The program currently funds efforts in California, Florida, Michigan, New York, Pennsylvania, Texas and West Virginia. These projects are working to develop ovarian cancer health messages for the general public and for health care providers.

*Johanna's Law: The Gynecologic Cancer Education and Awareness Act*

It is critical for women and their health care 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)—they 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. Together, Johanna's Law and the Ovarian Cancer Control Initiative will help increase awareness and understanding of ovarian cancer and work to reduce ovarian cancer morbidity and mortality.

Already, with only a small amount of seed money, the CDC has launched the Inside Knowledge: Get the Facts About Gynecologic Cancer campaign to raise awareness of the five main types of gynecologic cancer: ovarian, cervical, uterine, vaginal and vulvar. Many fact sheets, including the ovarian cancer fact sheet, are already available on the CDC's Web site for download. The CDC plans to develop broadcast advertisements, posters—such as dioramas for bus stops—and other print materials, a comprehensive brochure on gynecologic cancers, and materials aimed at health care providers.

NATIONAL CANCER INSTITUTE

*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 four currently funded Ovarian Cancer SPORes located at the MD Anderson Cancer Center, the Fred Hutchinson Cancer Research Center, the Fox Chase Cancer Center and the Dana Farber/Harvard Cancer Center.

These SPORes 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 SPORes 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. Two recent studies from NCI clinical trials show the impact of intraperitoneal chemotherapy in treating ovarian cancer (when chemotherapy is introduced directly into the woman's abdominal cavity, rather than her bloodstream) and the importance of ultrasound expertise in properly diagnosing the disease.

NCI supports the Gynecology Oncology Group, a more than 50-member collaborative focusing on cancers of the female reproductive system. In 2007 alone, GOG published 23 articles about ovarian cancer.

*A Sustained Commitment to Fund Cancer Research*

When funding stagnates or does not keep pace with inflation, progress in critical research programs is halted or slows significantly. Inadequate funding for the NIH and the NCI means smaller—trickle down—occurs for the lesser-known or less frequently occurring—yet terribly devastating—diseases such as ovarian cancer.

From fiscal year 2005 to fiscal year 2006, NCI funds decreased by only two percent, while the number of ovarian cancer research grants decreased by 20 percent. From fiscal year 2006 to fiscal year 2008, the NCI budget was flat, and the number of ovarian cancer research grants dropped 15 percent in the first year, and look to drop even more significantly for fiscal year 2008.

To ensure adequate funding for all types of cancer, particularly those most deadly and least understood, the Alliance joins the cancer community in asking for a 6.5 percent increase for NIH and a 9.5 percent increase for NCI in fiscal year 2009.

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. Thank you in advance for your support of \$10 million in fiscal year 2009 funding for the CDC’ Ovarian Cancer Control Initiative and \$10 million in fiscal year 2009 funding for Johanna’s Law as well as your continued support of the SPORES program, a 9.5 percent increase for NCI.

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#### PREPARED STATEMENT OF THE PANCREATIC CANCER ACTION NETWORK

Mr. Chairman and members of the subcommittee: My name is Dr. Randy Pausch. I am submitting testimony on behalf of the Pancreatic Cancer Action Network and the thousands of Americans who have suffered from this deadly disease.

In the way of background, I am Professor of Computer Science, Human-Computer Interaction and Design at Carnegie Mellon University. I had the good fortune of being named an NSF Presidential Young Investigator, spending time at Walt Disney’s Imagineering and Electronic Arts, and co-founding the University’s Entertainment Technology Center. That may sound like a boring resume to you, but to a geek like me, it’s nirvana!

My father always advised me that if there is an elephant in the room, introduce it. In September 2006, at the age of 45, I was diagnosed with pancreatic cancer. I have some of the best doctors in the world, but even they couldn’t stop what was happening. Last year I was told that my cancer had spread to my liver and spleen and that I had 3 to 6 months to live. According to the statistics, 75 percent of people diagnosed with pancreatic cancer die within the first year. So, for me, being alive today is a milestone of sorts.

In the academic world it’s become a common practice to invite professors to deliver a “last lecture,” the premise being, what knowledge would you impart to your students if you were delivering your last lecture? Last September I had the opportunity to deliver my last lecture at Carnegie Mellon. I talked about fulfilling childhood dreams, and how we go about enabling the dreams of others. I thought perhaps my testimony today could be a different take on those subjects.

For me and the 37,680 Americans who will be diagnosed with pancreatic cancer this year, the dream is to find a cure or a way to prevent what is the most lethal form of cancer. I say that because only 5 percent survive more than 5 years and the survival rate beyond that is even lower. Pancreatic cancer is truly the deadliest cancer and yet it is also the fourth leading cause of cancer related death. It seems strange to be talking about rankings in this context, but pancreatic cancer kills more people than prostate cancer and is just behind breast cancer. In other words, this is not a “little” disease. It just hasn’t received a lot of attention to date.

The money this subcommittee has invested in cancer research over the years has paid off in so many wonderful ways. The result has been that the death rates associated with many types of cancers have declined.

Not so with pancreatic cancer. In fact, the chances of surviving this unmerciful disease are about the same as they were over 30 years ago. Pancreatic cancer is where breast cancer was in the 1930’s—little understanding of the causes, no early detection, few effective treatments and single digit survival rates. It is not only the fourth leading cause of cancer death in the United States, but the number of people diagnosed with pancreatic cancer and the number of deaths it causes are going up—not down and have been even in the years when overall cancer deaths have decreased.

So how do we enable the dream of living without the threat of pancreatic cancer? How do we reverse the trend that will cause more Americans to suffer pain and anguish, and more families to bear the physical, emotional and financial burden of pancreatic cancer?

I am sure you can guess that the easy answer is, more money. The more accurate answer is, more money that is better targeted.

While I realize that Congress is reluctant to direct how NIH allocates research dollars, I would argue that something is wrong when one of the deadliest types of cancer receives so little attention. You may be surprised to learn that of the \$4.8 billion this Subcommittee appropriated for the National Cancer Institute, less than two percent—or about \$74 million—was spent on pancreatic cancer research. In fact, pancreatic cancer research receives the least amount of NCI funding of any of the top cancer killers. Please see the attached chart of NCI funding for the top five

cancer killers and the survival rates for the same cancers. There is no question that funding levels and survival rates are linked.

Of the more than 5,000 research grants awarded by the National Cancer Institute in 2006, only 134 grants, approximately 3 percent, were focused primarily on pancreatic cancer research.

And of the 160 cancer research centers NCI supports, only three specialize in pancreatic cancer research.

We have heard repeatedly from the brightest scientific minds in the country that pancreatic cancer research is an area that holds great promise—the ideas are there, we just need the funds to pursue them.

I believe that Congress and NIH have a leadership role to play—as you did in the 1970s, when the war on cancer was declared; in the 1980s, when this subcommittee provided the first appropriation to combat HIV/AIDS; at the start of this decade, with the launch of a bioterrorism research initiative and as you have done many times over the years for other cancers.

Ironically, the National Cancer Institute developed a pancreatic cancer research plan back in 2001. The problem is it was never fully implemented. In fact, only 5 of the plan's 39 recommendations were acted upon.

Last year, the Pancreatic Cancer Action Network gathered together the leading experts on this disease, many of whom crafted that original plan, and asked them to update it. What they came up with is a detailed plan called The National Plan to Advance Pancreatic Cancer Research, that:

- calls for a coordinated research initiative to support very specific research objectives, including finding more precise diagnostic methods and more innovative clinical trials testing;
- supports more pancreatic cancer research centers to serve as a staging area for highly targeted research on pancreatic cancer;
- takes the steps necessary to draw more scientists into this particular field of research; and
- promotes greater awareness among physicians and the general public.

The initial cost of implementing this plan would be \$170 million. While I recognize that that seems like a large number, please remember what I said about pancreatic cancer research being stuck in the 1930s. We need to bring it into the 21st Century.

The Pancreatic Cancer Action Network has supplied the subcommittee with a copy of this plan. Many of you may have learned about it from one of the 220 advocates who were here last month for Pancreatic Cancer Action Network's Advocacy Day. I urge you to support the implementation and funding of the National Plan.

I should also point out that we strongly support increasing the overall budget for the NCI. Therefore, we are also joining our partners in the One Voice Against Cancer (OVAC) Coalition in calling for a 9.5 percent increase over fiscal year 2008 levels.

My mother always liked to refer to me as her son, the doctor, but not the type of doctor who helps people. I hope that by being here today, I will help people by shining a spotlight on this disease and urging you to provide necessary research funding for this disease.

I will be glad to answer any questions you have, and thank you for the opportunity to present this testimony.

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#### PREPARED STATEMENT OF THE POPULATION ASSOCIATION OF AMERICA/ASSOCIATION OF POPULATION CENTERS

##### INTRODUCTION

Thank you, Mr. Chairman Harkin, Mr. ranking member Specter, and other distinguished members of the subcommittee, for this opportunity to express support for the National Institutes of Health (NIH), the National Center for Health Statistics (NCHS), and Bureau of Labor Statistics (BLS).

##### 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 30 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. Over 30 population research centers are located nation-

wide, including the University of Wisconsin-Madison, State University New York Albany, Brown University, Ohio State University, University of California at Los Angeles, University of North Carolina-Chapel Hill, and Pennsylvania State University.

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 Eunice Kennedy Shriver 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 Behavioral and Social Research (BSR) program 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 Program, 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. The HRS, now entering its 16th year, has tracked 27,000 people, and has provided 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. The Social Security Administration recognizes and funds the HRS as one of its "Research Partners" and posts the study on its home page to improve its availability to the public and policymakers. 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 recent HRS data indicating an increase in pre-retirees self-reported rates of disability. Next year, the HRS will begin collecting DNA, enhancing the value of this survey as an important source of biosocial data.

With additional support in fiscal year 2008, the NIA BSR program could fully fund its existing centers and support its ongoing surveys without enacting draconian cost cutting measures, such as cutting sample size. Additional support would allow NIA to expand the centers' role in understanding the domestic macroeconomic as well as the global competitiveness impact of population aging. NIA could also use additional resources to support individual investigator awards by precluding an 18 percent cut in competing awards, improving its funding payline, and sustaining training and research opportunities for new investigators.

#### NATIONAL INSTITUTE ON CHILD HEALTH AND HUMAN DEVELOPMENT

Since its establishment in 1968, the 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 Fragile Families and Child Well Being Study and National Longitudinal Study of Adolescent Health.

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.

In 2007, the DBSB issued a revised five-year strategic plan, *Future Directions for the DBSB*. With the help of its expert panel and with input from others inside and outside of the agency, the Branch identified three important research areas—family formation; causes and consequences for population health; and the effects of migration—for focus during the 2007 through 2011 period. In addition to these areas of emphasis, the Branch will continue to develop and support other areas within its portfolio, including research on HIV/AIDS; unintended pregnancy and infertility; race and ethnicity; and population and environment. Although the field is enthusiastic about the opportunities the revised strategic research plan presents, we recognize the Institute needs consistent, sufficient funding to realize its potential.

With additional support in fiscal year 2008, NICHD could restore 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 pipeline. Additional support could be used to preclude cuts of 17 percent to 22 percent in applications approved for funding and to support and stabilize essential training and career development programs necessary to prepare the next generation of researchers.

#### 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, National Health Interview Survey, 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.

The President's fiscal year 2009 budget requests \$125 million in program funds for NCHS. This recommendation represents an increase of \$11 million over fiscal year 2008. Although it may sound generous, this increase is absolutely essential for stabilizing the agency and its key operations. Before Congress increased the agency's budget last year by approximately \$4 million, NCHS had lost \$13 million in purchasing power since fiscal year 2005 due to years of flat funding and inflation. These shortfalls forced the elimination of some data collection and quality control efforts, threatened the collection of vital statistics, stymied the adoption of electronic systems, and limited the agency's ability to modernize surveys to reflect changes in demography, geography, and changes in health delivery.

If Congress fails to, at a minimum, provide the Administration's fiscal year 2009 request, NCHS will be forced to eliminate over-sampling of minority populations in its National Health and Nutrition Examination Survey, which will compromise our understanding of health disparities at a time when our society is becoming increasingly diverse. The agency also needs this funding increase to collect vital statistics from States for the remainder of the calendar year. Without an additional \$3 million, which is included in the President's request, the United States is at risk of becoming the first industrialized Nation unable to continuously collect birth, death, and other vital health information.

#### BUREAU OF LABOR STATISTICS

The Bureau of Labor Statistics (BLS) produces and disseminates valuable economic data used by our members to analyze trends in areas such as unemployment, income, health insurance coverage, and spending. In its fiscal year 2009 submission, the Administration proposed the elimination of an important survey BLS began in 2003, the American Time Use Survey (ATUS).

The ATUS provides the only available information on how Americans use their time. ATUS provides essential information on time use activities, including time spent caring for children, cleaning the house, working for pay, and caring for sick adults. Understanding how the population spends its time, outside of traditional work, is necessary for anyone who wants to understand the changing lives of American families, to monitor the well-being of the American population, to measure national output, productivity and other outcomes that are essential to forming sound economic policies and to making informed social policy decisions.

Although the ATUS is a relatively new survey, it has already proven to be an invaluable component of the statistical infrastructure, giving us unique insights into American society. Moreover, the power of the ATUS has grown as more years of data have accumulated. Every other advanced nation in the world collects time use data. If the ATUS is eliminated, American businesses, families, policymakers and researchers will lose out on critical information that can improve the quality of our lives.

The BLS needs an additional \$6 million in fiscal year 2009 budget to collect ATUS data from the full sample originally planned for the survey and to preserve its other ongoing survey operations with a full sample—most notably, the Current Population Survey.

#### SUMMARY OF FISCAL YEAR 2009 RECOMMENDATIONS

NIH is facing the prospect of another decrease in fiscal year 2009 and another year of funding below the level of inflation. PAA and APC join the Ad Hoc Group for Medical Research in supporting an fiscal year 2009 appropriation of \$31.1 billion, an increase of 6.6 percent over the fiscal year 2008 appropriation, for the NIH. For population research, this increased support is necessary to ensure the best research projects, including new and innovative projects, are being awarded, surveys and databases are supported, and training programs are stabilized. In addition, we urge the Subcommittee to include language in the fiscal year 2009 bill allowing NIH to continue the National Children's Study (NCS) and to appropriate \$192 million for NCS in fiscal year 2009 through the NIH Office of the Director.

PAA and APC, as members of the Friends of NCHS, support a fiscal year 2009 appropriation of \$125 million, an \$11 million increase over the fiscal year 2008 appropriation, for the NCHS. This funding is needed to maintain the Nation's vital statistics system and to sustain and update the agency's major health survey operations.

We also respectively ask the subcommittee to restore funding for the American Time Use Survey by allocating an additional \$6 million for the Bureau of Labor Statistics and by reversing the administration's proposal to end this essential data collection effort.

Thank you for considering our requests and for supporting Federal programs that benefit the field of demographic research.

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#### PREPARED STATEMENT OF THE RAILROAD RETIREMENT BOARD

Mr. Chairman and members of the committee: We are pleased to present the following information to support the Railroad Retirement Board's (RRB) fiscal year 2009 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 fiscal year 2007, the RRB paid \$9.8 billion in retirement/survivor benefits and vested dual benefits to about 616,000 beneficiaries. We also paid \$74.6 million in net unemployment/sickness insurance benefits to about 29,000 claimants.

#### PRESIDENT'S PROPOSED FUNDING FOR AGENCY ADMINISTRATION

The President's proposed budget would provide \$105,463,000 for agency operations in fiscal year 2009, which is about \$4 million less than we originally requested. By comparison, the Consolidated Appropriations Act, 2008 (Public Law 110-161) provided about \$101.9 million for RRB operations in 2008, which includes a rescission of \$1.8 million.

At the President's proposed level of funding, the RRB would be able to maintain a staffing level of 910 full-time equivalent staff years (FTEs) in 2009. This represents a reduction of eight FTEs from our current funded level, and continues a

downward trend which has reduced the RRB's staffing by nearly half since 1993. This downward trend adversely impacts our succession planning efforts as it restricts our ability to replace employees who leave the agency.

The President's proposed budget would provide \$2,370,000 for information technology (IT) investments. Nearly \$1.5 million of this amount will be needed for network operations, emergency equipment replacement, IT tools and task order services. The remaining funds, totaling about \$870,000, would be available for information security improvements, system modernization, and E-Government initiatives. At this budget level we would delay replacement of desktop computing equipment in accordance with the agency's life cycle replacement schedules for the second year in a row. In addition, we would delay development of electronic personnel files, which is part of the Enterprise Human Resources Initiative.

#### AGENCY STAFFING

Like many agencies, the RRB has an aging workforce. Current estimates show that about one in three RRB employees will be eligible for retirement by fiscal year 2009. To prepare for the coming transition in our workforce, we have undertaken major initiatives related to training and succession planning.

In connection with these initiatives, the agency is looking at a variety of critical positions to identify any gaps in particular competencies or skills that exist within the workforce. In some cases, we have provided supplemental developmental and training opportunities to current employees so that the activities associated with these positions will continue effectively as more experienced employees leave the agency. We have also continued hiring to fill essential positions as funding levels permit. In fiscal year 2007, for the first time in many years, the RRB was able to hire entry-level employees for two claims examiner training classes. Given the expected increase in the agency's attrition rate, new employees such as these will be key to the RRB's long-term success in continuing to provide outstanding service to our customers.

Partially in response to recommendations and suggestions made by the Office of Personnel Management, the RRB is also in the process of developing more formalized human capital management and succession planning documents. We have created an internal succession planning task force, chaired by the Director of Human Resources, to provide coordination and consolidation of existing plans, as well as identify new initiatives to address this important area.

#### FIELD SERVICE MODERNIZATION

During fiscal year 2007, we restructured the RRB's field service operations along the lines of a hub-and-satellite configuration, which will enable the agency to maintain customer service by utilizing new technologies more effectively. The hub-and-satellite configuration will support telephone and face-to-face service for our customers, and will allow agency management to more effectively balance and share workloads among the offices in each network. By the end of fiscal year 2008, we will close the RRB's three regional offices and consolidate them into corresponding hub offices.

The field restructuring plan also calls for the possibility of using "virtual offices" and/or "co-located offices." In 2007, the agency began pilot-testing an arrangement to provide customer service through an off-site claims representative. The pilot, which is continuing, is designed to serve as a test environment to determine the kinds of procedures and technologies that would be needed to establish virtual offices in the future.

Work is continuing to build, test and implement technology infrastructure improvements for the field service. The completion of this infrastructure is contingent upon sufficient funding being made available. Ongoing initiatives include, among other things:

—*Toll-Free Telephone Service.*—Nationwide toll-free service is a key component of our field technology plans. In fiscal year 2007, we contracted with Qwest Government Services, Inc. (under the General Services Administration's Network Universal) for development of the RRB's toll-free service. We plan to begin offering the service in 12 pilot offices between April and June 2008, as part of the initial proof-of-concept phase, and to complete overall implementation by December 31, 2008.

—*Expansion of Interactive Voice Response (IVR) Service.*—After the implementation of toll-free telephone service, we also plan to expand the range of services that can be accessed through the IVR system. The IVR system will continue to be accessible to callers through the 800 number, but will also be substantially modified in the future to allow for more interactive transactions and better se-

curity. Initially, it will continue to provide all current services, plus an option for the caller to be able to speak to a field service representative at any time during the call.

