

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES
APPROPRIATIONS FOR 2014

HEARINGS
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
HOUSE OF REPRESENTATIVES
ONE HUNDRED THIRTEENTH CONGRESS
FIRST SESSION

SUBCOMMITTEE ON THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES

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NOTE: Under Committee Rules, Mr. Rogers, as Chairman of the Full Committee, and Mrs. Lowey, as Ranking Minority Member of the Full Committee, are authorized to sit as Members of all Subcommittees.

SUSAN ROSS, JOHN BARTRUM, ALLISON DETERS,
JENNIFER CAMA, and LORI BIAS,
Subcommittee Staff

PART 6

	Page
Health and Human Services Public Health and Research Organizations	1
Addressing Social Security Administration's Management Challenges in a Fiscally Constrained Environment	269
Children's Mental Health	335
Budget Hearing—Department of Health and Human Services	413



Part 6

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WITNESSES

	Page
Clancy, Carolyn M	1
Collins, Francis S	1
Colvin, Carolyn	269
Conway, Patrick	1
Delisle, Deb	335
Frieden, Tom	1
Hyde, Pamela	335
Sebelius, Hon. Kathleen	413
Wakfield, Mary	1



**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, EDUCATION, AND RE-
LATED AGENCIES APPROPRIATIONS FOR
2014**

TUESDAY, MARCH 5, 2013.

**HEALTH AND HUMAN SERVICES PUBLIC HEALTH AND
RESEARCH ORGANIZATIONS**

WITNESSES

**PATRICK CONWAY, M.D., DIRECTOR, CENTER FOR CLINICAL STAND-
ARDS AND QUALITY, REPRESENTING MEDICARE AND MEDICAID IN-
NOVATION**

**FRANCIS S. COLLINS, M.D., PH.D., DIRECTOR, NATIONAL INSTITUTES
OF HEALTH**

**TOM FRIEDEN, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CON-
TROL AND PREVENTION**

**CAROLYN M. CLANCY, M.D., DIRECTOR, AGENCY FOR HEALTHCARE
RESEARCH AND QUALITY**

**MARY WAKEFIELD, PH.D., R.N., ADMINISTRATOR, HEALTH RESOURCES
AND SERVICES ADMINISTRATION**

Mr. KINGSTON. Good morning. I welcome everyone to the first hearing for the year for Labor, Health and Human Services, Education, and Related Agencies. We look forward to a good and vigorous hearing schedule. We will actually, you know, finish up, we think, in April. So we will go at a pretty fast clip. We will have a second hearing this week.

We are starting this hearing without the White House budget. The House budget, of course, has not been passed either, but we are going to go ahead and get to work on it.

We want to have good and nonpartisan hearings. We want to learn all about the agencies, and we want to have a good relationship with the agencies not necessarily always agreeing, but always communicating and there will be a lot of back and forth. And we know that you answer to lots and lots of constituencies, as do we. And so as we are hearing the outside noise and getting all kinds of advice, we will just work together in the best way we can.

I had mentioned to the panelists earlier that we are concerned about reprogramming, making sure that in this tight environment now that there is flexibility but also that we are not over-abusing reprogramming. And we want all the agencies to review programs and propose eliminations in terms of duplications and erring and straying from the normal mission statements, and we will talk more about that during the hearing.

At today's hearing, we will have the panelists from five of the key HHS organizations and those witnesses are Dr. Patrick Conway, Director of the Center for Clinical Standards and Quality and CMS Chief Medical Officer, who is here to represent and discuss the mission of CMS Innovation Fund activity; Dr. Francis Collins, Director of the National Institutes of Health; Dr. Tom Frieden, Director of the Centers for Disease Control and Prevention; Dr. Carolyn Clancy, Director of the agency for Healthcare Research and Quality, who has recently announced she is going to be stepping down in the coming months. I do not know what you will be doing with your time, but I know you will find lots of it after that job. Dr. Mary Wakefield, who is the Administrator of Health Resources and Services Administration.

So this is the first time that we will receive an overview from the full group of you at once. So we are excited about that. And I am looking forward to this.

We will ask you to have your opening statements in 3 minutes. If you have to go a little bit longer, we will go maybe 3 and a half, but that will be about it. And then we will jump into Q&A.

With that, I yield to my good friend and ranking member, Ms. DeLauro.

Ms. DELAURO. Thank you very much, Mr. Chairman. And I am proud to join you here today and obviously welcoming our speakers and waiting for their testimony today.

Just a very, very quick word, and I am going to apologize to the audience for this, but a week ago we had a wonderful gathering with staff and members to get acquainted with what the chairman proposed. And at that time, I was not able to bring any Italian pastry from New Haven, Connecticut, but I have got to say for staff and for the witnesses, there is Italian pastries from the Libby's Bakery on Olive Street in New Haven, Connecticut. To the audience, my apologies. [Laughter.]

Ms. DELAURO. Today we will review the mission and the programs of several of the major health agencies under the purview of the subcommittee. It is my hope that the discussion will serve to demonstrate the irrationality of the budget policies currently being pursued by the House majority. The agencies here today accomplish work that is critical to the health of all of us. This includes the basic medical research by the NIH, the CDC's efforts to detect and control dangerous diseases, HRSA's programs to expand access health care, the Agency for Health Research Quality, AHRQ's, work to improve the quality of health care. It includes the research and the demonstration work at CMS that tries to develop ways of delivering better and more effective health care at the same or lower cost.

Much of the work is vital to the health of the economy. For example, independent of all of the many health benefits, NIH research is vital to maintaining our Nation's leadership in emerging fields like biotechnology. That means good jobs and economic growth. According to one estimate, every dollar invested in the NIH generates well over \$2 in economic activity.

Many of the things these agencies do also help to reduce health-related costs while improving health. For example, AHRQ studies how to deliver health care more effectively, and both AHRQ and

NIH sponsor research into which treatments work best for which patients. CDC supports screening for diseases like cancer and HIV, education and outreach to help people better manage chronic conditions like diabetes and asthma, and efforts to expand immunizations that can prevent serious infectious diseases. HRSA works to expand the availability of primary care in underserved rural and urban communities, care designed to find and treat problems before they become crises. HRSA also works to expand the number of health professionals delivering that primary care in the places that they are most needed.

And despite the importance of these and other missions, the budgets for many of these programs have seriously eroded over the last decade. In many cases, funding has failed to keep up with the costs, and for some programs, funding has been cut in actual dollar terms.

For NIH, the purchasing power of its appropriation has dropped about 16 percent since 2003 after adjustment for rising costs of biomedical research. The number of NIH research project grants has fallen from a peak of just over 37,000 in 2004 to about 34,000 last year. NIH's work alleviates pain and saves lives, which is why we worked together in a bipartisan way to provide the funding that made it the gold standard for biomedical research not only in the United States but in the world. But we are now in jeopardy of ceding that leadership to other countries.

At HRSA, basic health professions training programs have been cut by \$37,000,000 since 2010. That is in actual dollars before any adjustments for costs or need. Discretionary appropriations for health centers are down \$623,000,000, 28 percent since 2010. Thankfully that cut has been offset with funds made available through the Affordable Care Act, but the intended purpose of those funds was to expand sources of primary care, not to backfill for cuts in appropriation for ongoing operations. Adjusted for inflation and population growth, the overall HRSA appropriation has lost \$2,000,000,000 in purchasing power since 2002.

CDC. Discretionary funding is down by more than \$700,000,000 since 2010, including the cuts of \$149,000,000 to chronic disease prevention programs, and \$104,000,000 to programs that improve the capacity of State and local health departments to respond to emergencies.

Under the 10-year caps on discretionary spending that are already in law, it will be extremely difficult to turn this situation around. In fact, before the decade is out, the cuts we have made will take non-defense discretionary spending to the lowest level as a share of GDP on record, and records go back 50 years.

Yet, some people are demanding further reductions in caps which would mean the shortfalls just get worse. And because a majority refused to act last week, we now have sequestration, an indiscriminate 5 percent cut to everything on top of all these cuts that have already been made. The sequester will take another \$1,500,000,000 from the NIH, \$325,000,000 from CDC, and so on. All of this will be bad for the health and the well-being of American families.

I hope our witnesses today will convey to us what their agencies do, why it is important, and how their efforts will be impacted by

all of the cuts that are on the table. I thank you and I look forward to your testimony.

Thank you, Mr. Chairman.

Mr. KINGSTON. Thank you very much.

Mr. Simpson, Ms. Roybal-Allard, do you have any statements?

With that, Dr. Conway.

Dr. CONWAY. Chairman Kingston, Ranking Member DeLauro and members of the subcommittee, thank you for this opportunity to highlight the efforts of the Centers for Medicare and Medicaid Services to strengthen public health. As Chief Medical Officer of CMS and practicing physician and a health services researcher, I am excited to discuss public health and research.

CMS has been focused on improving the quality of health care, keeping beneficiaries healthy, and ensuring payments reward value and excellent care.

While CMS primarily deals with the clinical health care delivery system, a 2010 Institute of Medicine report noted the importance of integrating the clinical delivery system with the public health system. CMS has multiple programs to support this integration. Today I will specifically discuss three areas: new payment initiatives aimed at improving quality while lowering cost; quality measurement and improvement; and data to support research into public health.

Through the Innovation Center, CMS has launched numerous innovative care delivery models designed to improve beneficiaries' health outcomes and reduce costs. The 30-day all-cause readmission rate has dropped from approximately 19 percent or more for many years to 17.8 percent in the last quarter of 2012. This decrease is an early sign that our payment delivery system improvements are having an impact.

In 2012, we launched Medicare Accountable Care Organizations, groups of providers working together to redesign care processes for high quality and efficient care delivery. To date, there are more than 250 Medicare ACO's in operation serving about 4,000,000 beneficiaries in almost every State.

Our Innovation Center is selecting and testing the most promising innovative payment and service delivery models and can expand those that are successful. Some of the models being tested are intended to reduce unnecessary hospital admissions among residents of nursing homes, improve care coordination for beneficiaries with end-stage renal disease, decrease premature births, and incentivize primary care providers to offer high quality coordinated care.

The Innovation Center has also partnered with the CDC to launch the Million Hearts Initiative, which is focused on preventing a million heart attacks and strokes over 5 years. Million Hearts has engaged partners across the Nation. It includes both clinical and community health goals. It has the potential to help Americans live longer and healthier lives.

Next I will discuss quality measurement and improvement. CMS funds numerous initiatives in all 50 States focused on improving the quality and the health of all Americans. Quality improvement organizations are working with physician practices to help these practices improve the health of their patients. Through large-scale

learning networks, QIO's accelerate the pace of change and rapidly spread best practices. Some of the QIO current initiatives include contributing to reductions in hospital-acquired conditions, working with nursing homes to reduce pressure ulcers, and boosting population health by improving the use of EHR's to increase preventive services.

Consistent with the national quality strategy, CMS is implementing quality measures related to population health and prevention across its programs. Examples include influenza and pneumonia vaccination and smoking cessation.

CMS has also launched health care-acquired infection measures in numerous quality reporting and payment programs. AHRQ, under Dr. Carolyn Clancy's leadership, has played a leading role in developing the evidence base and funding quality improvement science on how to decrease HAI's that we have collaboratively scaled nationally. We have benefitted from Tom Frieden and CDC's collaboration on reliable measurement of HAI's, supporting public reporting and links to State and local public health departments. Nationally this work, in collaboration with hospitals and other stakeholders, has led to a greater than 40 percent reduction in central line blood stream infections, meaning thousands of lives saved.

Finally, I will discuss data support research and public health. CMS is providing data to support health services research and the improvement of public health. CMS has launched a new office to provide data to health services researchers, as well as public use files for easy download. CMS has implemented an initiative requiring the provision of claims data to qualified entities across the country for the evaluation of performance and to support transparency efforts.

In conclusion, CMS is taking major steps to help transform the delivery system to achieve the best possible health outcomes for all Americans. While CMS is an agency that primarily deals with the clinical delivery system, we understand that the integration of the clinical delivery system and the public health infrastructure will allow our overall health system to be more effective and efficient and, most importantly, to improve the health of all Americans.

Thank you.

CMS Congressional Testimony
Committee on Appropriations Subcommittee on Labor, Health and Human Services, Education and
Related Agencies
Tuesday, March 5, 2013

Statement of
Dr. Patrick Conway
Chief Medical Officer, Centers for Medicare & Medicaid Services
Director, Center for Clinical Standards and Quality
U.S. Department of Health and Human Services

Chairman Kingston, Ranking Member DeLauro, and members of the subcommittee, thank you for this opportunity to highlight the efforts of the Centers for Medicare & Medicaid Services (CMS) to strengthen public health. As Chief Medical Officer of CMS, a practicing physician, and a health services researcher, I am excited to be here to discuss public health and research. CMS plays a vital role in this area by providing health coverage for 100 million people through Medicare, Medicaid, and the Children's Health Insurance Program. And with health reform and the Health Insurance Marketplaces, we are continuing to improve health care and help ensure health coverage for all Americans. In addition to expanding health insurance coverage, the Affordable Care Act included important reforms to improve the quality of health care for Medicare beneficiaries and lower costs for taxpayers and patients. These reforms include incentives and tools to help providers avoid costly mistakes and readmissions to the hospital that could have been avoided, keep our beneficiaries healthy, and make sure Medicare and Medicaid payments reward excellent care and not simply pay for the services furnished regardless of their value.

While CMS primarily deals with the clinical health care delivery system, a recent Institute Of Medicine Report noted the importance of integrating the clinical delivery system with the public health system.¹ CMS recognizes this need and has multiple programs and activities to support this integration. Today, I will specifically discuss three areas: quality measurement and improvement, data to support research and public health, and new payment initiatives that will improve the quality of health care while lowering costs.