—*Additional Internet Self-Service Options.*—By fiscal year 2009, we expect to implement a system that will enable railroad employees to file sickness insurance claims through the Internet. We also plan to provide expanded Internet reporting functions for rail employers.

—*Document Imaging.*—In fiscal year 2007, we conducted a pilot program involving the expansion of our existing document imaging system to four pilot field offices. During fiscal year 2008, we are expanding the use of document imaging to 25 additional offices. The remaining offices are scheduled for implementation during fiscal year 2009.

In March 2007, we also implemented an on-line system to allow our employees to track and record direct customer contacts. This system enhances our ability to handle telephone calls in a more effective manner, regardless of which field office answers the call. We are confident that the strategic use of technology in our telecommunications and other processes is the foundation needed for the most effective and efficient use of agency resources, allowing us to continue to provide the excellent service that our customers have come to expect.

The President's proposed budget includes \$72 million to fund the continuing phase-out of vested dual benefits, plus a 2 percent contingency reserve, \$1,440,000, 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 to the requests noted above, 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 (NRRIT), which was established by the Railroad Retirement and Survivors' Improvement Act of 2001 to manage and invest railroad retirement assets. Through fiscal year 2007, the RRB transferred about \$21.3 billion to the NRRIT for this purpose. During the same period, the NRRIT transferred approximately \$5.0 billion to the Railroad Retirement Account for payment of retirement and survivor benefits. During fiscal year 2007, these transfers totaled \$1.391 billion. As of September 30, 2007, the market value of NRRIT-managed railroad retirement assets was approximately \$32.7 billion.

In June 2007, 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, which reflects changes in benefit and financing provisions under the Railroad Retirement and Survivors' Improvement Act of 2001, addresses the 25-year period 2007–2031 and contains generally favorable information concerning railroad retirement financing. The report includes projections of the status of the retirement trust funds under three employment assumptions. These indicate that, barring a sudden, unanticipated, large decrease in railroad employment or substantial investment losses, the railroad retirement system will experience no cash flow problems throughout the projection period.

*Railroad Unemployment Insurance Account.*—The equity balance of the Railroad Unemployment Insurance Account at the end of fiscal year 2007 was \$100.7 million, an increase of \$3.4 million from the previous year. The RRB's latest annual report on the financial status of the railroad unemployment insurance system was issued in June 2007. The report indicated that even as maximum daily benefit rates rise 49 percent (from \$57 to \$85) from 2006 to 2017, experience-based contribution rates maintain solvency. The average employer contribution rate remains well below the maximum throughout the projection period, but a 1.5 percent surcharge, which is now in effect, is expected for calendar year 2009, and is likely for calendar year 2010. The report did not recommend any financing changes.

In conclusion, we want to stress the RRB's continuing commitment to improving our operations and providing quality service to our beneficiaries. 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 RAILROAD RETIREMENT BOARD

Mr. Chairman and members of the subcommittee: 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 committee for your continued support of the Office of Inspector General.

#### BUDGET REQUEST AND BACKGROUND INFORMATION

I wish to describe our fiscal year 2009 appropriations request and our planned activities. The Office of Inspector General (OIG) respectfully requests funding in the amount of \$7,806,000 to ensure the continuation of its independent oversight of the Railroad Retirement Board (RRB).

The agency's central mission is to pay accurate and timely benefits. During fiscal year 2007, the RRB paid approximately \$9.7 billion in retirement and survivor benefits to 600,000 beneficiaries. RRB also paid \$73 million in net unemployment and sickness insurance benefits to almost 28,000 claimants during the benefit year ending July 30, 2007. The Railroad Medicare Part B carrier, Palmetto GBA, paid approximately \$897 million in medical insurance benefits for more than 496,000 beneficiaries.

During fiscal year 2009, the OIG will perform reviews of significant policy issues and program operational areas. We will coordinate our efforts with agency management to identify and eliminate operational weaknesses. We will also continue our investigation of allegations of fraud, waste and abuse, and refer cases for prosecution and monetary recovery action.

#### NATIONAL RAILROAD RETIREMENT INVESTMENT TRUST

The OIG respectfully requests oversight authority to conduct audits and investigations of the National Railroad Retirement Investment Trust (NRRIT). The sole purpose of the NRRIT is to manage and invest railroad retirement assets in a diversified investment portfolio in the same manner as those of private sector retirement plans. The NRRIT is responsible for the investment of approximately \$32.7 billion in trust funds used to support Railroad Retirement Act benefit programs. We continue to express concerns about the RRB's passive relationship with the NRRIT. Federal oversight of the NRRIT does not include performance audits by an independent auditor such as the OIG, Government Accounting Office or a public accountant. The NRRIT plays a critical role in the financing and future solvency of the RRB program. If oversight authority is granted, my office would work to ensure sufficient reporting mechanisms are in place and that the NRRIT management is fulfilling their fiduciary responsibilities. The program and its public constituency would benefit from an OIG that is permitted to fulfill its statutory role by extending its oversight responsibilities to the NRRIT.

#### MANDATED REIMBURSEMENTS TO THE AGENCY

The OIG is currently required to reimburse the agency for office space, equipment, communications, office supplies, maintenance and other administrative services. We are the only Federal OIG that cannot negotiate a service level agreement with its parent agency. The current mandate has resulted in a burdensome accounting and reconciliation process. Removal of the current language would permit a more efficient and fair negotiation between the RRB and the OIG.

#### OFFICE OF AUDIT

The Office of Audit (OA) conducts financial, performance and compliance audits to ensure the economy, efficiency and effectiveness of RRB programs. The OA efforts are directed primarily to fulfilling the financial audit and information security evaluation requirements mandated by law. As resources permit, audit staff will undertake to perform other audits, evaluations and monitoring activities that will add value to agency operations.

The OA conducts the annual audit of the RRB's financial statements. During fiscal year 2009, the OA will complete the audit of the agency's fiscal year 2008 financial statements and begin the audit of the fiscal year 2009 statements. The annual financial statement audit is conducted using OA staff with technical assistance from actuarial specialists under contract to the OIG. Audit staff will continue to work with agency management to ensure that the necessary detailed, verifiable financial information is available from the NRRIT. This effort includes periodic stand-alone audits that support the office's overall financial audit responsibility.

Audit staff will also conduct the annual evaluation of the RRB's information security pursuant to the requirements of the Federal Information Security Management Act of 2002. This annual effort includes stand-alone audits of controls in various agency systems conducted during the year as well as the additional evaluation work required to respond to certain areas about which the Office of Management and



Budget requires more specific information. The related area of privacy of sensitive and confidential information will remain a concern.

OA will continue to monitor agency actions in response to audit recommendations. As resources permit, the OA will work to identify potentially at-risk areas of agency responsibility, perform risk assessments and plan audits to disclose deficiencies in internal control, compliance with applicable laws and regulations, and fraud vulnerabilities in the benefit programs administered by the RRB.

The OA does not anticipate performance audits of the NRRIT because, as we have previously stated, it is our understanding that the OIG does not have a role in oversight of the NRRIT.

#### 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 sickness, unemployment, disability or retirement benefits. OI also investigates railroad employers and unions when there is an indication that they have submitted false reports to the RRB. RRB Medicare oversight authority was reinstated to the OIG on December 26, 2007. This authority allows the OIG to investigate allegations of fraud, waste and abuse in the RRB Medicare program. Investigative efforts can result in criminal convictions, administrative sanctions, civil penalties and the recovery of program benefit funds.

OI initiates cases based on information from a variety of sources. The agency conducts computer matching of employment and earnings information reported to State governments and RRB benefits paid. Referrals are made to OI if a match is found. OI also receives allegations of fraud through the OIG Hotline, contacts with State, local, and Federal agencies, and information developed through audits conducted by the OIG's Office of Audit.

#### OI'S INVESTIGATIVE RESULTS FOR FISCAL YEAR 2007

Civil Judgments	Indictments/ Informations	Convictions	Recoveries/Collections
25 .....	32	46	\$4,655,049

OI anticipates an ongoing caseload of approximately 450 investigations in fiscal year 2009. During fiscal year 2007, OI opened 297 new cases and closed 295. At present, OI has cases open in 47 States, the District of Columbia and Canada with estimated fraud losses totaling almost \$11 million.

OI will continue to concentrate its resources on cases with the highest fraud losses.

We anticipate that these cases will relate to the RRB's disability, retirement and Medicare programs. These cases involve more complicated schemes and result in the recovery of substantial funds. They also require considerable time and resources such as travel by special agents to conduct sophisticated investigative techniques such as surveillance and witness interviews. These fraud investigations are extremely document-intensive and involve sophisticated financial analysis.

OI will also continue to investigate fraud violations of railroad employees collecting unemployment or sickness insurance benefits while working and receiving wages from an employer. OI will also investigate retirement fraud which typically involves the theft and fraudulent cashing of U.S. Treasury checks or the withdrawal of electronically deposited RRB benefits. OI will also use the Department of Justice's Affirmative Civil Enforcement Program to recover trust fund monies from cases that do not meet U.S. Attorney's guidelines for criminal prosecution.

OI will also investigate complaints involving administrative irregularities and any alleged misconduct by agency employees.

In fiscal year 2009, 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. Findings will be conveyed to agency management through OIG systemic implication reports to alert officials of operational weaknesses that may result in fraud against RRB programs. OI will also continue to work with RRB program managers to ensure the appropriate and timely referral of all fraud matters to the OIG.

## SUMMARY

In fiscal year 2009, the OIG will continue to focus resources on reviewing RRB program operations and ensuring the integrity of agency trust funds by aggressively pursuing individuals who engage in activities to fraudulently receive RRB funds. OIG will continue to keep the Subcommittee and other members of Congress informed of any agency operational problems or deficiencies. 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.

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PREPARED STATEMENT OF REACHING FOR THE STARS. A FOUNDATION OF HOPE FOR CHILDREN WITH CEREBRAL PALSY

Mr. Chairman and Members of the Committee: Thank you for allowing us to speak to you today on behalf of the more than 800,000 Americans with Cerebral Palsy, and their families. We are Cynthia Gray and Anna Marie Champion, mothers of children with cerebral palsy and Co-Founders of "Reaching for the Stars. A Foundation of Hope for Children With Cerebral Palsy," the only national nonprofit pediatric cerebral palsy foundation in the United States. And I am Dr. Janice Brunstrom, Medical Advisor to "Reaching for the Stars" and pediatric neurologist. Together with the thousands of parents across the country affiliated with Reaching for the Stars we ask you to help us change the course of the future for children, adolescents and adults with Cerebral Palsy from one of uncertainty to one of hope.

With your help of \$10 million to the CDC they will be able to establish a national CP surveillance and epidemiological research program that will provide crucial insights into this group of disorders, yield improved treatments, help prevent secondary complications and bolster additional research efforts so that we may someday prevent and even cure Cerebral Palsy.

## DR. JANICE BRUNSTROM

My expertise in Cerebral Palsy is both professional and personal. I am a pediatric neurologist, an Assistant Professor of Neurology, Pediatrics and Cell Biology and Director of the Pediatric Neurology Cerebral Palsy Center at Washington University School of Medicine and St. Louis Children's Hospital. Our CP Center enrolled its first patient on June 1, 1998 and now helps an estimated 2,000 children from across the United States and around the world to become more independent and productive members of society and to participate fully in all aspects of life. I am an NIH funded neuroscientist investigating mechanisms of prenatal brain development. I am a clinical research scientist developing and testing new treatment strategies for children with Cerebral Palsy. I am a mother and I am a woman with Cerebral Palsy. My Cerebral Palsy is due to complications associated with prematurity and low birth weight. I was born 3 months prematurely (29 weeks gestation) weighing about 3 pounds. Forty-five years ago my parents were told I would not survive. The experts also predicted I would never walk or talk and that I would have mental retardation. Thankfully the experts were wrong.

Unfortunately in the over four decades since my birth, treatments for Cerebral Palsy have not progressed much at all. In fact, today, there remains little consensus among medical professionals regarding what causes CP or how best to treat it. There is no cure. Why does one premature baby develop CP and another doesn't? Why do I see many cases of twins (including genetically identical twins) where one has CP and one doesn't? Or each twin has a different type of CP, despite being exposed to the exact same conditions in utero? Why do more than 800,000 Americans have CP, and yet we don't know much more about what causes it or how to prevent it than we did the day I was born?

## ANNA MARIE CHAMPION AND CYNTHIA GRAY

Like Dr. Brunstrom, our young daughters, Cathryn and Morgan were born prematurely and have Cerebral Palsy, but we aren't sure why Cathryn has CP or why Morgan has CP but her twin, Katelyn does not. After an exhausting roller-coaster of searching for answers and help for our children and finding there was little research to go on, we launched RFTS, Inc. in late 2004 to fill an important void that existed nationally for a parent-led voice of children with cerebral palsy focusing on advocacy, research and education. We now represent over 10,000 parents nationally across the United States.

There are several facts about CP that are worth noting.

Cerebral Palsy is one of the most common developmental disabilities in the United States, affecting at least 800,000 children, adolescents and adults in America. Cerebral Palsy is not a disease. It is not even a simple or single disorder but rather a broad range of disorders that disrupt a person's ability to move, sit, stand, walk, talk and use their hands. The severity of the movement disorder and the type of movement difficulties can vary greatly. Some patients have only mild difficulties with balance, walking and fine motor skills while patients at the other extreme are completely trapped in their own bodies, fighting rigid limbs, and unable to speak or swallow.

Cerebral Palsy is increasing in this country. Despite the introductions of modern prenatal testing, improved obstetric care, and newborn intensive care technologies, the prevalence of Cerebral Palsy is not declining, and appears to be increasing in many parts of the country.

Although the national prevalence of Cerebral Palsy is not known, recent estimates from CDC studies indicate that its prevalence is now as high as 3.6 per 1,000 live births (and even higher in certain segments of the population) equating to approximately 1 in 277 8 year-old U.S. children—a marked increase over previous prevalence data. In contrast, the prevalence of CP is significantly lower, and is declining, in other countries such as Sweden (1.9 per 1,000) according to the CDC.

And 75 percent of individuals with Cerebral Palsy also have one or more additional developmental disabilities including epilepsy, mental retardation, autism and visual impairments or blindness.

In over 80 percent of Cerebral Palsy cases is still unknown. Cerebral Palsy results from an injury to the brain during development and this injury can occur during pregnancy, around the time of birth or anytime within the first 2 years of life. Contrary to popular belief, only a small percentage of Cerebral Palsy is caused by birth "asphyxia" or a lack of oxygen at the time of birth.

There is currently no cure for Cerebral Palsy and in most cases, it is not preventable. In over 50 years, treatments for Cerebral Palsy have not progressed much at all. In fact, today, there remains little consensus among medical professionals regarding what causes CP or how best to treat it. With nearly 800,000 or more Americans with CP, we do not know much more about the root causes or how to prevent them than we did a half century ago.

As parents with young children we can tell you that living with Cerebral Palsy is expensive. The economic impact of Cerebral Palsy is enormous: Most children and adults with Cerebral Palsy need long-term services or medical care. The average lifetime cost for just one person with Cerebral Palsy is estimated to be well over \$1,500,000 above and beyond the cost of living for an average U.S. citizen—including doctor visits, therapy, surgeries, prescriptions, hospital stays, durable medical equipment, prescription drugs, orthotic equipment, education/home/car modifications, and so on. A family's personal resources and private insurance shoulder a portion of the burden when possible, however federal and state governments in the form of Medicaid and other social services currently absorb much of this cost.

It is estimated that the lifetime care and medical costs for all Americans with CP who were born in 2000 alone will total over \$13.5 billion. Investigating the cause of Cerebral Palsy will significantly reduce the cost—to society, the government and to the hundreds of thousands of families impacted across the United States—as ways to prevent CP are uncovered.

Cerebral Palsy research is severely under-funded. Mr. Chairman, we would be remiss if we did not thank you and the Subcommittee and your staff for your leadership in supporting the CDC's efforts regarding birth defects and developmental disabilities, which has included local surveillance in Atlanta, Alabama and Wisconsin for Cerebral Palsy. We also thank the committee for your ongoing support of the NIH, especially research to understand brain development and injury.

We are here to ask for some additional help from this subcommittee. There is currently no national surveillance for Cerebral Palsy. However, we believe that by using existing infrastructure at the Centers for Disease Control and Prevention (CDC) we can address the causes and cures for CP.

Reaching for the Stars supports national CP surveillance and epidemiological research in order to better understand how to prevent and identify causes of damage to the developing brain. In late 2004, a national group of committed parents and family members of children with Cerebral Palsy, concerned that virtually no progress has been made to treat or cure CP in the last 50 years, organized to form "Reaching for the Stars. A Foundation of Hope for Children with Cerebral Palsy".

It has been our goal to increase advocacy about the issue of Cerebral Palsy and raise national awareness. In fact, many national organizations have written letters stating their support for the need for the national CP surveillance and epidemiological research. The United Cerebral Palsy Education and Research Foundation, The

Child Neurology Society and the American Academy of Cerebral Palsy and Developmental Medicine all support our efforts.

That is why today we ask Congress to allocate \$10 million in Federal funding for the Centers for Disease Control and Prevention to conduct epidemiology research and surveillance for Cerebral Palsy nationwide. We believe a cure can be found for Cerebral Palsy by understanding the risk factors for CP, what causes CP, at-risk ethnic groups and why different clusters of prevalence and types of CP in different parts of the country exist.

We want a cure for Cerebral Palsy. The only way this will happen is to better understand the risk factors for CP, what causes CP, if certain ethnic groups are more susceptible and why there are different clusters of prevalence and types of CP in different parts of the country and world. The only way to begin to answer these questions is through national CDC surveillance.

Basic national surveillance and epidemiological research by the CDC will bolster basic science research efforts through the NIH, and assist scientists and the medical community to develop more effective strategies for the prevention and treatment of CP—much like the remarkable progress that has been made with Autism, Spina Bifida, Epilepsy and Cystic Fibrosis.

Cerebral Palsy is a complex problem leaving many feeling overwhelmed and hopeless. There is so much that needs to be done and so many children that need help. But it doesn't need to be hopeless.

Children with CP are learning to dream big dreams for their future and some aspire to become doctors, teachers, parents and even Congressional leaders. Physicians treating children with CP will tell you that the first step in helping them is to change their perception about themselves and to teach them to stop listening to "can't" and "never" and to start saying "I'll try."

We believe we can change the future for these children if we all work together and do our part. We believe we can cure these disorders someday.

On behalf of the over 800,000 impacted children and families across the country, we are asking for your support to ensure the CDC establishes a national Cerebral Palsy Surveillance Program to change the future for children and adults with Cerebral Palsy.

Mr. Chairman and members of the subcommittee, we thank you so very much for the opportunity to speak to you today and for your time and attention to this urgent matter.

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#### PREPARED STATEMENT OF THE REFUGEE COUNCIL USA

Chairman Harkin, ranking member Specter, and the members of the subcommittee: On behalf of Refugee Council USA (RCUSA), a coalition of 23 non-governmental organizations committed to refugee protection, assistance, and resettlement, I am pleased to submit this statement regarding fiscal year 2009 funding needs for the Department of Health and Human Services' Office of Refugee Resettlement (ORR). ORR, in funding the domestic assistance program for refugees once they have been resettled through the State Department's reception and placement program, is indispensable in providing the United States a viable and vital resettlement program.