Quality Measurement and Improvement

CMS funds numerous initiatives in all 50 states focused on improving quality and the health of all Americans. Quality Improvement Organizations (QIOs) are working with hospitals,

¹ Institute of Medicine. *For the Public's Health: Investing in a Healthier Future*. April 10, 2010. <http://www.iom.edu/Reports/2012/For-the-Publics-Health-Investing-in-a-Healthier-Future.aspx>

physicians, and other providers across America to help manage and improve the health of all patients. Through large-scale learning networks, QIOs accelerate the pace of change and rapidly spread best practices. Improvement initiatives encourage innovation, respond to community needs, and lead the way to patient-centered care by including an active role for Medicare beneficiaries. Some of the QIOs' current initiatives include contributing to the goal of achieving significant reductions in healthcare acquired conditions; working with nursing homes to reduce pressure ulcers; reducing central-line bloodstream infections; and boosting population health by improving use of electronic health records for care management to increase preventive services like immunizations and cancer screenings.²

The QIOs are helping to improve health outcomes for persons with cardiovascular disease and disease prevention by increasing preventive health services and immunizations. The QIOs provide technical assistance focused on how Electronic Health Records can be used to improve health outcomes for the physician practice's population of patients. CMS includes population health as a dimension of quality consistent with the National Quality Strategy.³ CMS is implementing quality measures related to population health and prevention across its quality and payment programs, from the Physician Quality Reporting System and the Hospital Value-Based Purchasing Program to the Medicare Shared Savings Program. These quality measures are expansive, but include such things as influenza and pneumonia vaccination, preventing hospitalizations for populations of patients, diabetes control, and smoking cessation. CMS has also included healthcare acquired infection measures in its quality reporting programs and programs

² Details about each of these projects is available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/Current.html>

³ 2012 Annual Progress Report to Congress on the National Strategy for Quality Improvement in Health Care. <http://www.ahrq.gov/workingforquality/>

linking quality to payment. Nationally, this work in collaboration with other stakeholders has led to a greater than 40% reduction of central line bloodstream infections.

Data to support Research and Public Health

CMS is providing data to support health services research, reduction of healthcare disparities and improvement of public health across the nation. As a former health services researcher, I know the power of using CMS data to help answer clinical questions that benefit patients. CMS has launched an Office of Information Products and Data Analytics focused on data and information dissemination. This office provides data to health services researchers as well as public use files for easy download. CMS has implemented an Affordable Care Act initiative requiring the provision of Medicare claims data to qualified entities across the country for the evaluation of the performance of providers and suppliers. Currently six qualified entities have been certified to publicly report provider and supplier performance.

New Payment Models

Medicare beneficiaries are already starting to enjoy better quality of care through more innovative care delivery systems designed to improve their health outcomes and reduce costs. For example, we are observing a decrease in the rate of patients returning to the hospital after being discharged. After fluctuating between 18.5 percent and 19.5 percent for the past five years, the 30-day all cause readmission rate dropped to 17.8 percent in the final quarter of 2012. This decrease is an early sign that our payment and delivery reforms are having an impact.

Growing numbers of physicians and other providers are participating in new payment initiatives that reward high quality and lower-cost care. In 2012, we debuted the first cohort of Medicare Accountable Care Organizations (ACOs), groups of providers working together to promote accountability for a patient population and redesigning care processes for high quality and efficient service delivery. To date, more than 250 Medicare ACOs are in operation, available in

almost every state. CMS estimates that these organizations serve about four million Medicare beneficiaries.

Congress created the Center for Medicare and Medicaid Innovation (Innovation Center) to test “innovative payment and service delivery models to reduce program expenditures...while preserving or enhancing the quality of care” provided to those individuals who receive Medicare, Medicaid, or Children’s Health Insurance Program (CHIP) benefits. The Innovation Center is focused on testing new payment and service delivery models, evaluating results and advancing best practices, and engaging a broad range of stakeholders to develop additional models for testing. Congress provided \$10 billion in direct funding for these purposes in fiscal years 2011 through 2019.

The Innovation Center’s mandate gives it flexibility within specified parameters to select and test the most promising innovative payment and service delivery models and expand those that prove successful at reducing program expenditures while preserving or enhancing quality of care. Some of the models being tested by the Innovation Center are intended to reduce unnecessary hospital admissions among residents of nursing homes; improve care coordination for beneficiaries with end-stage renal disease (ESRD); decrease premature births; and incentivize primary care providers to offer high-quality, coordinated care.

The Innovation Center has also partnered with the Centers for Disease Control and Prevention (CDC) to launch the Million Hearts Initiative, which is focused on preventing a million heart attacks and strokes over 5 years. Million Hearts has engaged partners across the nation, including providers, community-based organizations, private sector companies, patient groups, and others, to collaborate to prevent heart attacks and strokes. CMS is working to integrate the goals of the Million Hearts initiative in its quality improvement efforts.

While the work of the Innovation Center tests many payment and service delivery models, these initiatives are only a part of CMS' ongoing efforts to build a health care delivery system that will better serve all Americans.

Conclusion

CMS is taking steps to help transform the delivery system to achieve the best possible health outcomes for all Americans. Increasingly, we are also partnering with our fellow federal agencies and external stakeholders to support improvement of public health and research. While CMS is an agency that primarily deals with the clinical delivery system, we understand that the integration of the clinical delivery system and public health infrastructure will allow our overall health system to be more effective and efficient and most importantly, improve the health of all Americans.

Mr. KINGSTON. Thank you, Dr. Conway.
Dr. Collins.

Dr. COLLINS. Good morning, Chairman Kingston, Ranking Member DeLauro, and members of the subcommittee. This subcommittee has long supported NIH's mission and we are happy to be here with you with our distinguished colleagues this morning.

Our mission is to seek fundamental knowledge and apply it in ways that enhance human health, lengthen life, and reduce suffering.

NIH is the world's leading supporter of biomedical research in the world, investing more than \$30,000,000,000 annually in medical research for the American public. In fiscal year 2012, about 84 percent of NIH's appropriation supported scientists in all 50 States. NIH-funded advances in basic and translational science have fueled a revolution in the diagnosis, treatment, and prevention of disease. Let me share just three of our many stories of success.

First, the mortality rate due to stroke is less than a third of what it was in 1950. Less than a third, and it is still continuing to decline.

Second, since the mid-1990's, U.S. cancer death rates have fallen about 1 percent each year. Each percentage drop saves our Nation an estimated \$500,000,000.

Third, a diagnosis of HIV/AIDS is no longer a death sentence but is now compatible with an almost normal lifespan. In fact, you may have recently seen in press reports (about a very special two-and-a-half-year-old in Mississippi) that HIV/AIDS may even in some instances be curable. With effective prevention and treatment strategies, an AIDS-free generation may truly be within our grasp.

Innovation in medical research not only saves lives, it sparks economic growth, strengthening our global competitiveness. In fiscal year 2011, NIH research supported an estimated 432,000 jobs across the country, and directly spawned more than \$62,000,000,000 in new economic activity.

What is more, discoveries arising from NIH research serve as the foundation for our Nation's biotech and pharmaceutical industries which employ another 7,500,000 U.S. citizens.

But NIH does much more than stimulate our economy. Groundbreaking innovations are now happening at an accelerating and breathtaking pace. Time is short, so I will just mention one.

We just passed through our annual health challenge called influenza. In an average year, the flu claims about 24,000 American lives and costs the U.S. economy about \$87,000,000,000. But it does not have to be that way. The outside of the flu virus, if you look at it under an electron microscope, is studded with these tiny nail-shaped proteins. Current vaccines target the head of the nail which is constantly mutating. So to keep up, a new vaccine has to be produced each year, requiring people to get an annual flu shot. And despite best efforts, the vaccine is not always ideal, and each year many Americans go unvaccinated.

In collaboration with our CDC colleagues, NIH is working on a universal flu vaccine that would protect people against virtually all strains of the flu for extended periods of time. The goal is to teach the immune system to ignore the head and target the stem of that viral protein because that part of the virus remains relatively un-

changed from strain to strain. This would protect us from multiple flu strains and eliminate the need for an annual flu shot. It could also help protect against a future global influenza pandemic. This universal flu vaccine is not science fiction. Early clinical trials are already under way.

In closing, I just want to thank you for holding this hearing, and I welcome any questions the subcommittee members may have.

NIH Congressional Testimony
Committee on Appropriations Subcommittee on Labor, Health and Human Services, Education
and Related Agencies
Tuesday, March 5, 2013

Statement of
Francis S. Collins, M.D., Ph.D.
Administrator, National Institutes of Health
U.S. Department of Health and Human Services

NIH Mission and Facts

Good morning, Mr. Chairman and distinguished Members of the Subcommittee. It is an honor to appear before you today to provide an overview of NIH's critical role in enhancing our nation's health through scientific discovery.

First, I would like to offer my congratulations to Chairman Kingston for assuming leadership of the Subcommittee. I would also like to recognize the new members of the Subcommittee and express my desire to work closely with you in the future. This Subcommittee has a long history of supporting NIH's mission to seek fundamental knowledge about the nature of living systems and apply it in ways that enhance human health, lengthen life, and reduce suffering from illness and disability.

NIH is the leading supporter of biomedical research in the world. NIH-funded basic and translational scientific advances have prompted a revolution in the diagnosis, treatment, and prevention of disease. Due to the significant expansion in scientific and information technologies, we are poised to bring about even more exciting progress in human health and disease prevention. Also, NIH funding has important economic effects that stimulate growth and investment and create high-quality jobs in our communities.

Public Health Impact of NIH Research

Biomedical research funded by NIH has led to new diagnostics, treatments, and prevention strategies that together have improved the public's health and prevented immeasurable human suffering. Let me cite just a few of the benefits of NIH funded research:

- Steady progress in cancer research is paying off. U.S. cancer death rates have been falling about 1 percent each year since the mid-1990s; each 1 percent decline has been estimated to be worth \$500 billion as a result of gains in life expectancy.¹ There has also been extraordinary progress against childhood cancers. The five-year survival rate for the most common type, acute lymphocytic leukemia, is now 90 percent.

- Identification of risk factors for cardiovascular disease, the development of statins, and multiple other NIH-supported advances have resulted in a nearly 70 percent reduction in the death rate from heart attack since 1968.
- Death rates from stroke continue to fall and are now 70 percent below what they were in 1950. The 30 percent of stroke victims who promptly receive the only proven stroke treatment, tPA, show no neurological deficit as a result of their strokes.
- HIV/AIDS, once a death sentence, is now compatible with an almost normal life span. And due to the development of effective strategies for HIV/AIDS prevention and treatment, an AIDS-free generation may be within our grasp.
- Older Americans are not just living longer, they are also staying healthy and active. At age 65, Americans today can expect to live 19.2 more years, which is 40 percent longer than in 1950, and the majority of these adults continue to live without any physical activity limitations, a major improvement in just the past 30 years.

NIH Research is a Powerful Economic Engine

NIH invests more than \$31 billion annually in medical research for the American people.

In our knowledge-based and global economy, innovation in medical research sparks economic growth, high-quality jobs, and better health and quality of life for all Americans. In fiscal year 2012, approximately 84 percent of NIH's appropriation accounted for extramural grants awarded to investigators throughout the nation. Every state, along with almost every congressional district, benefited. NIH applies stringent critical peer review by outside scientists who are experts in a given field to rank the scientific opportunity and quality represented by the research proposals submitted. This intense competition has always ensured that NIH research is of the highest scientific quality.

According to a report released by United for Medical Research, a coalition of scientific advocates, institutions and industries, in fiscal year 2011, NIH-funded research supported an estimated 432,000 jobs all across the United States, enabled 13 states to experience job growth of more than 10,000 jobs, and generated more than \$62 billion in new economic activity.ⁱⁱ

The economic impact of NIH does not end there. It has been estimated that every \$1 of NIH funding generates about \$2.21 in local economic growth.ⁱⁱⁱ Also, discoveries arising from

NIH-funded research serve as a foundation for the entire U.S. biotech, pharmaceutical, and biomedical industries. Long considered the world's leader in innovation, that sector exports an estimated \$90 billion in goods and services annually and employs 7.5 million U.S. citizens.^{iv,v}

I had the privilege of leading the International Human Genome Project, where the return on investment has recently been calculated – and is spectacular. As quoted by the President just three weeks ago, the U.S. government's \$4 billion investment in the Human Genome Project spurred an estimated \$796 billion in economic growth from 2000-2010—a 141-fold return on investment, even after adjusting for inflation.^{vi}

Dramatic as these economic gains are, the main reason the public supports NIH is to advance human health. And the promise of biomedical research has never been greater.

Future Promise, Future Hope

Recent scientific advances have altered the way scientists and clinicians study and treat disease. Consider a disease that strikes many, and is feared by all: cancer. Cancer is not one disease, but a group of diseases characterized by uncontrolled cellular growth and the spread of these abnormal cells. Cancer is influenced by both environmental and genetic factors, and while we are all at risk for developing cancer, the risk increases as we age. In fact, nearly 80 percent of cancers are diagnosed in people over the age of 55.

Advances in treatments have raised the five-year survival rate for all cancers diagnosed in the first decade of this century to 68 percent, up from the 49 percent rate in the 1970s. This improvement in survival reflects both our progress in diagnosing cancers at an earlier stage and our success in developing new treatments. But cancer still inflicts tremendous suffering on our society. It will kill more than 580,000 Americans this year.^{vii}

The hopeful news is that cancer research has utterly transformed our understanding of the disease in the last few years. NIH's commitment to scientific research provides us with a promising therapeutic strategy for a deadly form of lung cancer. Non-small cell lung cancer (NSCLC) accounts for 80 percent of all lung cancer cases and patients, including non-smokers, are often diagnosed at advanced stages of the disease. In August 2011, the Food and Drug Administration granted accelerated approval for crizotinib for the treatment of patients with advanced NSCLC whose tumors have a specific genetic mutation in a gene called ALK as detected by an FDA-approved test. Historically, crizotinib treatment results in a dramatic reduction in tumors, including complete tumor eradication in some cases, but the disease almost always returns. NIH-supported research discovered that mutations in other key genes, such as the EGFR gene, can fuel cancer cell progression after treatment with crizotinib. The National Cancer Institute's Center for Cancer Research is currently testing combination therapies in clinical trials to target both ALK and EGFR mutations. Crizotinib represents how scientists apply knowledge gained from NIH-supported research to develop new therapies.