RCUSA recommends a fiscal year 2009 appropriation of at least \$983 million for ORR in order to resettle a recommended 100,000 refugees and help address ORR's ever-expanding mandate. In addition to providing services to resettled refugees, ORR will also assist Iraqi special immigrants who helped the United States during the conflict in Iraq (approximately 11,250 individuals), Cuban/Haitian entrants (approximately 20,000 people), and persons granted asylum in the United States (approximately 25,000). Accordingly, the total number of individuals being served by this amount would be 156,250.

If appropriated, these funds would also address necessary increases in resettlement services and programs for survivors of torture and human trafficking. RCUSA's recommendation for ORR would allow \$20 million for human trafficking programs and \$20 million for programs under the Torture Victims Relief Act. We also understand that ORR's responsibility for unaccompanied alien children will require at least \$150 million in fiscal year 2009.

Refugee Council USA recommends a total of \$983 million for refugee resettlement services which have traditionally included the below line items.

##### A. RESETTLEMENT SERVICES

RCUSA recommends an allocation of \$793 million for ORR's resettlement services for fiscal year 2009. A significant portion of this funding is necessitated by Congress'

decision to increase the admission of special immigrants from Iraq and to provide refugee-like services to them.<sup>1</sup>

ORR resettlement services include the following four line items:

1. *Transitional and Medical Services (TAMS)*.—ORR reimburses States for transitional cash and medical assistance to refugees for up to 8 months after their arrival in the United States. To be eligible for such assistance, refugees must participate in employment services aimed at ensuring self-sufficiency in the shortest amount of time possible. RCUSA recommends an allocation of \$500 million for ORR's Transitional and Medical Services for fiscal year 2009.

(a) Early Employment and Self Sufficiency: ORR utilizes a program, known as the Matching Grant Program, which matches federal dollars with private sector contributions of cash, goods, and volunteers. Together, these funds help newly arriving refugees become self-sufficient without entering the welfare system. This Match Grant program provides short-term cash assistance, intensive job development, employment services, and case management, and was nominated last year by ORR as a flagship program and a model for alternatives to welfare aimed at early self sufficiency through employment. This program regularly leverages \$1 of private resources for every \$2 of Federal funding for refugee self sufficiency, and, unlike other Federal programs, serves trafficking victims, asylum seekers, and Cuban/Haitian entrants in addition to refugees. In order to serve 75,000 refugees, Iraqi special immigrants, entrants and persons granted asylum at a cost of \$2200 per refugee, RCUSA recommends an allocation of \$165 million for the Matching Grant program for fiscal year 2009.

(b) Unaccompanied Refugee Minor (URM) Program: ORR provides funding for specialized foster care for unaccompanied refugee minors. This is a hallmark of the U.S. resettlement program and an internationally recognized model of good practice with unaccompanied refugee children. RCUSA recommends allocating \$10 million for this program in fiscal year 2009.

(c) Refugee Social Services and Special Needs Program (RSSP): Refugee Cash and Medical Assistance; Other: RSSP funds are allocated to States, which design their own refugee service delivery system emphasizing job training and placement, English language acquisition, and citizenship services. The Cash and Medical Assistance (CMA) Program provides reimbursement to States and alternative refugee assistance programs for services provided to refugees, as well as associated administrative costs. Refugees determined ineligible for Temporary Assistance for Needy Families (TANF) and Medicaid are may be eligible for RCA and RMA for up to 8 months from the date of arrival in the United States, date of final grant of asylum for asylees, and date of certification for trafficking victims. CMA also reimburses states for medical screening costs through local public health clinics. RCUSA recommends an allocation of \$325 million for these assistance programs for fiscal year 2009.

2. *Targeted Assistance Grants (TAG)*.—These grants provide services to refugees in counties where, because of factors such as high refugee concentrations, additional resources are needed. Targeted Assistance funds must be used to assist refugee families in achieving economic independence. RCUSA recommends an allocation of \$70 million for these assistance programs for fiscal year 2009.

3. *Preventative Health*.—ORR ensures outreach and access for newly arrived refugees to health screenings. The cost of the actual refugee health screening is billed either to Medicaid or Refugee Medical Assistance (as outlined above), depending on eligibility and time of screening. In some areas, interpretation, follow-up, treatment, and informational services are provided instead through the preventive health funds. RCUSA recommends an allocation of \$7 million for preventative health programs in fiscal year 2009.

4. *Social Services (discretionary)*.—This line item funds discretionary programs such as services to refugees with special needs; the unanticipated arrivals program; the "preferred communities" program; and capacity development programs for refugee Mutual Assistance Associations. RCUSA recommends an allocation of \$216 million for social services in fiscal year 2009.

<sup>1</sup>In 2007, Congress provided for the admission of up to 5,000 special immigrants from Iraq who helped the United States during the conflict there. RCUSA estimates that the cost of providing resettlement services to these special immigrants will be \$68 million in fiscal year 2009. According to the Department of State's Bureau of Population, Refugees, and Migration, the average family size for each special immigrant is expected to be between 2 and 2.5 persons. Thus, the \$68 million estimate is derived by multiplying the number of Iraqis expected to be admitted (11,250 persons) by our estimated \$6,070 per-capita cost (based on ORR's fiscal year 2006 budget figures) for resettling each special immigrant. This \$68 million has been accounted for in all of the budget categories which will serve these special immigrants (line items A1–4).

## B. SERVICES FOR UNACCOMPANIED ALIEN CHILDREN

The Homeland Security Act of 2002 (Public Law 107–296) transferred from the Immigration and Naturalization Service (INS) to ORR the responsibility for coordinating and implementing the care and placement of unaccompanied alien children. ORR ensures a safe and appropriate environment for these children and helps reunite children with guardians or sponsors when appropriate. In fiscal year 2007, ORR provided services to approximately 9,000 children, compared to about 7,000 in the previous year. More funding is needed in order to ensure quality custodial care and services even as the number of children served has risen; to increase the use of smaller, child-centered custodial settings that are more appropriate for children; and to ensure sufficient home studies and suitability assessments are performed. Of these funds, \$5 million are needed to expand ORR's pro bono legal services pilot that will sunset this year. RCUSA recommends an allocation of \$150 million for services for Unaccompanied Alien Children in fiscal year 2009.

## C. TORTURE VICTIMS

ORR is responsible for certain services to victims of torture. Currently, ORR is in the 2nd year of a 3 year cycle with 20 grantees and 2 technical assistance programs. Funding for torture rehabilitation has remained static for several years. The result has been a demand for services that far exceeds resources, and several programs have closed or drastically scaled back services to survivors. All these programs worked in areas with a significant refugee population. In addition, a number of sources have indicated that the percentage of torture victims within the Iraqi refugee population will be considerably higher than that of other recent refugee flows.<sup>2</sup> For all of these reasons, RCUSA recommends an allocation of \$20 million for services to victims of torture in fiscal year 2009.

## D. TRAFFICKING VICTIMS

ORR has a mandate to serve victims of trafficking—men, women and children whose migration to the United States is the result of forced labor or involuntary participation in the sex industry or other industry. Because the Trafficking Victims Protection Reauthorization Act of 2005 expanded programs to assist U.S. citizen and permanent resident trafficking victims, ORR has needed to serve a higher number of victims in recent years, while the number identified continues to grow. At the same time, current funding levels are not adequate to serve the number of victims that request them, and those that are being served would benefit greatly from a longer service period. While trafficking victims are currently eligible for four months of basic services after victim certification, we believe that the length of the service period should be 2–3 times longer so that victims can utilize necessary services until they are back on their feet after suffering the effects of such a horrendous crime. RCUSA recommends an allocation of at least \$20 million for services to trafficking victims in fiscal year 2009.

The U.S. resettlement program remains one of the most cost effective humanitarian efforts carried out by the U.S. Government given its ability to garner large scale private support for its goals. A program of \$983 million—the amount which we are asking Congress to consider—leverages millions more in maintaining the position of the United States as the world's leading society in extending a compassionate and caring hand to refugees who are fortunate enough to find their safety in our shores.

Thank you.

## PREPARED STATEMENT OF ROTARY INTERNATIONAL

Chairman Harkin, Senator Specter, members of the subcommittee, Rotary International appreciates this opportunity to submit testimony in support of the polio eradication activities of the U.S. Centers for Disease Control and Prevention (CDC). The effort to eradicate polio stands as an unprecedented model of cooperation among national governments, civil society and U.N. agencies which have worked together over many years to achieve a global public good. Longstanding collaboration has enabled us to overcome tremendous challenges: war, natural disasters, and lack of infrastructure among them, so that we are currently within reach of shared victory over polio. What have we learned? Polio eradication strategies work even in the most challenging environments and under the most trying circumstances.

<sup>2</sup>For more information, see UNHCR's recent report on the incidence of severe trauma among Iraqi refugees in Syria: <http://www.unhcr.org/news/NEWS/479616762.html>.

## PROGRESS IN THE GLOBAL PROGRAM TO ERADICATE POLIO

I would like to take this opportunity to thank you, Chairman Harkin, Senator Specter, and members of the subcommittee for your tremendous commitment to this effort. Thanks to your leadership in appropriating funds, progress toward a polio-free world continues.

- Only 4 countries are still polio-endemic—the lowest number in history: Nigeria, India, Pakistan and Afghanistan. And in these countries, polio circulates in very limited geographic areas.
- The number of polio cases has fallen from an estimated 350,000 in 1988 to slightly more than 1300 in 2007—a more than 99 percent decline in reported cases.
- Cases due to type 1 polio, the most virulent and paralytic of the two remaining types of polio, fell by 84 percent in 2007. The absence of type 1 polio from the western part of Uttar Pradesh state, India, is a particularly striking development as this is the only area in India which had never interrupted indigenous polio transmission.
- Polio was cut by 76 percent in northern Nigeria in 2007.
- 25 of the 27 countries that were reinfected between 2003 and 2007 have stopped transmission of imported poliovirus.
- Among the reinfected countries, Somalia has just demonstrated that polio eradication can be achieved even in countries where a functioning government does not exist, and where longstanding civil strife and insecurity prevail. March 25, 2008 marks the 1-year anniversary since the last case of polio was reported in Somalia.
- The tools to eradicate polio are better than ever—the program now has vaccines which are twice as effective and diagnostic tools that detect and track poliovirus twice as fast as before.
- Policies to minimize the risks and consequences of the international spread of wild poliovirus are now in place.

Prospects for polio eradication are bright, but significant challenges remain. For example, operational challenges in reaching every child in the four endemic countries range from issues related to campaign quality, security, and funding. In addition, outbreak response activities in countries such as the Democratic Republic of Congo, Angola, Chad and Sudan are tragic and costly reminders that no child is safe until polio has been eradicated everywhere.

The strong support received from the Department of Health and Human Services and the U.S. State Department in promoting global polio eradication efforts at various international forums, engaging with other donor countries to secure additional resources, and addressing challenges in polio-affected countries is greatly appreciated. The continued engagement of the U.S. State Department will also be necessary to help secure “Days of Tranquility” in zones of conflict in southern Afghanistan to provide safe access to vaccinators to reach and vaccinate children during polio eradication campaigns.

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

Since 1985, Rotary International, a global association of more than 30,000 Rotary clubs, with a membership of over 1.2 million business and professional leaders in more than 200 countries, has been committed to battling this crippling disease. In the United States today there are more than 7,700 Rotary clubs with over 375,000 members. All of our clubs work to promote humanitarian service, high ethical standards in all vocations, and international understanding. Rotary International stands hand-in-hand with the United States Government and governments around the world to fight polio through local volunteer support of National Immunization Days, raising awareness about polio eradication, and providing financial support for the initiative.

Rotary International’s financial commitment will reach U.S. \$850 million by the time the world is certified polio free—representing the largest contribution by an international service organization to a public health initiative ever. These funds have been allocated for polio vaccine, operational costs, laboratory surveillance, cold chain, training and social mobilization in 122 countries. More importantly, tens of

thousands of Rotarians have been mobilized to work together with their national ministries of health, UNICEF and WHO, and with health providers at the grass-roots level in thousands of communities. In the United States, hundreds of Rotarians have been inspired to travel at their own expense to assist their fellow Rotarians in polio-affected countries in Africa and Asia during National Immunization Days.

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 Birth Defects Foundation, the American Academy of Pediatrics, the Task Force for Child Survival and Development, the United Nations Foundation, and the U.S. Fund for UNICEF. These organizations join us in expressing appreciation to you for your staunch support of the Global 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. For fiscal year 2009, we would expect that CDC will spend \$101.254 million for their polio eradication efforts, equal to the fiscal year 2006 level. This investment has helped to make the United States the leader among donor nations in the drive to eradicate this crippling disease. Due to Congress's unwavering support, in 2008 CDC is able to:

- Support the international assignment of more than 350 long- and short-term epidemiologists, virologists, and technical officers to assist the World Health Organization and polio-endemic countries to implement polio eradication strategies, and 15 technical staff on direct assignment to WHO and UNICEF to assist polio-endemic countries.
- Provide \$40 million to UNICEF for approximately 240 million doses of polio vaccine and \$9 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.
- Provide more than \$25 million 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 all over the world in advanced poliovirus research and public health laboratory support. CDC's Atlanta laboratories serve as a global reference center and training facility.
- Provide the largest volume of both operational (poliovirus isolation) and technologically sophisticated (genetic sequencing of polio viruses) lab support to the 145 laboratories of the global polio laboratory network. CDC has the leading specialized polio reference lab in the world.
- Serve as the primary technical support agency to WHO on scientific and programmatic research regarding: (1) laboratory containment of wild poliovirus stocks following polio eradication, and (2) when and how to stop or modify polio vaccination worldwide following global certification of polio eradication.

#### 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 investigate cases of acute flaccid paralysis and manage massive immunization programs. Cold chain, transport and communications systems for immunization have been strengthened.

Increased political and financial support for childhood immunization has many documented long-term benefits. Polio eradication is helping countries to develop public health and disease surveillance systems useful in the control of other vaccine-preventable infectious diseases. Already all 47 countries of the Americas are free of indigenous measles, due in part to improvements in the public health infrastructure implemented during the war on polio. The disease surveillance system—the network of 145 laboratories and trained personnel established during the Polio Eradication Initiative—is now being used to track measles, rubella, yellow fever, meningitis, and other deadly infectious diseases. Most recently, polio health workers have been trained to recognize symptoms of Avian Influenza in order to support surveillance and potential outbreak response activities for this emerging public health threat. The AFP surveillance system and global laboratory network that supports it will



continue to support the surveillance of other diseases long after polio has been eradicated.

NIDs for polio have been used as an opportunity to give children essential vitamin A, which, like polio, is administered orally, saving the lives of at least 1.5 million children since 1998. The campaign to eliminate polio from communities has led to an increased public awareness of the benefits of immunization, creating a “culture of immunization” and resulting in increased usage of primary health care and higher immunization rates for other vaccines. It has improved public health communications and taught nations important lessons about vaccine storage and distribution, and the logistics of organizing nation-wide health programs. Also, the unprecedented public/private sector cooperation is a model for other public health initiatives.

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 \$5 billion already invested in polio eradication.

#### FISCAL YEAR 2009 BUDGET REQUEST

The World Health Organization estimates that \$1.8 billion is needed from donors for the period 2008–2012. For fiscal year 2009, we respectfully request that you maintain the level of funding that has been provided in the past (\$101.254 million) for the targeted polio eradication efforts of the Centers for Disease Control and Prevention. 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. 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.

Continued political commitment is essential in all polio-affected countries. Intense political commitment on the part of endemic nations is also essential to ensuring polio eradication is achieved. India, Nigeria and Pakistan have invested significant human and financial resources in their own polio eradication activities. In Afghanistan, President Karzai has appointed a special Polio Action Group to maximize ministerial coordination of all polio eradication activities. In Afghanistan, President Karzai has appointed a Polio Action Group that reports directly to him. Such strong leadership demonstrates the priority these countries place on polio eradication.

The strong resolve of the remaining polio affected countries combined with the continued leadership of the United States and other global donors will ensure that we seize the opportunity to banish the crippling polio virus to the history books. The lessons learned from the shared victory of governments, U.N. agencies, and civil society entities like Rotary International will leave a lasting legacy for future public health and development initiatives.

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#### PREPARED STATEMENT OF THE SCLERODERMA FOUNDATION

I am Cynthia Cervantes, I am 12 and in the eighth 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 affecting 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 45, 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.

#### SCLERODERMA FOUNDATION

The Scleroderma Foundation is a nonprofit organization based in Danvers, MA with a three-fold mission of support, education, and research. The Foundation has 21 chapters nationwide and over 175 support groups.

The Scleroderma Foundation was established on January 1, 1998 through a merger between two organizations, one on the west coast and one on the east coast. Both organizations can trace their beginnings back to the early 1970s.

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 and a quarterly magazine, *The Scleroderma Voice*.

The Foundation 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.

The Foundation awards over \$1 million in peer-reviewed research grants annually to institutes and universities to stimulate progress in the search for a cause and cure for scleroderma.

The Foundation strives to boost awareness about the disease to patients, families, the medical community and the general public to not only generate more funding for medical research, but foster a greater understanding of the complications faced by people living with the disease.

Among the many programs arranged by the Foundation is the Annual Patient Education Conference held each summer. The conference brings together an average of 500 attendees and experts for a wide range of workshops on such topics as the latest research initiatives, coping and disease management skills, caregiver support, and exercise programs.

#### SCLERODERMA OVERVIEW

Scleroderma is an autoimmune disease which means that it is a condition in which the body's immune system attacks its own tissues. In autoimmune disorders, this ability to distinguish foreign from self is compromised. As immune cells attack the body's own tissue, inflammation and damage result. Scleroderma (the name means "hard skin") can vary a great deal in terms of severity. For some, it is a mild condition; for others it can be life threatening. Although there are medications to slow down disease progression and help with symptoms, there is as yet no cure for scleroderma.

#### WHO GETS SCLERODERMA?

There are many clues that define 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 get worse scleroderma disease than Caucasians.

Women are more likely to get scleroderma. Environmental factors may trigger the disease in the susceptible host. Localized scleroderma is more common in children,

whereas scleroderma is more common in adults. However, both can occur at any age.

There are an estimated 300,000 people in the United States who have scleroderma, about one third of whom have the systemic form of scleroderma. Diagnosis is difficult and there may be many misdiagnosed or undiagnosed cases as well.

Scleroderma can develop and is found in every age group from infants to the elderly, but its onset is most frequent between the ages of 25 to 55. There are many exceptions to the rules in scleroderma, perhaps more so than in other diseases. Each case is different.

#### CAUSES OF SCLERODERMA

The cause 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

Research suggests that the susceptible host for scleroderma is someone with a genetic predisposition to injury from some external agent, such as a viral or bacterial infection or a substance in the diet or environment. In localized scleroderma, the resulting damage is confined to the skin. In systemic sclerosis, the process causes injury to blood vessels, or indirectly perturbs the blood vessels by activating the immune system.

Research continues to assemble the pieces of the scleroderma puzzle to identify the susceptibility genes, to find the external trigger and cellular proteins driving fibrosis, and to interrupt the networks that perpetuate the disease.

#### 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.

The face can be affected in both forms. The importance of making the distinction between limited and diffuse disease is that the extent of skin involvement tends to reflect the degree of internal organ involvement.

Several clinical features occur in both limited and diffuse cutaneous SSc. Raynaud's phenomenon occurs in both. Raynaud's phenomenon is a condition in which the fingers turn pale or blue upon cold exposure, and then become ruddy or red upon warming up. These episodes are caused by a spasm of the small blood vessels in the fingers. As time goes on, these small blood vessels become damaged to the point that they are totally blocked. This can lead to ulcerations of the fingertips.

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.

Calcinosis refers to the presence of calcium deposits in, or just under, the skin. This takes the form of firm nodules or lumps that tend to occur on the fingers or forearms, but can occur anywhere on the body. These calcium deposits can sometimes break out to the skin surface and drain whitish material (described as having the consistency of toothpaste).

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 six 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.

#### CONCLUSION

Unfortunately, support for scleroderma research at the National Institutes of Health over the past 5 years has been flat funded at \$11 million, down from \$13 million in 2003. These figures are 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.

As Congress works to finalize the HHS appropriations bill for fiscal year 2009, we encourage you to support a 6.5 percent increase for the NIH. This funding recommendation has been endorsed by over 300 health care organizations and would ensure additional support for scleroderma research. The main institute responsible for scleroderma at the NIH is the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

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#### PREPARED STATEMENT OF THE SOCIETY FOR NEUROSCIENCE

##### INTRODUCTION

Mr. Chairman and members of the subcommittee, I am Eve Marder, Ph.D., president of the Society for Neuroscience (SfN) and the Victor and Gwendolyn Beinfeld Professor of Neuroscience at Brandeis University. It is my honor to submit this testimony on behalf of SfN in support of the National Institutes of Health.

My research focuses on understanding how circuit function arises from the intrinsic properties of individual neurons and their synaptic connections. Of particular interest is the extent to which similar circuit outputs can be generated by multiple mechanisms, both in different individual animals, or in the same animal over its lifetime. To address this, my lab studies the central pattern generating circuits in the crustacean stomatogastric nervous system, such as those found in crabs and lobsters. Central pattern generators are groups of neurons found in vertebrate and invertebrate nervous systems responsible for the generation of specific rhythmic behaviors such as walking, swimming, and breathing. I am the recipient of Federal research and training support from the National Institutes of Health and National Science Foundation.

##### FISCAL YEAR 2009 BUDGET REQUEST

I respectfully request that Congress commit to continuing to expand the Nation's investment in medical research by increasing the NIH budget by \$1.9 billion in fiscal year 2009. This recommended increase would match biomedical inflation with 3 percent added to account for real growth. The administration's request of \$29.2 billion for NIH in fiscal year 2009 represents the sixth consecutive year that the President's proposed budget for the NIH has failed to keep pace with biomedical inflation. In that period, a combination of minimal increases and cuts has resulted in an approximately 11 percent decline in the agency's purchasing power due to inflation. If the President's fiscal year 2009 request becomes law, NIH will have lost 13.4

percent of its purchasing power due to inflation, undermining the value of the increases gained when Congress doubled the NIH budget.

This recommendation, supported across the research and patient advocacy communities, would increase NIH's budget by 6.5 percent, halting the erosion of the Nation's medical research effort, and allowing the world's pre-eminent research enterprise to accelerate the momentum of discovery to improve the health and quality of life for millions of Americans. NIH-funded research is driving the transformation of science, medicine and health care. At a time of unparalleled scientific opportunities and unprecedented health challenges, NIH must be given the resources to continue to move forward, not stand in place.

#### WHAT IS THE SOCIETY FOR NEUROSCIENCE?

The Society for Neuroscience is a nonprofit membership organization of basic scientists and physicians who study the brain and nervous system. Recognizing the field's tremendous potential, the Society was formed in 1969 with less than 500 members. Today, SfN's membership numbers more than 38,000 and it is the world's largest organization of scientists devoted to the study of the brain. Our member neuroscientists work to describe the human brain and how it functions normally, determine how the nervous system develops, matures and maintains itself through life; and improve treatment and prevention of many devastating neurological and psychiatric disorders.

Neuroscience is 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. SfN is devoted to education about the latest advances in brain research, and to raising awareness of the need to make neuroscience research a funding priority.

#### NIH-FUNDED RESEARCH SUCCESSES LEAD TO HEALTH ADVANCES

Today, scientists have a greatly improved understanding of how the brain functions thanks to NIH-funded research. To illustrate this progress, SfN has created a 36-part series, called Brain Research Success Stories, which discusses some of the progress that has resulted from Federal funding for biomedical research during the period of the doubling. The successes in neuroscience research outlined below would not have been possible without NIH funding, but future discoveries are threatened by eroding funds. Sustained, consistent and predictable NIH support is essential to fully exploring the possible advances unearthed by this exciting research.

—*Depression.*—Depression is one of the most common and costly brain diseases, afflicting 18.8 million adults in the United States each year—about 10 percent of the country's population over the age of 18. Depressed people are at increased risk for substance abuse, suicide, eating disorders, and illnesses like heart disease and stroke. Depression is also a drain on the economy. It costs \$44 billion in lost productivity in the United States every year. The National Institute of Mental Health now lists depression as the country's leading cause of disability. Over the past 10 years, research funded by NIH has led to a new generation of antidepressants—selective serotonin reuptake inhibitors (SSRIs)—that produce fewer serious side effects, and more recently, scientists are discovering potentially powerful strategies for entirely new classes of antidepressants. With continued NIH funding, scientists will uncover how these new drugs, sometimes in combination with psychotherapy, can dramatically improve the depressed brain's functioning. Investigations into brain stimulation, brain imaging, and genetics promise to yield better treatments for depression.

—*Traumatic Brain Injury.*—Whether it is from a slip on the ice, a crash into the windshield, or a blast from an improvised explosive device, each year an estimated 1.5 million Americans sustain a traumatic brain injury (TBI). Characterized by a sudden blow to the head, this type of injury can brutally damage the brain and its functioning, resulting in acute impairment of consciousness, or visual, motor, or sensory deficits. While patients with these symptoms often recover partially or even completely, those with even mild to moderate TBI can later develop epilepsy or related disorders. In fact, TBI is a leading cause of disability among American children and young adults. Recent research also has shown that TBI may increase a person's risk for future development of Alzheimer's disease. Research funded by NIH will lead to new strategies that could take direct action against the injury and create much greater improvement in patient care. Techniques that hold promise include the use of transplanted neural stem cells and imaging tests that can identify brain tissue swelling, allowing

early medical intervention. Continued funding for research could help scientists develop new therapies that reverse brain damage and significantly improve the lives of Americans.

—*Parkinson's Disease*.—Recent advances in understanding the causes of Parkinson's disease, and the possibility of new treatment options, have brought a renewed sense of optimism that Parkinson's disease can be treated more effectively. Current research programs funded by National Institute of Neurological Disorders and Stroke are using animal models to study how the disease progresses and to develop new drug therapies. Scientists looking for the cause of PD continue to search for possible environmental factors, such as toxins, that may trigger the disorder, and study genetic factors to determine how defective genes play a role. Other scientists are working to develop new protective drugs that can delay, prevent, or reverse the disease. Research on deep brain stimulation is a potentially revolutionary therapeutic approach that is being explored as a treatment for Parkinson's and other diseases and disorders. As scientists search for new treatments and a possible cure for Parkinson's disease, they are finding that this illness shares much with several other diseases and conditions, such as depression, Alzheimer's disease, Amyotrophic Lateral Sclerosis, and Huntington's disease. Basic research examining gene mutations, cell death, and how to repair damaged cells has been essential to discovering these commonalities. With continued funding, scientists will be able to follow those paths and bring about the medical advances needed to halt the progression of Parkinson's and diseases with similar traits.

—*Epilepsy*.—Researchers supported by NIH are studying potential antiepileptic drugs with the goal of enhancing treatment for epilepsy. Scientists continue to study how neurotransmitters interact with brain cells to control nerve firing and how non-neuronal cells in the brain contribute to seizures and are working to identify genes that may influence epilepsy. This information may allow doctors to prevent epilepsy or to predict which treatments will be most beneficial. Doctors are now experimenting with several new types of therapies for epilepsy, including transplanting fetal pig neurons into the brains of patients to learn whether cell transplants can help control seizures, transplanting stem cells, and using a device that could predict seizures up to 3 minutes before they begin. Funding is needed to pursue patient-oriented research, developmental neurobiology, genetics, advanced technology, imaging, pharmacotherapeutics, and other disciplines to develop innovative research proposals related to the field of epilepsy.

#### BASIC RESEARCH—FUNDAMENTAL SCIENCE

Continued investment in basic research funded by NIH is also essential to ensuring discoveries that will inspire scientific pursuit and medical progress for future generations. Basic research advances scientific knowledge and medical innovation by expanding understanding of the structure and function of molecules, genes, cells, systems and complex behaviors. Clinical researchers often use these fundamental findings to identify new applications that lead to medical treatments.

—*Plasticity and Alzheimer's Disease*.—Researchers in the 1960s wanted to understand more about growth and repair in the adult brain and conducted a number of experiments with rodents to help illuminate these processes. They made an amazing and unexpected discovery: newly created cells that later became neurons, or brain cells. This process, called neurogenesis, is just one example of how "plastic" or adaptable the brain is. With this knowledge, researchers are investigating how normal aging, as well as neurodegenerative diseases like Alzheimer's disease, affect that adaptability, and how we can maintain health brain function as we age. Future research may one day allow scientists to capture the adult brain's enormous capacity to adapt in order to help prevent, or perhaps even reverse, memory-robbing Alzheimer's disease.

—*Light-activated Molecules*.—The discovery of a new class of proteins from algae molecules is now enabling scientists to develop new tools to explore how specific types of nerve cells are interconnected and how they function in circuits in the brain. These molecules, called channelrhodopsins, can be used to effectively turn electrical activity in cells "on" and "off" with light. The new application allows researchers to use light to study and even manipulate brain activity, and could result someday in improved therapies that target only diseased cells and avoid unwanted side effects in disorders such as Parkinson's, depression, chronic pain, and epilepsy.

—*Central Pattern Generators and Spinal Cord Recovery*.—Central pattern generators are circuits in the brainstem and spinal cord that generate rhythmic move-

ments such as breathing and walking. Studies on central pattern generators in animals after spinal cord injury first suggested the importance of weight-assisted treadmill and bicycle training for spinal cord injured patients. These methods, together with advances in understanding the molecular control of regeneration and regrowth in the spinal cord, should lead to significant improvements in the outcomes of individuals with spinal cord injury.

#### THE PIPELINE OF NEW RESEARCHERS

Five consecutive years of flat funding the NIH budget is deterring promising young researchers. A recent report issued by a consortium of leading research universities and a major teaching hospital—A Broken Pipeline? Flat Funding of the NIH Puts a Generation of Science at Risk—warns that America stands to lose a generation of young researchers and the cures they could discover if current NIH funding trends continue.

The NIH budget constraints compromise all sections of the academic research pipeline. The overall success rate for NIH research project grants dropped from 32 percent in 1999 to 24 percent in 2007, meaning that more than three of every four research proposals are not funded. Undergraduate and graduate students watch their mentors struggling for funding, and are opting out of science as a career. Extremely productive senior investigators are forced to fire long-term research personnel, often compromising the transmission of important laboratory methods. Even if those investigators are refunded 6 months or a year later, the damage to the research enterprise may long outlast the time course of the lapsed funding, because of loss of momentum and loss of crucial trained laboratory personnel. In the past year, NIH has been very proactive to ensure that a number of first-time investigators are funded, even with the very restricted resources available. However, young investigators remain extremely vulnerable at the time of their first grant renewal. During the past year or two many investigators have been spending significantly more time writing, rewriting and reviewing grant applications, and consequently doing less actual science. The cost of the loss of productivity due to the grant squeeze is difficult to calculate, but is considerable.

This squeeze on the research workforce impacts the Nation's economic vitality globally, as the United States fights to retain its competitive edge in scientific and technological sectors. In fact, 70 percent of Americans believe the United States is losing its global competitive edge in science, technology, and innovation, according to a Research!America poll. We are especially concerned that the United States may soon no longer be the source of the basic and translational science that fosters advances in medicine. Also, decreases in the science workforce could have a deleterious effect on local and State economies, as universities and research institutions are the largest employers in some communities. The dollars brought in by these institutions help to spur growth in biotechnology, pharmaceutical, device and imaging manufacturing, and other industries.

#### CONCLUSION

The brain is the most complex living structure known in the universe. Neuroscience advances our understanding of the brain and nervous system. This enables us to better understand human behavior—from how we learn to why people have trouble getting along together—and to discover ways to prevent or cure many devastating brain disorders. The more than 1,000 disorders of the brain and nervous system result in more hospitalizations than any other disease group, including heart disease and cancer.

As SfN members continue to pursue exciting new avenues of research and make amazing breakthroughs everyday, I urge Congress not to limit these innovations and revelations by providing inadequate Federal funding. Sustained, healthy increases for the National Institutes of Health that keep up with inflation are essential to neuroscientists who conduct the research that advances scientific understanding and leads to health improvements urgently needed by countless Americans.

Thank you for the opportunity to submit this testimony.

PREPARED STATEMENT OF THE SOCIETY OF TEACHERS OF FAMILY MEDICINE, ASSOCIATION OF DEPARTMENTS OF FAMILY MEDICINE, ASSOCIATION OF FAMILY MEDICINE RESIDENCY DIRECTORS, AND THE NORTH AMERICAN PRIMARY CARE RESEARCH GROUP

Mr. Chairman, the Society of Teachers of Family Medicine, the Association of Departments of Family Medicine, the Association of Family Medicine Residency Directors, and the North American Primary Care Research Group, thank you for the opportunity to provide this statement for the record on behalf of funding for family medicine training programs under the Health Services and Resources Administration (HRSA), the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH).

HEALTH PROFESSIONS—PRIMARY CARE MEDICINE AND DENTISTRY (TITLE VII, SECTION 747)

We request that this committee return funding of the Primary Care Medicine and Dentistry Cluster (Section 747 of Title VII) to its earlier (fiscal year 2002) funding level of \$93 million. Since fiscal year 2004, this program has lost more than 50 percent of its funding. Currently (fiscal year 2008), the program is funded at less than \$48 million. The President's budget for fiscal year 2009 continues to zero out funding for this cluster.

*Primary Care in Crisis*

Why should Congress restore funding for this program? Primary care in the United States is in crisis. The United States Government Accountability Office (GAO) testified before the Senate HELP Committee in February of this year. It described the difficulties of increasing the number of primary care physicians in the United States and the benefits to the nation of doing so. One of its findings concluded:

"Health professional workforce projections that are mostly silent on the future supply of and demand for primary care services are symptomatic of an ongoing decline in the nation's financial support for primary care medicine."<sup>1</sup>

Data from the Congressional Research Service (CRS) also show that reduced funding for the primary care medicine and dentistry cluster had a deleterious impact on the effectiveness of these programs—at a time when more, rather than less primary care is needed. For example, "In fiscal year 2006, the program supported a total of 17,870 individuals in clinical training in underserved areas, a decrease from the support of 31,153 individuals in fiscal year 2005."<sup>2</sup> This is a decrease of almost 43 percent.

Additional testimony before the Senate HELP Committee last month clarified the problems that primary care in the United States currently faces. Kevin Grumbaugh, MD, Professor and Chair, UCSF Department of Family and Community Medicine, and a recognized expert in workforce research, put it this way: "The primary care infrastructure in the United States is crumbling, and patient access to primary care is suffering throughout the nation. From 1997 to 2005, the number of U.S. medical school graduates entering careers in family medicine residencies dropped by 50 percent, as did the number of internal medicine residents planning careers in primary care rather than specialty medicine. In a 2006 survey of 92 large or medium-sized physician groups, 94 percent of the respondents ranked internists or family physicians as the most difficult to recruit. Federally funded community health centers reported more than 750 vacant positions for primary care physicians in 2004. In 2007, 29 percent of Medicare beneficiaries reported a problem finding a primary care physician, up from 24 percent in 2006."

*The Primary Care Payoff*<sup>3</sup>

According to a report prepared by the National Association of Community Health Centers, The Robert Graham Center, and Capitol Link, "There is a growing consensus among the nation's political and industry leaders that the U.S. health care crisis has shifted from the realm of the poor and disenfranchised, to the doorstep of middle-class America." Additionally, they cite the following: "If every American

<sup>1</sup>Testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate. Primary Care Professionals: Recent Supply Trends, Projections and Valuation of Services. Statement of A. Bruce Steinwald, Director Health Care, United States Accountability Office. February 12, 2008 GAO-08-472T.

<sup>2</sup>CRS Report to Congress. February 7, 2008 Title VII Health Professions Education and Training: Issues in Reauthorization (Order Code RL32546).

<sup>3</sup>Access Granted: The Primary Care Payoff, August 2007, National Association of Community Health Centers, The Robert Graham Center, Capitol Link (pgs 1-2).



made use of primary care, the health care system would see \$67 billion in savings annually. This reflects not only those who do not have access to primary care, but also those who rely extensively on costly specialists for most of their care, leading to inefficiencies in the system. More specifically, the expansion of Medical homes can even more dramatically facilitate effective use of health care, improve health outcomes, minimize health disparities, and lower overall costs of care.”

The GAO also cites the importance of primary care in terms of quality and cost:

“Ample research in recent years concludes that the Nation’s over reliance on specialty care services at the expense of primary care leads to a health care system that is less efficient. At the same time, research shows that preventive care, care coordination for the chronically ill, and continuity of care—all hallmarks of primary care medicine—*can achieve improved outcomes and cost savings.*”<sup>4</sup> [emphasis added]

An April, 2004 Health Affairs article found the quality of health care lower in states with higher levels of Medicare spending. The authors suggest that more specialists and fewer primary care physicians mean higher costs and lower quality. A small increase in the number of primary care physicians in a state was associated with a large boost in that state’s quality ranking.

#### *The Success of Title VII, Section 747*

A 2006 study by the University of California San Francisco and the Robert Graham Center shows that medical schools that receive primary care training dollars produce more physicians who work in Community Health Centers (CHCs) and serve in the National Health Service Corps (NHSC) compared to schools without Title VII primary care funding. This finding is particularly true for family physicians. Without funding for primary care training, fewer family physicians will be trained to work in CHCs and serve in the Corps. Almost 4,000 family physicians and general practitioners exposed to Title VII funding during medical school subsequently chose to work in a CHC. Without this exposure, we would anticipate a decrease of over 750 family physicians working in a CHC in 2003. The JAMA article mentioned below shows 600 current vacancies for family physicians in CHCs. Without Title VII dollars, these data point to twice as many vacancies.

The Health Resources and Services Administration (HRSA) has provided some new data regarding the success of Title VII programs as part of the fiscal year 2009 budget justification document published by the administration. It directly counters the administration’s claims of ineffectiveness of these programs, and shows the folly of zeroing out these programs. Below are some selected excerpts:

“During the [PART] review Health Professions developed new long-term and annual performance measures and established baseline data and has since begun regularly collecting data and reporting on performance.

In 2007, 57 percent of graduates and program completers of Titles VII and VIII supported programs were underrepresented minorities and/or from disadvantaged backgrounds. This exceeded the target by 17 percent.