As our population ages, cancer is just one of the health challenges our nation faces. The number of people afflicted with Alzheimer's disease and other forms of dementia is projected to increase dramatically in the coming decades. Alzheimer's is the most common form of dementia, slowly destroying memory and cognitive ability and eventually even the ability to carry out the simplest tasks of daily life. Although treatment can help manage symptoms in some people, currently there is no cure for this devastating disease. According to the Alzheimer's Association, it costs nearly \$44,000 a year to care for a person with Alzheimer's, adding up to \$200 billion in overall health care costs last year. The annual treatment figure is projected to spike to \$1.1 trillion in 2050.^{viii} We must invest now in the critical research we need

to develop new strategies for diagnosing, treating, and preventing Alzheimer's disease that are both effective and affordable.

Despite these staggering dollar amounts, progress is accelerating toward understanding the pathogenesis of Alzheimer's. In just the last two years, scientists found five new genes associated with Alzheimer's disease, which provides new hope for developing therapies. Scientists have also discovered a genetic mutation that may play a protective role in preventing Alzheimer's disease, providing a natural model of the kind of protection we hope to develop through drug therapy. The use of induced pluripotent stem (iPS) cells derived from patients with Alzheimer's disease is giving new insights into the molecular causes of the disease and providing a powerful new platform to screen drugs without putting patients at risk. And a drug developed for a rare type of cancer has shown dramatic benefit in the best mouse model of Alzheimer's disease, and human trials have just begun. Discoveries like these are not only going to improve the health of Americans, but they will also improve the health of the American economy.

We have never witnessed a time of greater promise for advances in medicine than right now. NIH is prepared to continue our long tradition of leading the world in the public support of biomedical research. Successful development of prevention strategies, diagnostics, and therapeutics will require bold investments in research across the spectrum from basic science to clinical trials, as well as new partnerships between the public and private sectors. With your support, we can promise continuing advances in health, creation of new economic opportunities, and stimulation of American global competitiveness in science, technology, and innovation.

Mr. Chairman and Members of the Subcommittee. I appreciate the opportunity to provide this overview of the NIH mission and contribution to our Nation, and would be pleased to answer any questions you may have.

ⁱ Murphy, K.M., & Topel, R.H. (2006). The value of health and longevity. *Journal of Political Economy*, 114(5), 871-904.

ⁱⁱ Ehrlich, Everett. NIH's Role in Sustaining the U.S. Economy: A 2011 Update, *United for Medical Research* (2012).

ⁱⁱⁱ In Your Own Backyard: How NIH Funding Helps Your State's Economy, *Families USA* (2008).

^{iv} Ehrlich, Everett. An Economic Engine: NIH Research, Employment and the Future of the Medical Innovation Sector, *United for Medical Research* (May 2011).

^v Technology Talent and Capital: State Bioscience Initiatives 2008, *Battelle, BIO, SSTI* (2008).

^{vi} Economic Impact of the Human Genome Project, *Battelle Technology Partnership Practice* (2011).

^{vii} Cancer Facts & Figures 2013, *American Cancer Society* (2013).

^{viii} 2012 Alzheimer's Disease Facts and Figures, *Alzheimer's Association* (2012).

Mr. KINGSTON. Thank you very much.

Dr. Frieden.

Dr. FRIEDEN. Mr. Chairman, Ranking Member DeLauro, members of the subcommittee, thank you so much for this opportunity to discuss CDC's unique role working 24/7 to protect Americans from health threats. I am honored to be Director of the CDC at a time of both particular vulnerability and the crucial window of opportunity for health progress.

CDC is at the forefront of finding and stopping the spread of threats to health, whether they are things like Ebola or antivirus or emerging problems in this country. We respond to emergencies, including by deploying resources within hours, as we did for Superstorm Sandy.

CDC also provides childhood vaccines, many of them developed through NIH's research. This program has been a stunning success saving millions of lives and billions of dollars. Each year we estimate that the childhood vaccines we give prevent 42,000 deaths, save more than \$13,000,000,000 in health care costs, and return nearly \$70,000,000,000 to the economy.

Because we have worked to find these disease outbreaks where they emerge and stop them before they spread, we invest heavily in supporting State and local entities. And in fact, most of our budget goes to support work in your communities. We have staff in all 50 States and funding to all 50 States.

To give you two examples of this, during the deadly listeria outbreak in 2011, it was CDC's supportive work at the Colorado Health Department that identified the listeria in cantaloupe, which had never been found before, within days, got the product off the shelves. And we know that even a slight delay could have doubled what was already one of the most deadly outbreaks that we have seen.

Similarly, last year, we had a fungal meningitis outbreak which has now affected more than 700 people and killed 48. That infection was identified first by a CDC-trained epidemiologist in Tennessee working with her CDC-funded staff to identify the problem. It was then identified in the laboratory in Virginia by a staff person who had been trained by CDC. We at CDC had our laboratorians, who are state-of-the-art scientists, work around the clock to develop a PCR test for this rare infection. We have done about 1,000 of them. We also worked with health departments in 23 States to inform 14,000 patients that they had been exposed, and we convened daily conference calls to give doctors the best advice that they could have to take the best possible care of their patients. The result was fewer serious infections, fewer deaths, lower health care costs, and a lot of suffering avoided.

Microbes evolve in minutes, and we at CDC work to keep pace with them using scientific breakthroughs such as analyzing the microbial genome to find outbreaks sooner and stop them earlier. Most U.S. health care costs are spent treating preventable conditions. CDC promotes evidence-based prevention initiative as the most effective, common sense way to improve health and reduce health care costs.

Most of the information you see about the health status of the U.S. comes from CDC. We have a unique role in definitive health monitoring used by doctors, businesses, insurers and others.

We also prevent health threats that begin overseas from reaching our borders. The movie “Contagion” was fiction, but in real life, our scientists and disease detectives have investigated more than 1,000 outbreaks and identified at least five new organisms in recent year. These outbreaks include organisms that are resistant to just about all antibiotics such as extensively drug-resistant tuberculosis and organisms that kill most of the people they infect like hemorrhagic fevers.

CDC is unique. No other organization in the world has our capacity to detect and respond to outbreaks. No other organization in the world leads an interconnected global network at the cutting edge of health security with disease detectives in labs to keep people safe from food-borne illness, bio-security threats, and other health threats.

In sum, CDC puts science into action to saves lives today, prevent illness tomorrow, and increase our productivity. I am honored to work at CDC.