The proportion of trainees in Titles VII and VIII supported programs training in medically underserved communities was 43 percent in 2007 which exceeded the target of 41 percent. The percentage of health professionals supported by the program entering practice in underserved areas was 35 percent in 2007. This exceeded the target by 14 percent.”

We have demonstrated (1) the Nation needs more primary care physicians, (2) the efficacy of primary care in reducing costs and promoting quality, and (3) the success of Title VII programs in producing more primary care physicians. Based on these factors, we recommend that the Committee reinvigorate these programs by increasing the Primary Care Medicine and Dentistry funding to a previous level of \$93 million.

#### *The Agency for Health Care Research and Quality (AHRQ)*

We request funding of \$360 million for AHRQ in fiscal year 2009. This is an increase of \$25 million over fiscal year 2008, and \$34 million more than the President’s fiscal year 2009 Budget request. For the last several years, even with an increase in fiscal year 2008, funding for AHRQ has remained relatively stagnant, while its portfolio of work has increased dramatically. Our researchers are finding that investigator-initiated grants are very difficult to obtain.

It should be noted that a much larger investment should be made, as recommended by The Institute of Medicine’s report, *Crossing the Quality Chasm: A*

<sup>4</sup>Testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate. Primary Care Professionals: Recent Supply Trends, Projections and Valuation of Services. Statement of A. Bruce Steinwald, Director Health Care, United States Accountability Office. February 12, 2008 GAO–08–472T.

New Health System for the 21st Century (2001). It recommended \$1 billion a year for AHRQ to “develop strategies, goals, and actions plans for achieving substantial improvements in quality in the next 5 years . . .” The report looked at redesigning health care delivery in the United States. AHRQ is critical to retooling the American health care system.

One of the hallmarks of the patient centered medical home is evidence-based medicine. Comparative effectiveness research, which compares the impact of different options for treating a given medical condition, is vital to improving the quality of health care. Studies comparing various treatments (e.g. competing drugs) or differing approaches (e.g. surgery and drug therapy) can inform clinical decisions by analyzing not only costs but the relative medical benefits and risks for particular patient populations.

Comparative effectiveness research holds out the promise of reducing health care costs while improving medical outcomes. AHRQ’s Effective Health Care Program is critical if we are to realize that promise. Although the President’s budget request proposed to hold this important program at \$30 million, the same as fiscal year 2008, we hope that the Congress will increase our investment in comparative effectiveness research.

#### *National Institutes of Health (NIH)*

Historically, the research at NIH has failed to pose the questions asked by family doctors in primary care practice regarding treatment of their patients. We are encouraged by the development of the NIH Roadmap and the Clinical and Translational Science Awards (CTSA), along with the establishment, in statute, of a funding stream for the common fund that demonstrates the willingness of NIH to become a more fertile arena for family medicine and other primary care research. Hence, we support the Ad Hoc Group for Medical Research and others’ call for an increase in NIH funding. In addition, we would like to see some report language that would help NIH ensure that the promise of bench to bedside research truly becomes bench to bedside to community—and back.

We support the inclusion of the following language in the report to accompany the Labor/HHS appropriations bills for fiscal year 2008.

“Translational Research has been identified by the Director of the National Institutes of Health (NIH) as a road map initiative. The committee supports this effort and encourages NIH to integrate such research as a permanent component of the research portfolio of each institute and center. The committee urges NIH to begin discussions to determine how best to facilitate progress in translating existing research findings and to disseminate and integrate these findings at the practice level. Translational research should also include the discovery and application of knowledge within the practice setting using such laboratories as practice-based research networks. This research spans biological systems, patients, and communities, and arises from questions of importance to patients and their physicians, particularly those practicing primary care. The Committee requests that the Director of NIH include a progress update in next year’s Budget Justification.”

#### CONCLUSION

We hope that the committee will be able, with the more generous figures included in the fiscal year 2009 House and Senate Budget Resolutions this year, to fund increases in these three important programs: health professions primary care medicine and dentistry training, AHRQ, and NIH. Certainly, at a minimum, we request that funding cuts to the health professions primary care medicine and dentistry training program be restored to at least fiscal year 2005 levels of \$88.8 million. However, these programs were funded at a historic high of \$93 million in fiscal year 2002, and we support a return to that figure.

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#### PREPARED STATEMENT OF THE SOCIETY FOR WOMEN’S HEALTH RESEARCH AND WOMEN’S HEALTH RESEARCH COALITION

On the behalf of the Society for Women’s Health Research and the Women’s Health Research Coalition, we are pleased to submit the following testimony in support of Federal funding of biomedical research, and more specifically women’s health research.

The Society for Women’s Health Research is the only national non-profit women’s health organization whose mission is to improve the health of women through research, education, and advocacy. Founded in 1990, the Society brought to national attention the need for the appropriate inclusion of women in major medical research studies and the need for more information about conditions affecting women dis-

proportionately, predominately, or differently than men. In 1999, the Women's Health Research Coalition was created by the Society as a grassroots advocacy effort consisting of scientists, researchers, and clinicians from across the country that are concerned and committed to improving women's health research.

The Society and Coalition are committed to advancing the health of women through the discovery of new and useful scientific knowledge. We believe that sustained funding for biomedical and women's health research programs conducted and supported across the Federal agencies is absolutely essential if we are to meet the health needs of the population and advance the Nation's research capability.

#### NATIONAL INSTITUTES OF HEALTH

From decoding the human genome to elucidating the scientific components of human physiology, behavior, and disease, scientists are unearthing exciting new discoveries which have the potential to make our lives and the lives of our families longer and healthier. The National Institutes of Health (NIH) has facilitated these advances by conducting and supporting our Nation's biomedical research. World-class researchers, scientists, and programs at NIH are dedicated to understanding how the human body works and to gaining insight into countless diseases and disorders. Congressional investment and support for NIH has made the United States the world leader in medical research and has provided a direct and significant impact on women's health research and the careers of women scientists over the last decade.

Great strides and advancements have been made since the doubling of the NIH budget from \$13.7 billion in 1998 to \$27 billion in 2003. However, we are concerned that the momentum driving new research has been eroded under the current budgetary constraints. Medical research must be considered an essential investment—an investment in thousands of newly trained and aspiring scientists; an investment to remain competitive in the global marketplace; and an investment in our Nation's health.

Unfortunately, the administration's proposed fiscal year 2009 budget request of \$29.2 billion for NIH is identical to the final approved budget for fiscal year 2008. This trend of flat lining not only unravels the successes gained from the doubling of NIH's budget, but it directly contributes to decreasing NIH's purchasing power by almost 14 percent due to inflation. NIH only receives \$28.3 billion in the proposed budget due to the transfer of \$300 million to the Global Fund to Fight HIV/AIDS. Not only does the proposed decrease not keep pace with the inflation rate, but it is lower than that of the Biomedical Research and Development Price Index (BRDPI) which is indicative of how much funding the NIH needs to maintain purchasing power and compensate for the average yearly cost increases that occur in maintaining research activity at the previous year's level.

Without a robust budget, NIH will be forced to reduce the number of grants it is able to fund. The number of new grants funded by NIH has been dropping steadily since fiscal year 2003 and this trend must stop. This shrinking pool of available grants has a significant impact on scientists who depend upon NIH support to cover their salaries and laboratory expenses to conduct high quality biomedical research. Failure to obtain a grant results in reduced likelihood of achieving tenure. This means that new and less established researchers will be forced to consider other careers, the end result being the loss of the critical workforce so desperately needed to sustain America's cutting edge in biomedical research.

In order to continue the momentum of scientific advancement and expedite the translation of research findings from the laboratory to the patients who depend on these advances for improved health and welfare, the Society proposes \$31.1 billion for NIH, an increase of \$1.9 billion over the fiscal year 2008 funding level. In addition, we request that Congress strongly encourage the NIH to assure that women's health research receives resources sufficient to meet the health needs of all women.

Scientists have long known of the anatomical differences between men and women, but only within the past decade have they begun to uncover significant biological and physiological differences. Sex-based biology, the study of biological and physiological differences between men and women, 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. It is imperative that research addressing these important differences between males and females be supported and encouraged. Congress clearly recognizes these important sex-based differences and should support NIH at an appropriate level of funding and direct NIH to continue expanding research into sex-based biology.

## OFFICE OF RESEARCH ON WOMEN'S HEALTH

The NIH Office of Research on Women's Health (ORWH) has a fundamental role in coordinating women's health research at NIH, advising the NIH Director on matters relating to research on women's health; 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. ORWH has a pivotal role within the NIH structure and beyond to maintain and advance not only biomedical research in women's health but also to support careers of women in science and medicine. Furthermore, ORWH strives to address sex and gender perspectives of women's health and women's health research, as well as differences among special populations of women across the entire life span, from birth through adolescence, reproductive years, menopausal years and elderly years.

Two highly successful programs supported by ORWH that are critical to furthering the advancement of women's health research are Building Interdisciplinary Research Careers in Women's Health (BIRCWH) and Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCOR). These programs benefit the health of both women and men through sex and gender research, interdisciplinary scientific collaboration, and provide important support for young investigators in a mentored environment.

The BIRCWH program 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. It is expected that each scholar's BIRCWH experience will culminate in the development of an established independent researcher in women's health. In 2007, ORWH funded 15 new or type II centers in the fourth round of BIRCWH. Since 2000, 287 scholars have been trained (76 percent women) in the twenty-four centers resulting in over 882 publications, 750 abstracts, 83 NIH grants and 85 awards from industry and institutional sources. Each BIRCWH receives approximately \$500,000 a year, most of which comes from the ORWH budget.

The SCOR program, administered by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, was developed by ORWH in 2000 through an initial RFA that resulted in 11 SCOR Centers out of 36 applications. SCORs are designed to increase the transfer of basic research findings into clinical practice by housing laboratory and clinical studies under one roof. The eleven SCOR programs are conducting interdisciplinary research focused on major medical problems affecting women and comparing gender difference to health and disease. Each SCOR works hard to transfer their basic research findings into the clinical practice setting. Each program costs approximately \$1 million per year.

ORWH has made significant strides in raising awareness for women's health issue. This past year it launched a national educational and awareness campaign on vulvodynia in collaboration with other DHHS agencies and non-Federal partners; co-sponsored the 8th International Association for Chronic Fatigue Syndrome conference; co-sponsored an agency-wide training session on sex/gender, race and ethnicity issues in clinical research attended by over 300 NIH staff members; awarded the co-funding of sixteen grants to 9 institutes and centers exceeding \$3.8 million for the advancement of sex/gender specific biomedical research; and led the NIH observance of the National Women's Health week.

Despite the advancement of women's health research and ORWH's innovative programs to advance women scientists, it has been flat lined at \$40.9 million for fiscal year 2008 and 2009 after having also received a cut of \$249,000 in fiscal year 2006 and no additional funding in fiscal year 2007. Flat funding must not continue to happen. It imperative that the ORWH programs and research grants continue to thrive. This research is vital to women and men and we implore Congress to direct NIH to continue its support of ORWH and its programs.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Department of Health and Human Services (HHS) has several offices that enhance the focus of the government on women's health research, in addition to ORWH described above. Agencies with offices, advisors or coordinators for women's health or women's health research are the Department of HHS, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Agency for Healthcare Quality and Research, the Indian Health Service, the Substance Abuse and Mental Health Services Administration, the Health Resources and Services Administration, and the Centers for Medicare and Medicaid Services. These agencies must be funded at levels adequate for them to perform their assigned missions. We

ask that the Committee Report clarify that Congress supports the permanent existence of these various offices and would like to see them appropriately funded to ensure that their programs can continue and be strengthened in the coming fiscal year.

The focus on women's health within HHS has been critical to the advances made in women's health in communicating the appropriate message to patients and health care providers. Scientists have only just scratched the surface of understanding female biology, with new information forthcoming as a result of the recent sequencing of the human X chromosome. Now is the time to strongly press ahead with this vital research to continue making discoveries and educating women about their health and these offices are critical to the success of this effort. Although many important programs can be identified from these women's health offices, we would like to bring two such programs to your specific attention, as follows.

#### HHS 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, health care services, and education that have historically placed the health of women at risk. The OWH coordinates women's health efforts in HHS to eliminate disparities in health status and supports culturally sensitive educational programs that encourage women to take personal responsibility for their own health and wellness.

In 2007, the OWH led efforts to improve breastfeeding information available to women of all cultures by offering multilingual websites and helplines. They collaborated with other organizations to lead a conference on "Charting New Frontiers in Rural Women's Health," as well as hosting the third Minority Women's Health Summit to address the unique health issues many women of color experience. The OWH has continued their efforts to improve the health of young women by providing information on their website to address eating disorders and HIV/AIDS prevention for adolescent girls, in conjunction with conducting their HIV/AIDS National Awareness Day.

Since the beginning of 2008, the OWH has led a series of Women's Heart Health Fairs nationwide. In addition, they will empower women across the country to get healthy by sponsoring the National Women's Health Week in May of 2008. In conjunction with families, communities, business and other governmental and health organizations, the OWH will educate women on how they can improve their physical and mental health through various behavior modifications.

It is only through continued funding that the OWH will be able to achieve its goals. While the budget for fiscal year 2008 increased the OWH budget by \$2 million to a total of \$30 million, it has been flat lined for fiscal year 2009. This is, in essence, a decrease due to inflation. Considering the amount and impact of women's health programs from OWH, we urge Congress to provide an increase of \$2 million for the HHS OWH.

#### AGENCY FOR HEALTHCARE AND RESEARCH QUALITY

The Agency for Healthcare Research and Quality (AHRQ) is the lead public health service agency focused on health care quality, including coordination of all Federal quality improvement efforts and health services research. AHRQ'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 health care. This important information provided by AHRQ is brought to the attention of policymakers, health care providers, and consumers all of whom make a difference in the quality of health care that women receive.

AHRQ has a valuable role in improving health care for women. Through AHRQ's research projects and findings, lives have been saved and underserved populations have been treated. For example, 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.

While AHRQ has made great strides in women's health research, the Administration's budget for fiscal year 2009 could threaten such life-saving research. While AHRQ's fiscal year 2008 budget received an \$11 million increase, the President's proposed fiscal year 2009 budget marks an almost \$9 million decrease. With the cost of inflation and years of flat funding, AHRQ has lost \$19 million in purchasing power since 2005. With the President's proposed budget of approximately \$325 million, the agency stands to lose an additional \$9 million. This Agency has been oper-

ating under a major shortfall for years. Decreased funding seriously jeopardizes the research and quality improvement programs that Congress mandates from AHRQ. We encourage Congress to fund AHRQ at \$360 million for fiscal year 2009, an increase of \$26 million over the fiscal year 2008 level. This will ensure that adequate resources are available for high priority research, including women's health care, sex and gender-based analyses, Medicare, and health disparities.

In conclusion, Mr. Chairman, we thank you and this Committee for its strong record of support for medical and health services research and its unwavering 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

SUMMARY

The Spina Bifida Association (SBA) respectfully requests that the Subcommittee provide the following allocations in fiscal year 2009 to help improve quality-of-life for people with Spina Bifida:

—\$7 million to the National Spina Bifida Program at the National Center on Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention (CDC) to support existing program initiatives and allow for the further development of the National Spina Bifida Patient Registry.

BACKGROUND ON SPINA BIFIDA

On behalf of the more than 70,000 individuals and their families who are affected by Spina Bifida—the Nation's most common, permanently disabling birth defect—the SBA appreciates the opportunity to submit written testimony for the record regarding fiscal year 2009 funding for the National Spina Bifida Program and other related Spina Bifida initiatives. SBA is the national voluntary health agency working on behalf of people with Spina Bifida and their families through education, advocacy, research and service. The Association was founded in 1973 to address the needs of the Spina Bifida community and today serves as the representative of 45 chapters serving more than 125 communities nationwide. SBA stands ready to work with Members of Congress and other stakeholders to ensure our nation takes all the steps necessary to reduce and prevent suffering from Spina Bifida.

Spina Bifida, a neural tube defect (NTD), occurs when the spinal cord fails to close properly during the early stages of pregnancy, typically 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 neural tube defect 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 long enough to become adults with Spina Bifida. These gains in longevity principally are due to breakthroughs in research, combined with improvements generally in health care and treatment. However, with this extended life expectancy, our nation and people with Spina Bifida now face new challenges—education, job training, independent living, health care for secondary conditions, aging concerns, among others. Despite these gains, individuals and families affected by Spina Bifida face many challenges—physical, emotional, and financial. Fortunately, with the advent of the National Spina Bifida Program 4 years ago, individuals and families affected by Spina Bifida now have a national resource to provide them with the support, information, and assistance they need and deserve.

While the consumption of 400 micrograms of folic acid daily prior to becoming pregnant and throughout the first trimester of pregnancy, can help reduce the incidence of Spina Bifida by up to 75 percent, 1,500 babies are born with Spina Bifida

each year and our nation still must take steps to ensure that the tens of thousands of individuals living with Spina Bifida 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. Our nation must do more to help reduce the emotional, financial, and physical toll of Spina Bifida on the individuals and families affected. Efforts to reduce and prevent suffering from Spina Bifida help to save money and save lives.

#### IMPROVING QUALITY-OF-LIFE THROUGH THE NATIONAL SPINA BIFIDA PROGRAM

SBA has worked with Members of Congress to ensure that our nation is taking all the steps possible to prevent Spina Bifida and diminish suffering for those currently living with this condition. With appropriate, affordable, and high-quality medical, physical, and emotional care, most people born with Spina Bifida likely will have a normal or near normal life expectancy. The National Spina Bifida Program at the CDC 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 program seeks to ensure that what is known by scientists is practiced and experienced by the 70,000 individuals and families affected by Spina Bifida. Moreover, the National Spina Bifida Program works to improve the outlook for a life challenged by this complicated birth defect—principally identifying valuable therapies from in-utero throughout the lifespan and making them available and accessible to those in need.

The National Spina Bifida Program serves as a national center for 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 allergy, 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 taught what they need to know 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 70,000 individuals living with Spina Bifida with the goal being living well with Spina Bifida.

One way to increase research in Spina Bifida, improve quality and save precious resources is to establish a patient registry for Spina Bifida. Plans are underway to create the National Spina Bifida Patient Registry intended to determine both the best practices clinically and the cost effectiveness of treatment of Spina Bifida and the support the creation of quality measures to improve care overall. It is only through research towards improved care that we can truly save lives while realizing a significant cost savings.

In fiscal year 2008, SBA requested \$7 million be allocated to the National Spina Bifida Program to support and expand the National Spina Bifida Program. While the Senate version of the fiscal year 2008 LHHs appropriations bill provided \$5.5 million request, the fiscal year 2008 Continuing Appropriations Resolution provided just \$5.198 million for this program. SBA understands and appreciates that the Congress and the nation face difficult budgetary challenges. However, the progress being made by the National Spina Bifida Program must be sustained and expanded 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 advocates that Congress allocate \$7 million in fiscal year 2009 to the National Spina Bifida Program it can continue its current scope of the work and increase its folic acid awareness and Spina Bifida prevention efforts, further develop the National Spina Bifida Patient Registry, and sustain the National Spina Bifida Clearinghouse and Resource Center. Increasing 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 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 are at-risk of having a child born with Spina Bifida and each year approximately 3,000 pregnancies in this country are affected by Spina Bifida, resulting in 1,500 births. As mentioned above, the consumption of 400 micrograms of folic acid daily prior to becoming pregnant and throughout the first trimester of pregnancy can help reduce incidence of Spina Bifida up to 75 percent. There are few public health challenges that our nation can tackle and conquer by three-fourths in such a straightforward fashion. However, we must still be concerned with addressing the 25 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.

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. 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. This public health success should be celebrated, but it is only half of the equation as approximately 3,000 pregnancies still are 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.

SBA is the managing agent for the National Council on Folic Acid, a multi-sector partnership reaching over 100 million people a year with the folic acid message. The goal is to increase awareness of the benefits of folic acid, particular 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 additional funding in fiscal year 2009 these 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 additional funding to CDC to allow for a particular 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 \$7 million fiscal year 2009 allocation for the National Spina Bifida Program, SBA urges the Subcommittee to provide increased funding for the NCBDDD so the agency can enhance its programs and initiatives to prevent birth defects and developmental disabilities and promote health and wellness among people with disabilities.

#### IMPROVING HEALTH CARE FOR INDIVIDUALS WITH SPINA BIFIDA

The mission of the Agency for Healthcare Research and Quality (AHRQ) is to improve the outcomes and quality of health care; reduce its costs; improve patient safety; decrease medical errors; and broaden access to essential health services. The work conducted by the agency is vital to the evaluation of new treatments in order to ensure that individuals and their families living with Spina Bifida continue to receive the high quality health care that they need and deserve—SBA urges the Subcommittee to provide \$360 million to AHRQ so the agency can continue to provide guidance to support the National Spina Bifida Patient Registry.

#### SUSTAIN AND SEIZE SPINA BIFIDA RESEARCH OPPORTUNITIES

Our nation has benefited immensely from our past federal investment in biomedical research at the National Institutes of Health (NIH). SBA joins with the rest of the public health and research community in advocating that NIH receive a 6.4 percent increase (\$30.842 billion) in fiscal year 2009. 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 requests that the Subcommittee include language in the report accompanying the fiscal year 2009 LHHS measure to:



- Urge the National Institute of Child Health and Human Development (NICHD)—expansion of its role—and support of—a more comprehensive Spina Bifida research portfolio;
- Commend the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for its interest in exploring issues related to the neurogenic bladder and to encourage the institute to forge ahead with its work in this important topic area; and
- Encourage the National Institute of Neurological Diseases and Stroke (NINDS) to continue and expand its research related to the treatment and management of hydrocephalus.

## CONCLUSION

SBA stands ready to work with the Subcommittee and other Members of Congress to advance policies that will reduce and prevent suffering from Spina Bifida. Again, we thank you for the opportunity to present our views on funding for programs that will improve the quality-of-life for the 70,000 Americans and their families living with Spina Bifida and stand ready to answer any questions you may have.

PREPARED STATEMENT OF THE STATE ASSOCIATION OF ADDICTION SERVICES AND  
LEGAL ACTION CENTER

State Associations of Addiction Services (SAAS) and Legal Action Center (LAC) appreciate the opportunity to submit testimony on fiscal year 2009 funding for substance abuse prevention and addiction treatment, recovery, and research programs. SAAS is a national organization representing State provider associations and community-based alcohol and drug abuse prevention and addiction treatment programs in 44 States. The mission of SAAS is to ensure the availability and accessibility of quality drug and alcohol treatment, prevention, education, and research programs. LAC is a non-profit law and policy organization that works to expand services for people with alcohol and/or drug addictions, people living with HIV/AIDS, and people with criminal records.

FIELD RECOMMENDATIONS FOR DRUG AND ALCOHOL PREVENTION, TREATMENT,  
EDUCATION AND RESEARCH FUNDING FOR FISCAL YEAR 2009

In partnership with other prevention and treatment advocates, we urge Congress to adopt the following funding levels in fiscal year 2009 for alcohol and drug prevention, treatment, recovery and research programs in the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Education, and the National Institutes of Health. These investments will provide desperately needed services in communities across the country:

- \$1.8587 billion for the Substance Abuse Prevention and Treatment Block Grant
- \$420 million for the Center for Substance Abuse Treatment (CSAT)
- \$215 million for the Center for Substance Abuse Prevention (CSAP)
- \$346.5 million for the Safe and Drug Free Schools and Communities State Grants program
- \$465.5 million for the National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- \$1.0678 billion for the National Institute on Drug Abuse (NIDA)

## CLOSING THE PREVENTION AND TREATMENT SERVICES GAP

According to SAMHSA, in 2006 23.6 million Americans, or 9.6 percent of the population aged 12 or older, needed treatment for an illicit drug or alcohol use problem. Of these, just 2.5 million individuals received treatment at a specialty facility, leaving 21.2 million persons in need of these life-saving services. Over forty percent of those who tried to get help for their addiction were denied treatment because of cost or insurance barriers. Such barriers mean that for many people, Federal- and State-funded programs are the only means available to obtain these critical services.

## ADDICTION CAN BE PREVENTED AND TREATED WITH COST-EFFECTIVE SERVICES

Numerous studies have demonstrated the effectiveness of substance abuse prevention and addiction treatment services in reducing alcohol and drug addiction and use. Addictions treatment has been shown to cut drug use in half, reduce crime by 80 percent and reduce arrests up to 64 percent. Addiction treatment is also sustainable; addictions treatment is significantly associated with a 67 percent reduction in weekly cocaine use, a 65 percent reduction in weekly heroin use, a 52 percent decrease in heavy alcohol use, a 61 percent reduction in illegal activity, and a 46 per-

cent decrease in suicidal ideation one year post treatment. Moreover, these outcomes are generally stable for the same clients five years post treatment.

Prevention activities and strategies have also been shown to be effective in reducing alcohol and drug use and the risk of addiction, and in effecting academic achievement. A recent University of Washington study found that the level of peer substance use in schools has a substantial impact on academic performance; students whose peers avoided substance use had test scores that were on average 18 points higher for reading, and 45 points higher for math. The Center for Substance Abuse Prevention (CSAP) has identified numerous models of prevention programs backed by research findings of effectiveness that empower communities to meet their unique needs.

In addition to reducing drug use, treatment and prevention are cost-effective. According to SAMHSA, for every dollar the U.S. Government spends on addictions treatment it saves \$7 to \$25 in other costs. A number of State studies have also demonstrated the cost-effectiveness of treatment and prevention. One study found that in Ohio, every \$1 spent on addiction treatment saved \$11 in other health care costs. A Washington State study showed a 50 percent decrease in all other medical expenses for those receiving treatment. In addition, a Washington State study of school-based prevention programs found that a number of these programs resulted in a \$70.34 benefit for each dollar of programming spent for each participating young person. These savings resulted from increased productivity and reduced health care, criminal justice, and social services costs.

#### FEDERAL FUNDING IS ESSENTIAL TO PREVENT SUBSTANCE ABUSE AND TREAT ADDICTION

Programs that serve people with alcohol and drug addiction depend nearly exclusively on public funds. According to SAMHSA's recent National Expenditure Report, public funding provides the vast majority of substance abuse expenditures, increasing from 62 percent in 1991 to 76 percent in 2001. Private insurance represented only 13 percent of addiction treatment expenditures in 2001, while it covered 36 percent of all health care expenditures. However, although the alcohol and drug addiction treatment system relies heavily on public funds, an extremely small percentage of health care spending is used for treatment. In 2001, of the \$1.4 trillion spent on health care, an estimated \$18 billion was devoted to treatment of alcohol and drug addiction, constituting just 1.3 percent of all health care spending. In 1998, the total economic costs of alcohol and drug addiction, including medical consequences, lost earnings linked to premature death, lost productivity, motor vehicle crashes, crime, and other social consequences, were estimated at \$328 billion. Expenditures on addiction treatment grew 1.7 percentage points less than the growth rate of all health care.

#### THE CONTINUUM OF DRUG AND ALCOHOL PROGRAMMING MUST BE ADEQUATELY FUNDED

We urge Congress to improve access to, and the effectiveness of, life-saving drug and alcohol services and research by increasing support for the following programs:

##### *\$1.8587 billion for the Substance Abuse Prevention and Treatment Block Grant*

Funding for the Substance Abuse Prevention and Treatment (SAPT) Block Grant, the foundation of the publicly supported prevention and treatment system in this country, has been cut by over \$20 million over the past several years. As the cornerstone of the nation's prevention and treatment system, the SAPT Block Grant must receive increased funding in order to meet current demand and increase access to services. SAMHSA's most recent data indicates that the SAPT Block Grant serves nearly 2 million people every year, providing roughly half of all public funding for treatment services. Over 10,500 community-based organizations receive Block Grant funding from the States. The Block Grant also provides crucial support for the States' prevention programs, designating 20 percent of the total funding for this purpose.

In many local jurisdictions, individuals can wait long periods before they are able to access appropriate drug and alcohol treatment. This access problem is caused in part by the fact that private and public insurance frequently do not cover the cost of treatment and States face unprecedented financial pressures, making treatment funding even more scarce and increasing the importance of the Block Grant. Funding the full continuum of services is extremely difficult for many jurisdictions given the limited amounts of funds that are available, the pressures facing other funding streams, such as Medicaid, and the restricted coverage provided by private insurance. Additional Block Grant funding would help alleviate the pressure on services

and provide greater access to high-quality drug and alcohol prevention and treatment services.

*\$420 million for the Center for Substance Abuse Treatment (CSAT)*

Although the fiscal year 2009 proposes a \$62.8 million cut to CSAT, sustaining and increasing funding for CSAT programming is essential to close the treatment gap. Funding for CSAT's Programs of Regional and National Significance supports States and communities to carry out an array of activities for service capacity expansion, service improvements and other priority needs. These programs are critical in order to ensure that what is learned about addiction through scientific research is effectively shared with the treatment provider community. In addition, funding for CSAT's Capacity category of programming that support services that are tailored to address specific and emerging drug epidemics and/or underserved populations, such as youth, pregnant and parenting women, and communities of color must be strengthened. Unfortunately, under the fiscal year 2009 budget, these programs would be cut by \$48.5 million from last year. These CSAT funds are critical and enable States and regions dealing with emerging needs, such as veterans returning home in need of essential addiction treatment services, to appropriately address them. Another key program we urge support for within CSAT is the Screening, Brief Intervention, and Referral to Treatment (SBIRT) program which helps to link primary care and emergency services providers with treatment programs.

We also support the innovative approaches that SAMHSA has developed to expand the continuum of services offered and the range and capacity of providers. Peer recovery support services, provided through CSAT's Access to Recovery and Recovery Community Services Programs, are integral to recovery-oriented systems of care. We support building on these program's successes, including providing additional support for recovery support services critical to helping individuals stay healthy and drug-free.

*\$215 million for the Center for Substance Abuse Prevention (CSAP)*

Addiction is a disease that begins in adolescence; young people who start drinking before the age of 15 are five times more likely to have alcohol problems later in life than those who begin drinking at age 21 or older. Research by the National Institute on Drug Abuse (NIDA) has shown that if we can stop use and abuse before age 25, we will significantly reduce the prevalence of addiction. Under the proposed budget, CSAP would receive a cut of \$36 million. Prevention efforts are effective in deterring young people from using illicit drugs and alcohol. We strongly support CSAP's Strategic Prevention Framework to promote the use of performance measurement by providers, expand collaboration across community agencies, and support implementation of effective prevention programs at the State and community levels. Unfortunately, the President's request would cut funding for this critical program by \$9.3 million. CSAP's Strategic Prevention Framework is helping communities to promote youth development, reduce risk-taking behaviors, build assets and resilience, and prevent problem behaviors across the life span and needs increased funding to continue and to expand its reach.

*\$346.5 million for the Safe and Drug Free Schools and Communities State Grants program*

The Safe and Drug Free Schools and Communities (SDFSC) State Grants Program is the backbone of school-based prevention efforts in the United States, and supports community-based prevention programming throughout this country. According to recent data, upwards of 37 million youth are served annually by programs funded through SDFSC. The SDFSC program has had a significant impact on helping to achieve the 17 percent overall decline in youth drug use over the past three years, documented by the 2004 Monitoring the Future survey, and is having a significant impact in many States. We strongly urge the subcommittee to support this program and to protect its funding. The President's budget proposes funding of \$100 million for the SDFSC State Grants program, a crippling cut of nearly \$195 million. Cutting the SDFSC program will leave millions of American children without any drug prevention education.

*\$465.5 million for research at the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and \$1.0678 billion at the National Institute on Drug Abuse (NIDA)*

Research into the causes, costs, treatment, and prevention of alcoholism and drug addiction plays an essential role in improving the quality of services. Increasing the support available for research on drug and alcohol addiction would allow future research to focus on additional effective prevention strategies, medications development, and treatment and service delivery throughout the criminal justice system.

NIAAA and NIDA are both taking steps to promote the transfer of new research to practice, including collaboration with SAMHSA, State agencies and providers. Over the past several years, NIDA has made extraordinary scientific advances in understanding the nature of addiction, such as those made through the use of imaging technologies like PET scans, and through the development of the new treatment technologies and medications. Additionally, NIDA's Criminal Justice Drug Abuse Treatment Studies (CJ-DATS) research is designed to improve outcomes for people with substance use disorders by improving the integration of drug abuse treatment with other public health and public safety systems. Research on addiction as a disease has been useful in the development and testing of new science-based therapies. NIAAA also has conducted breakthrough research that has improved clinical practice, with much of this research focusing on the genetics, neurobiology, and environmental factors that underlie alcohol addiction. NIAAA also has sought to use new information about alcohol use to promote education and an effective public health response to this problem.

#### CONCLUSION

Our Nation is spending only a fraction of what is necessary to prevent alcohol and drug abuse and treat addiction—a total of \$18 billion from all sources of funds, compared to social and economic costs estimated well in excess of \$300 billion. Funding appropriated by Congress is the critical foundation for prevention, treatment, education, and research. We urge the Subcommittee to approve the funding levels that we and other organizations in the field have recommended. Thank you for your consideration.

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#### PREPARED STATEMENT OF THE SUSAN G. KOMEN CURE ADVOCACY ALLIANCE

Chairman Harkin, ranking member Specter, and members of the subcommittee: On behalf of the Susan G. Komen for the Cure Advocacy Alliance, I would like to thank you for the opportunity to submit written testimony regarding Federal funding to fight breast cancer. Specifically, I would like to take this time to stress the importance of increased funding for the National Institutes of Health (NIH), including the National Cancer Institute (NCI), and the Centers for Disease Control and Prevention (CDC), both of which play a critical role in finding and delivering the cures for breast cancer. In addition, Komen for the Cure supports full funding for the Patient Navigator Outreach and Chronic Disease Prevention Act of 2005 administered by the Health Resources and Services Administration. As the appropriations subcommittee with jurisdiction over these agencies, we hope you will consider our request.

#### BACKGROUND ON SUSAN G. KOMEN FOR THE CURE

Susan G. Komen for the Cure is the world's largest grassroots network of breast cancer survivors and activists fighting to save lives, empower people, ensure quality care for all and energize science to find the cures. Thanks to events like the Komen Race for the Cure, in its first 25 years, Komen for the Cure invested \$1 billion to fulfill its promise, becoming the largest source of nonprofit funds dedicated to the fight against breast cancer in the world. To continue this progress, Komen for the Cure has pledged to invest another \$2 billion in the next 10 years. In 2007 alone, Komen for the Cure awarded almost \$70 million in community health grants for education, screening and treatment, and more than \$75 million in grants for cancer research. And Komen is on track to award more than \$100 million in research grants this year. But while Komen has had a significant impact on breakthrough research in breast cancer, we can't do it alone. Federal funding for research must keep pace with biomedical inflation and the ever-changing world of science.

In addition to grant-making, Komen has advocated tirelessly for improved access to high quality care for breast cancer patients. We have long been a champion of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), and we successfully advocated for the program's reauthorization last year. But again, we can't do it alone. Successful programs such as the NBCCEDP must be fully funded to allow all women access to the screening and treatment services they deserve.

#### THE IMPORTANCE OF NIH AND NCI FUNDING

Komen for the Cure supports the One Voice Against Cancer (OVAC) request of \$30.81 billion for the NIH in fiscal year 2009. This represents a 6.5 percent increase over the fiscal year 2008 budget. In addition, Komen supports OVAC's request for a 9.5 percent increase in funding for fiscal year 2009 for the NCI (\$5.26 billion). The

NCI funding increase is based on the professional judgment budget (also known as the “by-pass” budget) issued by the NCI and would provide sufficient funding for continuing current services. It should be noted that the appropriation given to the NCI by Congress has traditionally met or exceeded the amount requested in the by-pass budget. Fiscal year 2006 marked the first year that the appropriation dipped below the by-pass budget—we must reverse this trend. In addition, a 9.5 percent increase provides the NCI only with enough resources to continue current services. The Institute has stated that a 25 percent increase would be needed to implement new initiatives. In this context, we believe 9.5 percent is a reasonable request.

Previous investments in research have allowed us to make significant progress toward discovering and delivering the cures for breast cancer. During the “doubling” of the NIH budget from 1998–2003, incredible advances were made in our understanding of the genetic causes of cancer, how to disrupt the growth and spread of cancerous cells without destroying healthy cells, and in the development of diagnostic tools and treatments that can be tailored to an individual or specific type of cancer based on genetic traits. Today, research opportunities abound in both basic and translational settings, including:

- Adult Stem Cell Research*.—Some researchers believe that stem cells (cells that give rise to all cells in the body) are the source of at least some, and perhaps all, cancers. Breakthroughs in adult stem cell research may allow us to develop more effective treatments;
- RNA Interference*.—A technology with the potential to turn off the genes that make cancer grow;
- Nanotechnology*.—Tiny particles can be coated with a special material, and when introduced into the body, these particles may be able to target and kill cancer cells from the inside out;
- Gene Therapy*.—In gene therapy, a specific gene can be transferred into a patient’s cancer cells to make them more responsive to treatment. A gene can also be transferred into a patient’s immune system cells to make them better able to fight the cancer;
- Anti-angiogenesis Drugs*.—Anti-angiogenesis drugs work by preventing tumors from developing new blood vessels, thereby preventing growth of the tumor; and
- Targeted Therapies and Personalized Medicine*.—An ever-expanding list of targeted therapies is making breast cancer treatment more specific and possibly less toxic.

However, many of these promising areas of research will not receive funding if the NIH and the NCI continue to be under-funded. A recent report by a group of concerned universities, “A Broken Pipeline?: Flat Funding of the NIH Puts a Generation of Science at Risk” paints a grim picture for the future of science. Only 24 percent of NIH R01 grants (or equivalents) were funded in 2007, down from 32 percent in 1999. Even worse, only 12 percent of grants were funded on the first submission in 2007, compared to 29 percent in 1999. Scientists spend more time writing than researching. For young investigators, the success rate is particularly difficult—1 in 4 NIH grants is awarded to a first-time grantee. Persistent under-funding at the NIH is costing us a generation of promising young scientists and untold missed opportunities to find a cure for breast cancer. Opportunities we can’t recoup if we do not act now to reverse the downward trend in the NIH budget.