I am happy to answer your questions.

CDC Congressional Testimony
Committee on Appropriations Subcommittee on Labor, Health and Human Services, Education and
Related Agencies
CDC 24/7: Keeping Americans Healthy, Safe and Secure, and Competitive
Tuesday, March 5, 2013

Statement of
Thomas Frieden, M.D., M.P.H.
Director, Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

Good morning, Mr. Chairman, Congresswoman DeLauro, and other distinguished Members of the Subcommittee. It is a pleasure to appear before you as Director of the Centers for Disease Control and Prevention (CDC), the nation's leading health protection agency and an operating division of the Department of Health and Human Services. Today I would like to focus on how CDC works 24 hours a day, 7 days a week with boots on the ground protecting Americans from health threats.

CDC's mission is to keep Americans safe, healthy and secure. CDC leads an interconnected network around the country and the world to: put science into action to save lives and money; stay on the cutting edge of health security; and protect our communities by supporting state and local health departments to investigate and control life-threatening diseases.

Working to Provide Health Security 24/7

CDC helps save lives 24/7 by preventing, detecting, and controlling the growing risks of new infectious disease outbreaks, emerging infectious diseases, drug resistant bacteria, and natural and man-made hazards and disasters. We provide emergency response support, technical expertise, and critical rapid development of prevention technologies, including vaccines and other medical countermeasures. CDC's laboratory capacity, and its support to state and local health departments, were critical elements in the response to the recent multistate fungal meningitis outbreak, as CDC was able to quickly identify rare and obscure pathogens and provide added capacity to the states. During the peak of the outbreak, CDC's fungus laboratory was operating 7 days a week to test the hundreds of samples so we could provide timely critical guidance to medical professionals and the public. This outbreak also underscored the role of CDC to protect our nation's health and the pressing need to invest in new bioinformatics and genomics technologies that can more rapidly detect, respond to, and control large outbreaks.

CDC's state-of-the-art laboratories are critical to our nation's safety and health. We capitalize on that excellence by having diagnostic capabilities available close to the source of an outbreak -- which means more rapid detection and response. For this reason, CDC supports and trains a network of

geographically distributed public health labs. These local, state, and global public health labs form a national disease detection tracking network to identify, track and respond to disease outbreaks and other health threats as quickly as possible. For example, CDC's PulseNet is a national lab network which "fingerprints" the DNA of bacteria that cause foodborne illnesses. CDC and other local public health labs use this evidence to quickly identify and stop outbreaks. Just think about the difference between the U.S. *listeria* outbreak, which was identified in cantaloupes in Colorado in less than 12 days leading to a rapid national recall, versus the *E. coli* outbreak in Europe, lingering for months, sickening thousands during the long search for the culprit, and crippling some agricultural markets.

The crucial data CDC and its state and local partners gather allows the public, clinicians, health plans, and policy-makers to make rapid decisions based on objective evidence. CDC's systems help identify our Nation's health priorities, providing hard evidence of what works and what doesn't. As a science-based agency, CDC data are used to guide decisions that protect Americans and prevent illness.

CDC is also home to our nation's Epidemic Intelligence Service (EIS). These disease detectives undergo a unique 2-year learn-by-doing program in the practice of applied epidemiology. This corps of highly trained health professionals responds at a moment's notice to emerging threats and disease outbreaks across the country and around the world. Most recently, EIS officers were dispatched to multiple states including Michigan, Indiana, and Tennessee to investigate and control the 2012 multistate fungal meningitis outbreak. That outbreak underscored CDC's ability to track down and solve urgent threats in concert with local public health authorities.

CDC focuses on low-cost, high-impact, sustainable programs such as building a public health workforce that is prepared, diverse, and flexible. CDC assigns fellows for the Public Health Associate Program (PHAP) to serve on the frontlines of public health in state and local public health departments. More than 50% of the PHAP fellows have stayed in the public health field, and CDC places 600 or more staff in health departments at any given time. More importantly, health departments around this country

could not provide basic services to protect Americans without CDC's expertise and support – in fact, about two thirds of all CDC appropriations are sent to State and local entities to detect, control, and prevent health threats in every State in the United States.

Our response to diseases such as influenza, salmonella, hantavirus, HIV, and fungal meningitis outbreak are highly visible ways CDC protects the public from health threats. But it's often what the public does not see every day that keeps American's safe from ever-present health threats. CDC plays a pivotal role in our country's ability to respond to potentially catastrophic events such as pandemics, natural disasters, and acts of bioterrorism by ensuring that state and local public health systems are prepared for public health emergencies. CDC operates the Public Health Emergency Preparedness (PHEP) program, which provides approximately \$700 million annually to 50 states, four localities, and eight U.S. territories to strengthen their abilities to respond to natural or man-made health threats. This was the funding State and local governments used to prepare for and respond to the health effects of Superstorm Sandy. Additionally, CDC is responsible for the nation's Strategic National Stockpile (SNS), a distributed national repository of medical countermeasures. The SNS contains antibiotics, antiviral drugs, chemical antidotes, antitoxins, vaccines, life-supporting medications, and medical supplies that are made available to state and local health departments within 12 hours of a public health emergency. CDC also maintains a 24/7 command center for emergency response to public health threats here and abroad. Since its inception in 2001, the Emergency Operations Center has responded to more than 50 public health emergencies, including many natural disasters and foodborne outbreaks.

Keeping the Home-front Safe through Global Health Security

Diseases and disasters know no borders; we are all connected by the air we breathe, the water we drink, and the food we eat. CDC scientists and disease detectives are deployed globally 24/7 because outbreaks that start in remote corners of the world can travel here as quickly as a plane—or a bird—can fly. Detection and response time is critical. The most effective and most cost-effective way to protect

Americans from health threats that begin overseas is to stop them before they reach our borders. The foundation for CDC's global health engagement is technical rigor and expertise, strong partnerships, and enhanced disease tracking and laboratory networks around the world. From 2006 to 2012, CDC's global disease detection network responded to 1,134 disease outbreaks, and discovered five pathogens that were new to the world. During that time, CDC helped detect, track, and respond to major health threats that started abroad but threatened U.S. citizens—including Ebola, Marburg virus disease, plague, the cholera outbreak in Haiti, and the earthquake and tsunami in Japan and the subsequent nuclear radiation.

Keeping America Competitive Through Improved Health

CDC plays another critically important role in protecting Americans from the leading causes of death and disability. CDC applies life-saving solutions that work to drive down the incidence of costly diseases and improve the lives of Americans. Many of today's greatest opportunities for improving health fall outside the traditional health care system. CDC is at the epicenter of a public health system which empowers people to live healthier, longer, more productive lives with lower health care costs. From folic acid to prevent birth defects, to preventing senior falls, we support individuals and communities with tools to protect themselves from health threats. This not only improves health but also increases economic competitiveness by creating a more competitive workforce.

For example, the United States sustains economic costs of over \$80 billion annually, and U.S. businesses endure over one hundred million workdays lost due to the flu alone. To reduce this crushing burden on our economy, CDC develops effective strategies for employers to promote seasonal flu vaccination. These science-based and low cost strategies have been shown to dramatically increase vaccine participation among employees which can lead to a healthier and more productive workforce.

Beyond the workplace, CDC leads community-based prevention efforts to improve health and reduce chronic diseases such as heart disease, cancer, and diabetes, which account for 75% of the \$2.7 trillion in health care costs spent in the United States each year. Together with state and local partners,

CDC develops tests, and implements practical, scalable solutions that are building healthier communities. For example, to better address heart disease and stroke, the first and fourth leading causes of death, CDC, CMS, and private-sector partners, launched the Million Hearts initiative, which brings together communities, health systems, nonprofit organizations, and private-sector partners from across the country to prevent 1 million heart attacks and strokes by 2017 by scaling up proven community and clinical strategies.

Challenges in a 24/7 World

In the next few years, CDC and our nation will face ongoing and new challenges in protecting our health security in a time of fiscal constraint. We must accurately detect disease threats, whether natural or man-made, and respond effectively and quickly. We must also ensure that CDC is able to protect Americans from the leading causes of death and disability that weaken our economic productivity and global standing. CDC has already received more than \$750 million in cuts to its base appropriation since fiscal year 2009. Cuts to CDC's budget impact state and local operations, and their ability to detect and respond to life threatening diseases. We take very seriously our role as stewards of public funds. We have streamlined our administrative operations, contracts, and business services, and continue to look for innovative ways to maximize the funding we receive. I hope to engage in a dialogue with you all today—and after the 2014 budget is released—so we can discuss the health security of the nation and how CDC will continue to save lives and protect America from health threats. Thank you for your continued support of CDC's important work to serve this nation, and I am happy to answer any questions.

Mr. KINGSTON. Thank you, Dr. Frieden.

Dr. Clancy.

Dr. CLANCY. Good morning, Chairman Kingston and Ranking Member DeLauro, and members of the subcommittee. I am very pleased to be here to discuss the role that AHRQ plays in creating a health care system in which the care provided is consistently safe, high quality, and affordable.

AHRQ is the only Federal agency whose sole mission is improving health care. AHRQ supports research that builds a solid evidence base on how to make care safer and of high quality. We work with our partners, which include providers, patients, hospitals, States, and other Federal agencies like my distinguished colleagues, to get these lessons implemented into practice.

For example, today we are releasing a report identifying the top 10 patient safety strategies ready for immediate use. This report provides a clear road map for high priority areas where the health care system is failing, and these 10 strategies, if widely implemented, have the potential to vastly improve patient safety and save lives.

Today I would like to highlight our efforts related to health care-associated infections. AHRQ supports practical studies to help eliminate infections in the real world. We translate this research into practical solutions that have saved lives and lowered health care costs. For example, an AHRQ-funded project had very gratifying results, and Dr. Conway mentioned a moment ago how that had been scaled up, courtesy of the Innovation Center. But in our project the over 1,100 intensive care units nationwide that implemented this program achieved a 41 percent reduction in the rate of these deadly infections, saving over 500 lives and avoiding more than \$36,000,000 in excess costs. Neonatal ICU's saw a 58 percent reduction in these infections, avoiding 41 infant deaths and more than \$2,000,000 in health care costs.

So our research helps the health system where the rubber meets the road by outlining how to spread and implement proven methods of infection prevention and on the impact prevention efforts.

Two other unique areas for us in patient safety include work to support the development and use of health care teams. Health care professionals often speak of teams metaphorically. In fact, they have had no training in how to do that. And this training has now literally been part of every military health care facility worldwide and a vast number of civilian hospitals in this country. The other area is in the use of simulation to make care safer. Everyone should be able to have a surgical or other procedure without having to think about am I the first person here, confident that their clinician has been well trained and practiced in a laboratory.

Armed with critical information from the Centers for Disease Control about these infection rates and AHRQ's practical evidence-based solutions to reducing these infections, CMS has used payment incentives to help establish a new normal for hospitals and other settings. My colleague, Jonathan Blum from CMS was here speaking to the Senate last week about the tangible results that Medicare patients have seen right now.

Ensuring that patients are not harmed when they receive health care services is a shared goal among AHRQ and its sister agencies,

and we each play specific but interrelated roles in making sure that happens. Each piece of the puzzle needs to be completed and connected for health care to improve.

Mr. Chairman, thank you again for inviting me to discuss AHRQ's efforts to make health care safer. I appreciate this opportunity and look forward to answering any questions.

AHRQ Congressional Testimony
Committee on Appropriations Subcommittee on Labor, Health and Human Services, Education
and Related Agencies
Tuesday, March 5, 2013

Statement of
Carolyn M. Clancy, M.D.
Director, Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services

Good morning, Mr. Chairman and members of the committee. I am very pleased to be here to talk about public health and research and the important and unique role that the Agency for Healthcare Research and Quality (AHRQ) plays in creating a high quality, safe, and affordable health care system.

In 1999, the Congress directed AHRQ to work with health care providers and other key partners to build the foundation to make care safer. AHRQ is the only federal agency with the sole purpose of improving health care.

AHRQ supports research that builds a solid evidence-base to help health care providers and patients understand what approaches work best to make care safe and high quality. AHRQ then works with its partners – such as physician groups, hospital organizations, states, and other Federal agencies — to translate the research into practices that health care providers can adopt. This isn't a simple task because no two states or health systems are alike, and sometimes practices that work in one facility are difficult to replicate in other settings. However, we can help health care providers improve their performance by identifying examples where systems are providing quality and safe care, figuring out what accounts for their success, and determining which practices can be adapted in other settings and how. AHRQ then helps institutions implement solutions to make health care not only safe but also more responsive to patients' needs.

For example, AHRQ today released a report identifying the top 10 patient safety strategies ready for immediate use. These 10 strategies, if widely implemented, have the potential to vastly improve patient safety and save lives in U.S. health care institutions. The strategies are rigorously evaluated so we know that they work.

AHRQ also oversees rich data resources such as the Medical Expenditure Panel Survey and the Healthcare Cost and Utilization Project. The Agency's direct access to this data enables AHRQ to rapidly provide answers to pressing questions from those on the frontline of our health care delivery system. Moreover, providers have confidence in AHRQ products and they understand that the agency provides evidence-based information that they can use in everyday practice. This puts AHRQ in an ideal position to accelerate the adoption of evidence-based care. AHRQ-supported research can also help providers make a business case for high quality care. AHRQ also arms patients with the information they need to demand high-quality services from their providers and choose treatment options wisely. When physicians and patients have information on what works best, they are empowered to choose what's best for them.

Reducing Healthcare-Associated Infections

AHRQ focuses on many different areas to improve the quality and care in our health care system. I would like to discuss a specific example of our work—our efforts to reduce deadly healthcare-associated infections—and how we are working across the Department to reach our shared goals.