One in eight women will be diagnosed with breast cancer in the course of her lifetime. In 2008, more than 182,000 women will be diagnosed with breast cancer and more than 40,000 women will die from the disease. The burden of breast cancer, and of all cancers, remains enormous. Cancer deaths account for one out of every four deaths in the United States and cost our economy over \$200 billion annually, and yet we spend only \$5 billion at NCI on oncology research. We owe it to all of those affected by this disease, and to their families, friends and loved ones, to adequately fund the NIH and the NCI so that we can find a cure for cancer. We owe it to young investigators who have dedicated their professional lives to cancer research to provide adequate federal funding through the NIH and NCI so they can continue to make innovative breakthroughs in science. And finally, we owe it to the United States, as the global leader of biomedical research to continue to provide increases in funding to the NIH.

#### THE CDC NATIONAL BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM

In addition to an increase in funding for NIH and NCI, Komen for the Cure also requests that Congress appropriate \$250 million for CDC’s National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

The NBCCEDP is designed to reach underserved women to provide screening services for breast and cervical cancer as well as appropriate referrals for treatment

and support services as necessary. In addition to clinical services, NBCCEDP programs develop and disseminate public information about the importance of screening, improve the education, training and skills of health professionals in the detection of breast and cervical cancer, engage in outreach efforts to serve as many eligible women as possible, monitor and evaluate the program, including the quality of screening services, and report certain data to CDC. The heart of the program is to provide screening services to low-income, uninsured, and underinsured women aged 18 to 64 with incomes under 250 percent of the Federal poverty level. The women served are often in at-risk populations and those least likely to be screened. According to the CDC, since 1991, the NBCCEDP has served more than 3 million women by providing more than 7.2 million screening examinations, and diagnosing 30,963 breast cancers, 1,934 invasive cervical cancers, and 101,624 precursor cervical lesions.

The NBCCEDP is an invaluable service to women who are served by the program. There is no cure for breast cancer. Without a cure, early detection is key to survival. Timely mammography screening of women over age 40 could prevent 15 to 30 percent of all deaths from breast cancer—when breast cancer is detected early, while still confined to the breast, the 5-year survival rate is more than 98 percent. However, many low income women are uninsured or underinsured and would never receive a mammogram without access to NBCCEDP services.

From a high of \$210 million in fiscal year 2004, funding for the NBCCEDP has either declined or remained essentially flat for the subsequent years. In fiscal year 2008, the program received only approximately \$200 million, despite an authorization level of \$225 million. Programs are severely strained by the lack of adequate resources—only 14.7 percent of eligible women were screened for breast cancer and only 6.7 percent of eligible women were screened for cervical cancer in 2006. We urge Congress to fully fund NBCCEDP to allow these programs to reach as many women as possible and save as many lives as possible.

#### PATIENT NAVIGATORS

Finally, Komen for the Cure would like to offer support for full funding (\$6.5 million) for fiscal year 2009 for the Patient Navigator Outreach and Chronic Disease Prevention Act of 2005 administered by the Health Resources and Services Administration. The Act authorizes appropriations of \$2 million for fiscal year 2006, \$5 million for fiscal year 2007, \$8 million for fiscal year 2008, \$6.5 million for fiscal year 2009, and \$3.5 million for fiscal year 2010, however no money has been appropriated to date.

Patient navigation services are critical to address barriers to quality cancer care, particularly for minority and underserved patients who often do not speak English, have low literacy skills, are uninsured, and/or live long distances from treatment centers. These patients have difficulty accessing quality care and have trouble coordinating their cancer care, leading to disjointed treatment, inadequate patient-doctor communication, difficulty with follow-up appointments, and poor adherence to treatment regimens. Patient navigators help patients “navigate” the maze of doctors, insurers and patient support groups. For breast cancer patients, a patient navigator can provide personalized education on breast surgery options, chemotherapy, and radiation therapy, as well as facilitating communication with physicians and other health professionals.

Komen for the Cure is committed to ensuring all breast cancer patients have access to a patient navigator if they so desire. To this end, we urge Congress to fully fund the Patient Navigator Outreach and Chronic Disease Prevention Act at \$6.5 million for fiscal year 2009.

#### FUNDING REQUESTS

Thank you for the opportunity to submit this written testimony. To reiterate, our fiscal year 2009 funding requests are as follows:

- NIH*.—\$30.81 billion (6.5 percent increase over fiscal year 2008);
- NCI*.—\$5.26 billion (9.5 percent increase in over fiscal year 2008);
- CDC’s National Breast and Cervical Cancer Program*.—\$250 million.
- Patient Navigator Outreach and Chronic Disease Prevention Act*.—\$6.5 million.

#### PREPARED STATEMENT OF TEANYA DAVIS

##### MY FIBROMYALGIA

My name is Teanya Davis and I have Fibromyalgia. It has taken years to, finally, get a diagnosis to explain what is wrong with me. To this day, I don’t understand

why it took so long to reach that conclusion, all the while, being made to feel “it was all in my head”. The following is my story, in hopes that it will help bring light to the needed research and obvious help we, as sufferers, must have so that we may lead as normal a life as possible with this dreaded syndrome. Please, help us so we can, prayerfully, live a more fulfilling life for our families and ourselves.

I’m going to try to explain what it’s like for me to live with this syndrome so that, hopefully, you will understand me better.

I have spent years (approx. 5) suffering with all kinds of pain and different phenomenon going on with my body, yet, not understanding why. In the same turn, have spent the same being told, or made to feel, “it’s all in my head” and I’m a “hypochondriac”. Being referred from one specialist to another, finding little things here and there, but no real answers to the big problems I’ve been plagued with. Some even going so far as to look at my psychotropic med list and, instantly, write me off as “depressed”.

First of all, who wouldn’t be depressed living with so much going on with their bodies and feeling as though most were writing them off as a hypochondriac, especially, their own family members? But think how it would feel if you knew that, even though you were depressed, you knew the pain wasn’t caused from that; it was the other way around and, yet, you couldn’t get people to understand that.

Picture having blinding headaches (migraines) that hurt so bad, you find yourself worrying when the next one will strike—a debilitating/blinding pain that keeps you from being able to do anything but pray for it to stop. It hurts so much you can’t even cry, fearing your head will explode so, lying motionless, awaiting precious sleep/unconsciousness to take you away and pray you’ll wake to less, or no pain, if you’re lucky.

Picture knowing that, when you walk, you must look like some kind of clown because your hips have an unbearable ache and one of your legs is forever threatening to give way, feeling as though you’re a walking slinky, on top of the further pain that spreads through your back and legs.

Picture the “simple” task of merely sweeping your floor, with every muscle in your body screaming in agony, as you try to remind yourself, “it has to be done” and, “this is not actually causing physical damage, even though it feels like it’s killing me”. And, at the same time, you have to pry your hands open because the muscles have painfully contracted and formed themselves around the broom handle, as they do with about anything else, when held in position for any length of time.

Picture yourself just standing and having a conversation with someone when, all of a sudden, you get a stabbing pain in your lower back that turns into a horrible ache, as you find your muscles are pulling you in the wrong direction (like you’re doing a backbend).

Picture the worst flu you’ve ever had and multiply it by 10, if not more, and imagine someone telling you that the reason you’re vomiting has to be, “because you must have gorged on a meal” or, making you feel guilty because you literally can’t get out of bed, due to the constant ache, fatigue, etc.

Picture yourself trying to do something as simple as sitting to watch a movie and, in a split second, your legs get an almost unbearable ache that’s indescribable, and there’s no way to relieve it, except just wait for it to go away on its own.

Picture being afraid of a mere hug from someone because it actually hurts but, since you want to hug the person, you have to mentally prepare yourself for the pain you know is coming. A simple act you say? For you, yes; for me, I can only wish!

Picture being so exhausted that you could, literally, collapse right where you stand, or even sit (yes, even sitting can hurt). Now, think of having that exhaustion 24/7, while knowing at times it just can’t matter because there are things you have to do, no matter what’s going on with you, even when you feel like you could die and sometimes wish it.

Picture feeling every kind of weird sensation that a body can experience and knowing that there are days you are going to have them all happen at once, or at least in a single day. Anything from twitches that can be so strong, you actually see them; indescribable aches/pains; itching for no reason, except that it feels there’s a hair/feathery-like feeling on your skin; shocking sensations that make you feel like you could wet yourself; finding your hair actually hurts to move it; stabbing, shooting, aching, prickling, tingling, shocking; a really odd sensation I still don’t understand when I find out it’s from the barometric pressure.

Picture talking to someone and feeling frustrated because you’re finding it hard to follow the conversation (not because you’re distracted); you can be looking right into the person’s eyes and, all of a sudden, it’s like they might as well be speaking a foreign language. Also, think of trying to say something and tripping over every word. If you can recall what you were saying in the first place, or mid-sentence. Frustrating for both parties, no?

Picture having times when your chest hurts, in a way that feels like you must be having a heart attack because it spreads through your entire chest, up into your jaw, and down your left arm but you're afraid to say anything, just in case it's not, but wondering if you'll actually die, one of these days, from not knowing the difference.

Now, take all of the above, put them together, and you have my life with fibromyalgia. Yes, I have other health, and emotional, problems but have found this to be the most frustrating factor because there is no "fix". Visualize yourself in my shoes. Even though I, finally, have had a name put to the face of all this, I still feel I have a constant battle, trying to get people to truly understand it. You may say you do but, do you really? If so, why are you still taking it personal when I say I can't go somewhere or do something that, at first, I thought I would be able to do? Why are you still wondering why I was able to do something one moment but not the next, as with days? Why are you judging me, as though I'm being lazy or making things up, "just to get out of things", or making me out to be a hypochondriac?

I didn't ask to be this way! I hate not feeling well, disappointing you, and feeling like a couch potato 90+ percent of the time, feeling inadequate, etc. Please, understand the way I am physically is not the way I am emotionally or psychologically! I need your prayers and encouragement, not judgment or ridicule! The latter only makes me want to withdraw into my own little world and brings more negative thoughts I care to admit, or you'd want to know about. I ridicule myself enough for everyone; I don't need that kind of help.

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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 2009 Labor, Health and Human Services, Education and Related Agencies appropriation measure. We thank you for your consistent support of these programs and trust you will do your best to adequately fund them in the future in order to provide for, and protect the health of many Americans.

#### HIV/AIDS

HIV/AIDS remains one of the world's worst health pandemics in history. Here in the United States, according to the CDC, 984,155 people have been diagnosed with AIDS, and 550,394 people have died. It is estimated there are more than 40,000 new infections in the United States each year, although this number may soon be revised to as high as 55,000 to 60,000. At the end of 2005, an estimated 1.2 million people in the United States were living with HIV/AIDS.

Persons of minority races and ethnicities are disproportionately affected by HIV/AIDS. African Americans, who make up 12 percent of the U.S. population, account for half of the HIV/AIDS cases. HIV/AIDS also disproportionately affects the poor, and about 70 percent of those infected rely on public health care financing.

The AIDS Institute, working in coalition with other AIDS organizations, has developed funding request numbers for federally funded AIDS programs. We ask you to do your best to adequately fund them at the requested level.

We are keenly aware of budget constraints and competing interests for limited dollars. Unfortunately, despite the growing need, several domestic HIV/AIDS programs have experienced cuts in recent years including HIV prevention funding at the CDC and some parts of the Ryan White HIV/AIDS Program.

This year, the President has proposed to cut CDC HIV Prevention even more, and increase Ryan White programs by a mere .004 percent, while cutting some parts of the program. The AIDS Institute asks you to reject these cuts and increase the entire program at the community requested level. Below are the program requests and supporting explanation by The AIDS Institute:

#### CENTERS FOR DISEASE CONTROL AND PREVENTION—HIV PREVENTION AND SURVEILLANCE

[In millions of dollars]

Fiscal year	Amount
2008 .....	692
2009 President's request .....	691
2009 community request .....	1,300



While the CDC has reported for many years the number of new HIV infections in the United States is estimated to be 40,000 each year, they have announced they will release new incidence numbers in the near future in which, according to press reports, indicate the number is more like 55,000 to 60,000. While the current numbers are enough to cause alarm, the new estimates will hopefully convince Congress there is a heightened immediate need for increased funding, rather than additional cuts.

The increase in new infections is particularly occurring in certain populations, such as the poor, African-Americans, men who have sex with men, Latinos, substance users, and the incarcerated. In order to address the specific needs of these populations, CDC is going to need additional funding.

Investing in prevention today will save money tomorrow. Every case of HIV that is prevented saves, on average, \$1 million of lifetime treatment costs for HIV. One recent study concluded the cost of new HIV infections in the United States in 2002 was estimated at \$36.4 billion, including \$6.7 billion in direct medical costs and \$29.7 billion in productivity losses. Another study concluded preventing the estimated 40,000 new HIV infections in the United States each year would avoid obligating \$12.1 billion annually in future medical costs.

Despite the savings of lives and costs that prevention provides, the Congress cut the program by \$3.5 million in fiscal year 2008 and the Administration is proposing to cut it in fiscal year 2009 by another \$1 million. Cuts of greater magnitude have been occurring for actual direct prevention programming while increases have gone for HIV testing. Since one quarter of the over one million people living with HIV in the United States are unaware of their HIV status, The AIDS Institute supports increased testing programs. However, we do not support funding these efforts at the expense of prevention intervention programs.

The administration is also proposing \$30 million to implement the Early Diagnosis Grant Program. The AIDS Institute does not support this request and urges that the money should be directed instead to CDC HIV/AIDS prevention programs.

#### RYAN WHITE HIV/AIDS PROGRAMS

[In millions of dollars]

Fiscal year	Amount
2008 .....	2,167
2009 President's request .....	2,168
2009 community request .....	2,782

The centerpiece of the government's response to caring and treating low-income people with HIV/AIDS is the Ryan White HIV/AIDS Program. Ryan White currently reaches over 531,000 low-income, uninsured, and underinsured people each year.

In fiscal year 2008, the program overall received an increase of \$29 million, although some parts of it experienced cuts. The President has proposed a .004 percent increase for Ryan White in fiscal year 2009, or only \$1.1 million. The AIDS Institute urges you to reject this budget proposal and instead provide substantial funding increases to all parts of the Ryan White Program. Consider the following:

(1) Caseload levels are increasing. People are living longer due to lifesaving medications; there are at least 40,000 new infections each year; and increased testing programs, according to the CDC, will identify 12,000 to 20,000 new people infected with HIV each year.

(2) The price of healthcare, including medications, is increasing and State and local budgets are experiencing cutbacks due to the economic downturn.

(3) 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. A CDC study concluded 212,000 or 44 percent of eligible people living with HIV/AIDS, aged 15–49 in the United States, are not receiving antiretroviral therapy.

Given these factors, cuts in funding or flat or minor increases are unacceptable. 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 urge you to reject the President's proposed cut of \$7.7 million and instead request an increase of \$213 million, for a total of \$840 million.

Part B base provides essential services including diagnostic, viral load testing and viral resistance monitoring and HIV care to all 50 states, DC, Puerto Rico and the territories. We are requesting a \$95 million increase, for a total of \$482 million.

The AIDS Drug Assistance Program (ADAP) provides life-saving HIV drug treatment to over 100,000 people; the majority of whom are people of color (60 percent) and very poor (80 percent are at or below 200 percent of the federal poverty level). Due to a lack of funding, states have not been able to include all necessary drugs on their formularies, have limited eligibility and capped enrollment. In order to address the 386 new ADAP clients each month and drug cost increases, we are requesting an increase of \$134.6 million for a total of \$943.5 million.

Part C provides early medical intervention and other supportive services to over 225,000 people at over 360 directly funded clinics. We are requesting a \$100.5 million increase, for a total of \$299 million.

Part D provides care to over 53,000 women, children, youth and families living with and affected by HIV/AIDS. This family-centered care promotes better health, prevents mother-to-child transmission, and brings hard-to-reach youth into care. We are requesting a \$48.8 million increase, for a total of \$122.5 million.

Part F includes the AIDS Education and Training Centers (AETCs) program and the Dental Reimbursement program. We are requesting a \$15.9 million increase for the AETC program, for a total of \$50 million, and a \$6 million increase for the Dental Reimbursement program, for a total of \$19 million.

The AIDS Institute supports increased funding for the Minority AIDS Initiative (MAI). MAI funds services nationwide that address the disproportionate impact that HIV has on communities of color.

#### NATIONAL INSTITUTES OF HEALTH—AIDS RESEARCH

[In billions of dollars]

Fiscal year	Amount
2008 .....	2.9
2009 President's request .....	2.9
2009 community request .....	3.35

Through the NIH, research is conducted to understand the AIDS virus and its complicated mutations; discover new drug treatments; develop a vaccine and other prevention programs such as microbicides; and ultimately, a cure. The critically important work performed by the NIH not only benefits those in the United States, but the entire world.

As neither a cure nor a vaccine exists, and patients continue to build resistance to existing medications, additional research must continue. NIH also conducts the necessary behavioral research to learn how best HIV can be prevented in various affected communities. We ask the committee to fund critical AIDS research at the community requested level of \$3.35 billion.

#### ADMINISTRATION FOR CHILDREN & FAMILIES: COMMUNITY BASED ABSTINENCE EDUCATION

Efforts to improve prevention methods and weed out non-effective programs should be a constant undertaking and be guided by science and fact based decision-making. It is for these reasons The AIDS Institute opposes abstinence-only-until-marriage programs, for which the President requested a \$28 million increase. While we support abstinence-based prevention programs as part of a comprehensive prevention message, there is no scientific proof that abstinence-only programs are effective. On the contrary, they reject proven prevention tools, such as condoms, and fail to address the needs of homosexuals, who can not marry, and who remain greatly impacted by HIV/AIDS.

#### SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Many persons infected with HIV also experience drug abuse and/or mental health problems, and require the programs funded by SAMHSA. Given the growing need for services, we are disappointed by proposed funding cuts at SAMHSA, including \$63 million for the Center for Substance Abuse Treatment, \$36 million for the Center for Substance Abuse Prevention, and \$126 million for the Center for Mental Health Services. We ask the Committee to reject these cuts, and adequately fund these programs.

## VIRAL HEPATITIS

Viral Hepatitis is an infectious disease that also deserves increased attention by the federal government. According to the CDC, there are an estimated 1.25 million Americans chronically infected with Hepatitis B, and 60,000 new infections each year. Although there is no cure, a vaccine is available, and a few treatment options are available. An estimated 4.1 million (1.6 percent) Americans have been infected with Hepatitis C, of whom 3.2 million are chronically infected. Currently, there is no vaccine and very few treatment options. It is believed that one-third of those infected with HIV are co-infected with Hepatitis C.

Given these numbers, we are disappointed the administration is calling for a decrease in funding for Hepatitis at the CDC. The program is currently being funded at a level that is substantially less than what it was funded in fiscal year 2003 and falls short of the \$50 million that is needed. These funds are needed to establish a program to lower the incidence of Hepatitis through education, outreach, and surveillance.

The AIDS Institute asks that you give great weight to our testimony and remember it as you deliberate over the fiscal year 2009 appropriation bill. Should you have any questions or comments, feel free to contact Carl Schmid, Director of Federal Affairs, The AIDS Institute, 1705 DeSales Street, Suite 700, Washington DC 20036, (202) 462-3042, [cschmid@theaidsinstitute.org](mailto:cschmid@theaidsinstitute.org). Thank you very much.

## PREPARED STATEMENT OF THE TRUST FOR AMERICA'S HEALTH

Trust for America's Health (TFAH), a national non-profit, nonpartisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority, is pleased to provide the subcommittee with the following testimony.

Americans deserve a well-financed, modern, and accountable public health system. As we worry about rising health care costs and continued threats from terrorism or natural threats such as pandemic influenza, resources for public health should be on the rise, not decreasing as proposed in the President's fiscal year 2009 budget. Indeed, the Centers for Disease Control and Prevention's (CDC) budget would be cut by \$433 million, or 7 percent. Almost every program that provides support for prevention and public health at the State and local level would be cut, continuing an alarming trend of disinvestment in the very programs that save lives and reduce long-term health care costs.

## CASE FOR SUPPORT

There is increasing evidence that community level interventions, the kind of programs that CDC funding supports, make a difference in health outcomes and health care costs. TFAH is leading a consensus building initiative entitled, the Healthier America Project. One of the central elements of the Project is to define the financing needs for public health for the next decade. TFAH and the New York Academy of Medicine have convened an expert panel to ascertain the current spending levels by the public health sector. The panel will soon be making a recommendation regarding how much additional funding the United States should invest in public health. TFAH is also working with the Urban Institute and Prevention Institute to develop an economic model that demonstrates the return on investment of certain community-level public health interventions, like physical activity, improved nutrition, or smoking cessation programs, and the corresponding savings by funding source. We hope the results of this model, to be released later this spring, will influence your investment choices as you consider the fiscal year 2009 budget. To help ensure the implementation of effective community-based interventions, Trust for America's Health supports increased funding for a number of programs.

## CHRONIC DISEASES

Chronic diseases, most of which are preventable, account for 70 percent of deaths in the United States and approximately 75 percent of health care spending. Yet the President's budget would cut funding for chronic disease prevention and health promotion by over \$28 million, bringing cuts to over \$100 million in inflation-adjusted dollars since fiscal year 2003.

In the United States, two-thirds of adults are obese or overweight, and the rate of childhood obesity has tripled over the last 20 years. CDC's Division of Nutrition, Physical Activity and Obesity (DNPAO), which provides funding that allows State health departments to develop a nutrition and physical activity infrastructure, has been virtually flat funded over the past 3 years, with only small increases that have

not kept pace with inflation. Similarly, funding levels for the Division of Adolescent School Health (DASH) have actually decreased over the last 5 years. DASH's School Health Program assists States in improving the health of children through a school level program that engages families and communities and develops healthy school environments. To begin to mitigate the obesity epidemic, we need chronic disease prevention and promotion programs in all 50 States. That will require \$65 million for the DNPAO and at least an additional \$20 million for DASH's School Health Program to fund all states that have been approved. Another important anti-obesity program is Steps to a Healthier United States. Steps grants support communities, cities and tribal entities to implement health promotion programs and community initiatives. TFAH supports at least \$30 million for the Steps Program.

#### PREPARING FOR PUBLIC HEALTH EMERGENCIES

In December of last year, TFAH released its annual "Ready or Not" report on our Nation's preparedness. TFAH found significant improvement in State preparedness over prior years. Unfortunately, there are many areas, such as creating medical surge capacity, where we remain woefully under-prepared. That is why we are concerned that the diminished Federal support for an all-hazards approach to preparedness will put the progress we have made at risk.

Funding for the Public Health Emergency Preparedness (PHEP) Cooperative Agreements to States and localities—where public health actually happens—has been drastically cut in recent years. With these funds, local health departments have enhanced their disease surveillance systems and trained their staff in emergency response. Over 90 percent of local health departments have developed mass vaccination and prophylaxis planning, conducted all-hazards preparedness training, and implemented new or improved communication systems. All States have established the infrastructure necessary to evaluate urgent disease reports and to activate emergency response operations 24 hours a day. A recent report by the National Association of County and City Health Officials clearly detailed the impact of recent cuts, with staff time, planning, and acquisitions of equipment and supplies cut by upwards of 25 percent.

Unfortunately, the President's budget proposes another cut, totaling 18 percent, as well as cuts of \$62 million, or over 14 percent, to hospital preparedness funding due to a proposed realignment of grant funding cycles. The primary focus of the Hospital Preparedness Program (HPP) is to improve the capacity of the Nation's hospitals and other supporting healthcare entities to respond to bioterrorist attacks, infectious disease epidemics, and other large-scale emergencies by enabling hospitals, EMS and health centers to plan a coordinated response. TFAH recommends restoring funding for the PHEP cooperative agreements to fiscal year 2005 levels (\$919 million) and providing \$474 million for the HPP.

The President's budget proposes \$250 million for the Biomedical Advanced Research and Development Authority (BARDA). BARDA was established to help jumpstart a new cycle of innovation in vaccines, diagnostics and therapeutics to combat health threats. BARDA provides incentives and guidance for research and development of products to counter bioterrorism and pandemic flu and manages Project BioShield, which includes the procurement and advanced development of medical countermeasures for chemical, biological, radiological, and nuclear agents. TFAH requests \$500 million for BARDA, with 2 years of fiscal availability.

#### PUBLIC HEALTH WORKFORCE

In order to prepare for any public health emergency, it is necessary to have a well-trained workforce. The Office of the Civilian Medical Reserve Corps, located in the Office of the Surgeon General, supports local public health and helps provide for an adequate supply of volunteers in the case of a public health emergency. MRC units are community-based and serve as a way to locally organize and utilize volunteers desiring to prepare for and respond to emergencies and promote healthy living throughout the year. TFAH supports fully funding the President's request of \$15 million for the Office of the Civilian Volunteer Medical Reserve Corps to enable the MRC to award more capacity building grants, which local units use for a variety of purposes, such as purchasing equipment, training, purchasing uniforms and providing salaries for coordinators.

Public health epidemiologists are another important part of our Nation's public health workforce. They investigate and monitor public health threats, identify potential relationships between exposures and disease, provide the foundations for public health interventions, and help combat disease outbreaks. A 2006 national assessment of epidemiologic capacity shows the number and level of training of epidemiologists is perceived as seriously deficient in most States. CDC's training fel-

lowship program for epidemiologists can help expand State capacity and provide future leadership in the field. TFAH recommends providing \$5 million for CDC's Office of Workforce and Career Development to support 65 CDC/Council of State and Territorial Epidemiology (CSTE) first year applied epidemiology fellows.

BOLSTERING THE NATION'S ABILITY TO DETECT AND CONTROL INFECTIOUS DISEASES  
SUCH AS PANDEMIC INFLUENZA

Since 2003, scientists have become increasingly concerned that the H5N1 strain of avian influenza could become more contagious among humans and mutate into a strain against which humans have little or no immunity. H5N1 has infected millions of birds and resulted in 235 deaths in humans, with a human case fatality rate of over 61 percent.

In November 2005, President Bush requested \$7.1 billion over 3 years for emergency funding for pandemic influenza preparedness. In fiscal year 2006, Congress appropriated \$5.6 billion to the Department of Health and Human Services (HHS) for emergency and agency funding for pandemic preparedness. The funding has been used for stockpiling enough antiviral drugs for the treatment of more than 50 million Americans, licensing a pre-pandemic influenza vaccine, developing rapid diagnostics and completing the sequencing of the entire genetic blueprints of 2,250 human and avian influenza viruses.

To enhance our pandemic preparedness, TFAH recommends fully funding the President's fiscal year 2009 request for \$313 million for ongoing pandemic preparedness activities at the CDC, National Institutes of Health (NIH), Food and Drug Administration (FDA) and the Office of the Secretary. TFAH also supports the President's request of \$507 million to be used to build vaccine production capacity, maintain a ready supply of eggs for the production of vaccine, and enable HHS to purchase medical countermeasures for its critical employees and contractors, as well as the Indian Health Service population. The administration has also requested that Congress fund the \$870 million requested by the President in fiscal year 2008 for one-time pandemic preparedness activities, including acquiring vaccine, purchasing antivirals, and accelerating research and development for rapid diagnostic tests. TFAH supports this request.

The one major gap in pandemic preparedness not addressed in the President's budget is funding for States and localities. In April, the Department of Health and Human Services will release the final installment of the \$600 million appropriated in fiscal year 2006 for State and local pandemic preparedness activities. This funding has been used to conduct statewide pandemic influenza preparedness summits, assess and address preparedness gaps, develop antiviral distribution plans, review and update State pandemic plans, and conduct exercises at the State and local levels, including mass vaccination using seasonal flu clinics, school closures and medical surge. These are clearly not one-time activities. We are concerned that these cuts will limit States' ability to continue to conduct exercises. As a result, we urge you to provide \$350 million in recurring, annual funding for State and local pandemic preparedness activities.

ENVIRONMENTAL HEALTH

One final area of interest for TFAH is the connection between our environment and our health. For more than 30 years, the Environmental Health Laboratory of the National Center for Environmental Health has been performing biomonitoring measurements. Biomonitoring is the direct measurement of people's exposure to toxic substances in the environment. By analyzing blood, urine, and tissues, scientists can measure actual levels of almost 300 chemicals in people's bodies, and determine which population groups are at high risk for exposure and adverse health effects, assess public health interventions, and monitor exposure trends over time. Additional funds are needed to upgrade facilities and equipment and to bolster the workforce. Of the suggested \$20 million increase, \$10 million would be used to enhance State public health laboratory biomonitoring capabilities, including upgrading facilities and equipment and bolstering workforce capacity. The remaining \$10 million would be used to provide technical assistance and training to States.

The Pew Commission on Environmental Health in 2000 recommended the development of a Nationwide Health Tracking Network to help track environmental hazards and the diseases they may cause. The Network would coordinate and integrate local, State, and Federal health agencies' collection of critical health and environmental data. Since 2002, Congress has provided funding for pilot programs, funding only 16 States and one city in fiscal year 2007, down from 24 grantees. Since fiscal year 2002, tracking has led to 38 public health actions to prevent or control potential adverse health effects from environmental exposures. In fiscal year 2007, 17

public health actions were completed based on information obtained from tracking. The Tracking Network is scheduled to be launched in 2008. TFAH recommends providing \$50 million for CDC's Environmental and Health Outcome Tracking Network to expand it to 22 new States and support the continued development of a sustainable Network.

Mr. Chairman, thank you again for the opportunity to submit testimony on the urgent need to enhance Federal funding for public health programs which will save countless lives and protect our communities and our Nation.

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#### PREPARED STATEMENT OF THE UNITED TRIBES TECHNICAL COLLEGE

For 39 years, United Tribes Technical College (UTTC) has provided postsecondary career and technical education, job training and family services to some of the most impoverished Indian students from throughout the nation. We are governed by the five tribes located wholly or in part in North Dakota. We have consistently had excellent results, placing Indian people in good jobs and reducing welfare rolls. The Perkins funds constitute about half of our operating budget and provide for our core instructional programs. We do not have a tax base or State-appropriated funds on which to rely. Our program is entirely consistent with one of the stated goals of the U.S. Department of Education's Strategic Plan: access to postsecondary education.

The request of the United Tribes Technical College Board is:

- \$8.5 million or \$1 million above the fiscal year 2008 enacted level under Section 117 of the Carl Perkins Act. These funds are shared by United Tribes Technical College and Navajo Community College.

- \$1 million from Title III of the Higher Education Act (HEA) to continue the infrastructure development of our south campus.

*Authorization.*—Section 117 of the Carl Perkins Career and Technical Education Act (20 U.S.C. section 2327) is the source of authorization of Perkins funding for UTTC. Funding under this Act has in recent years been distributed on a formula basis to UTTC and to Navajo Technical College, neither of which receive funding under the Tribally Controlled Colleges or Universities Act. Funds have been authorized and appropriated by Congress for the program since fiscal year 1991.

*Administration Request.*—Despite the explicit Congressional authorization for Carl Perkins funding for section 117, and despite the administration's requests for funding for section 117 in all previous years, the administration has requested nothing for this program for fiscal year 2009. This crass, outrageous and irresponsible cut, if carried out, would irreparably harm Indian students who often have no other chance for improving their lives but through UTTC and Navajo Technical College. It represents a failure to understand our educational mission, the nature of the populations we serve and contradicts the Department of Education stated goal of access to postsecondary education mentioned above.

Our students are disadvantaged in many ways. They often come from impoverished backgrounds or broken families. They may be overcoming extremely difficult personal circumstances as single parents. They often lack the resources, both culturally and financially, to go to other mainstream institutions. UTTC provides a set of family and culturally-based campus services, including: an elementary school for the children of students, housing, day care, a health clinic, a wellness center, several on-campus job programs, student government, counseling, services relating to drug and alcohol abuse and job placement programs that enable our students to start on the road to realizing their potential.

The administration states that UTTC has other sources of funding to carry out its mission. This is not correct. Our present Perkins and Bureau of Indian Education funds (also cut entirely from the President's fiscal year 2009 budget) provide for nearly all of our core postsecondary educational programs. Almost none of the other funds we receive can be used for core career and technical educational programs; they are supplemental and help us provide the services our students need to be successful. Moreover, these other programs are competitive, which means we have no guarantee that such funds will be available to us in the future. We cannot continue operating without Perkins funds.

*Core Perkins Funding.*—Below are some important facts about United Tribes Technical College which supports our request for \$8.5 million under the Perkins Act. UTTC Performance Indicators. UTTC has:

- An 81 percent retention rate
- A placement rate of 94 percent (job placement and going on to 4-year institutions)
- A projected return on Federal investment of 20-to-1 (2005 study comparing the projected earnings generated over a 28-year period of UTTC Associate of Ap-

plied Science and Bachelor degree graduates of June 2005 with the cost of educating them.)

—The highest level of accreditation. The North Central Association of Colleges and Schools has accredited UTTC again in 2001 for the longest period of time allowable—10 years or until 2011—and with no stipulations. We are also the only tribal college accredited to offer accredited on-line (Internet based) associate degrees.

—More than 20 percent of our students now go on to 4-year or advanced degree institutions.

*The Demand for our Services is Growing and we are Serving More Students.*—For the 2007–2008 year we enrolled 1,122 students (an unduplicated count), nearly four times the number served just 6 years ago. Most of our students are from the Great Plains, where the Indian reservations have a jobless rate of 76 percent (Source: 2003 BIA Labor Force Report), along with increasing populations. The need for our services will continue to increase at least for the next 5 to 10 years.

In addition, we are serving 248 students during school year 2007–2008 in our Theodore Jamerson Elementary school and 252 children, birth to 5, are being served in our child development centers.

*UTTC Course Offerings and Partnerships With Other Educational Institutions.*—We offer 15 vocational/technical programs and award a total of 15 2-year degrees (Associate of Applied Science (AAS)) and (6) 1-year certificates, as well as a 4-year degree in elementary education in cooperation with Sinte Gleska University in South Dakota. We are accredited by the North Central Association of Colleges and Schools for the longest accrediting period provided of 10 years.

*Licensed Practical Nursing.*—This program has one of the highest enrollments at UTTC and results in the greatest demand for our graduates. Our students have the ability to transfer their UTTC credits to the North Dakota higher educational system to pursue a 4-year nursing degree.

*Medical Transcription and Coding Certificate Program.*—This program provides training in transcribing medical records into properly coded digital documents. It is offered through the college's Exact Med Training program and is supported by Department of Labor funds.

*Tribal Environmental Science.*—Our Tribal Environmental Science program is supported by a National Science Foundation Tribal College and Universities Program grant. This 5-year project allows students to obtain a 2-year AAS degree in Tribal Environmental Science.

*Community Health/Injury Prevention.*—Through our Community Health/Injury Prevention Program we are addressing the injury death rate among Indians, which is 2.8 times that of the U.S. population, the leading cause of death among Native Americans ages 1–44, and the third leading cause of death overall. This program has in the past been supported by the Indian Health Service, and is the only degree-granting Injury Prevention program in the nation.

*Online Education.*—We are continuing to create increased opportunities for education by providing web-based and Interactive Video Network courses from our North Dakota campus to American Indians residing at other remote sites as well as to students on our campus. Online courses provide the scheduling flexibility students need, especially those students with young children.

We offer online fully accredited degree programs in the areas of Early Childhood Education, Community Health/Injury Prevention, Health Information Technology, Nutrition and Food Service and Elementary Education. Over 50 courses are currently offered online, including those in the Medical Transcription and Coding program. We presently have 59 online students.

Another significant online course is suicidology—the study of suicide: its causes, prevention and the behavior of those who threaten or attempt suicide. Suicide in Indian country dramatically affects our communities, particularly our youth. According to the IHS, suicide rates in Indian Country are 6–8 times the national rate.

We also provide an online Indian Country Environmental Hazard Assessment program, offered through the Environmental Protection Agency. This is a training course designed to help mitigate environmental hazards in reservation communities.

*Computer Information Technology.*—This program is at maximum student capacity because of limitations on resources for computer instruction. In order to keep up with student demand and the latest technology, we need more classrooms, equipment and instructors. We provide all of the Microsoft Systems certifications that translate into higher income earning potential for graduates.

*Nutrition and Food Services.*—UTTC helps meet the challenge of fighting diabetes in Indian Country through education. Indians and Alaska Natives have a disproportionately high rate of type 2 diabetes, and have a diabetes mortality rate that is three times higher than the general U.S. population. The increase in diabetes

among Indians and Alaska Natives is most prevalent among young adults aged 25–34, with a 160 percent increase from 1990–2004. (Source: fiscal year 2009 Indian Health Service Budget Justification).

As a 1994 Tribal Land Grant institution, we offer a Nutrition and Food Services AAS degree in order to increase the number of Indians with expertise in nutrition and dietetics. Currently, there are very few Indian professionals in the country with training in these areas. Our degree places a strong emphasis on diabetes education, traditional food preparation, and food safety.

We have also established the United Tribes Diabetes Education Center that assists local tribal communities, our students and staff to decrease the prevalence of diabetes by providing educational programs, training and materials. We publish and make available tribal food guides to our on-campus community and to tribes.

*Business Management/Tribal Management.*—Another critical program for Indian country is business and tribal management. This program is designed to help tribal leaders be more effective administrators and entrepreneurs. As with all our programs, curriculum is constantly being updated.

*Job Training and Economic Development.*—UTTC continues to provide economic development opportunities for many tribes. We are a designated Minority Business Development Center serving South and North Dakota. We administer a Workforce Investment Act program and an internship program with private employers in the region.

*South Campus Infrastructure Development.*—The bulk of our current educational training and student housing is provided in 100 year old buildings, part of a former military base used by UTTC since its founding in 1969 and donated to us by the United States in 1973. They are very expensive to maintain, do not meet modern construction and electrical code requirements, are not generally ADA compliant, and cannot be retrofitted to be energy efficient.

As a result, UTTC has developed plans for serving more students in new facilities that will provide training and services to meet future needs. These plans include the development of infrastructure on adjacent land purchased with a donation that will become our south campus. We have received some funds for this project and have the plans in place. We are asking for an additional \$1 million in fiscal year 2009 from Title III of the HEA to be able to continue this work.

Our vision for the south campus is to serve up to 5,000 students. We expect that funding for the entire project will come from Federal, State, tribal, and private sources. Aside from student housing, the first building will be a combined science and administration building.

We cannot survive without the core career and technical education funds that come through the Department of Education. These funds are essential to the operation of our campus. Our programs at UTTC continue to be critical and relevant to the welfare of Indian people throughout the Great Plains region and beyond. Thank you for your consideration of our request.



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