AHRQ supports studies on interventions to help eliminate health care infections in hospitals. Many of our studies take place in the health care setting—in hospitals or outpatient departments instead of controlled environments—which allows us to understand how infections start and spread, and helps us move promising discoveries quickly into actual practice to prevent infections. Further, since this research is being conducted in health care facilities, we know that solutions to the problem are not theoretical—they actually work in practice.

Within our patient safety research budget, AHRQ has deliberately increased funding for comprehensive safety programs to prevent healthcare-associated infections. AHRQ invests in this program because of its outstanding return on investment in terms of deaths prevented and excess costs saved.

To illustrate this point, AHRQ supported a landmark study promoting ways to prevent central line-associated blood stream infections – one of the more common health care-associated infections. This program was first shown to be effective in reducing these infections in the more than 100 Michigan intensive care units in 2004-2006. With the success in Michigan, AHRQ launched this program nationwide. The results of the project are extraordinary in terms of saving lives and dollars: The 1,000 or more ICUs in 44 states, the District of Columbia, and Puerto Rico that implemented this program achieved a 41 percent reduction in the rate of these deadly infections, preventing more than 2,100 cases, saving over 500 lives, and avoiding more than \$36 million in excess costs.

In addition, a separate component of the project found a 58 percent reduction in the same infections in neonatal ICUs. Frontline caregivers in 100 NICUs in nine states relied on the program's prevention practice checklists and rigorous communication training that was customized it to the unique needs of NICUs to prevent an estimated 131 infections and up to 41 deaths and to avoid more than \$2 million in health care costs.

As part of the national expansion of the infection prevention program, AHRQ has been working intensively with hospitals in a number of states. In one example, NorthCrest Medical Center in Springfield, Tennessee, adopted the AHRQ-funded program to reduce central line bloodstream infections and has experienced great success – reducing its infection rate to zero and maintaining it there.

This joint effort by AHRQ, CDC, and HHS is showing significant progress nationally toward the benchmarks set in the National Action Plan to Prevent Healthcare Associated Infections. Early this month, CDC released new state and national HAI estimates on progress toward HAI prevention, including a 41 percent reduction in central-line associated bloodstream infections from 2008-2011. Data indicate that steady progress is occurring towards the HHS Action Plan goal of a 50 percent reduction in central line-associated bloodstream infections over the course of five years.

Relationship with Other Public Health Agencies

As I pointed out, AHRQ plays a unique and crucial role in supporting innovative research that will build a solid evidence-base to help health care providers and patients understand what approaches work best in making care safer and of high quality. Our research focuses primarily on the application and implementation of practices, such as studies on the effectiveness of combinations of infection control interventions, where the rubber meets the road, on ways of spreading and implementing proven methods of infection prevention, and on the impact of prevention efforts. As I noted, many of these studies take place in clinical settings.

Conclusion

Ensuring that patients aren't harmed when they receive health care services is a shared goal among AHRQ and its sister agencies, and we each play specific, but interrelated roles in making that happen. Each piece of the puzzle needs to be completed and connected for improvement to take place.

AHRQ works to implement what we know from research to prevent, mitigate, and decrease patient safety risks and hazards, and quality gaps associated with health care and their harmful impact on patients. AHRQ's goal is to improve the quality, safety, efficiency, and effectiveness of the health care system itself, in order to help ensure that America's \$2 trillion investment in health care can be the most effective, highest value, and best aligned with the needs of all Americans.

Mr. Chairman, thank you again for inviting me to discuss AHRQ's work in public health and research, and to highlight for you, our work on reducing deadly healthcare-associated infections. I appreciate this opportunity and look forward to answering any questions.

Mr. KINGSTON. Dr. Wakefield.

Ms. WAKEFIELD. Thank you, Mr. Chairman and Ranking Member, for the opportunity to highlight the important work of the Health Resources and Services Administration.

While some may not be familiar with HRSA, they nevertheless often know about the organizations that we support in their local communities and States. They know, for example, their local community health center, their colleges' health care workforce training programs. They might know about the poison control centers that are called in emergencies, among other programs that we support.

Across the Nation in every State and in almost every congressional district, more than 3,100 local nonprofits, faith- and community-based organizations receive HRSA grants that enable them to provide health care to millions of people to train the next generation of health care providers and to maintain and even strengthen the health care safety net.

HRSA's investments in communities and States are important, both for the people who are served and for local economies. For example, our funding to community health centers enables 8,900 primary health care clinics to provide care to more than 20,000,000 people. And health centers are also important local economic engines, employing more than 138,000 people from doctors and dentists to medical assistants and receptionists.

On another front, the number of National Health Service Corps clinicians has increased to an all-time high, providing health care in some of our most underserved urban and rural areas. Today, nearly 10,000 corps providers are impacting the health of over 10,000,000 patients and in the process impacting the economic health of the communities where they work.

Many of HRSA's programs are a lifeline for some of America's most vulnerable people. Funding through the Ryan White Program means that more than half a million people with HIV/AIDS have access to lifesaving services.

We support the Nation's Organ Procurement and Transplant Network, and Congress has given HRSA the extraordinary challenge to help meet growing demands for this gift of life.

And HRSA's support of maternal and child health programs has helped reduce infant mortality in the United States.

HRSA's investments also seed local innovations that can grow to improve health across the Nation. For example, in terms of training, Texas A&M's nursing school is using funds to help veterans build on their military training and move more swiftly into health careers, and we are working to expand those training initiatives. And rural communities are using HRSA's outreach grants to support approaches like mobile dental clinics to reach more people who do not have access to oral health care.

Finally, across all of HRSA's programs, we are working to implement new ways to improve the quality of our agency's work, from developing new tools for fiscal monitoring and oversight to using the latest technologies to educate both our staff and grantees on fraud and waste.

Thank you again, Mr. Chairman, for the opportunity to speak about our programs and I welcome questions.

HRSA Congressional Testimony
Committee on Appropriations Subcommittee on Labor, Health and Human Services, Education
and Related Agencies
Tuesday, March 5, 2013

Statement of
Mary Wakefield, Ph.D., R.N.
Administrator, Health Resources and Services Administration
U.S. Department of Health and Human Services

Mr. Chairman and members of the Committee, thank you for the opportunity to meet with you today on behalf of the Health Resources and Services Administration (HRSA). HRSA is the health care safety net agency, charged with ensuring access to high-quality primary care. HRSA's mission is to improve health and achieve health equity through access to quality services and a skilled health care workforce. There are approximately 80 different programs authorized in statute and operated by HRSA

Across these programs, HRSA's mission is carried out by about 3,100 grantees that are located in every state and U.S. territory. HRSA funds grant activities through a variety of mechanisms and then works to make sure they are carried out following both the program intent as determined by Congress and strong program integrity and effective management practices. Let me briefly give you a snapshot of what HRSA does to improve access to health care services primarily for people who are low income, medically vulnerable, and geographically isolated.

First, I would like to provide an overview of two programs that support the delivery of health care services; the Health Centers program and the Ryan White HIV AIDS program. Our Health Center programs are community-based, patient-directed organizations that deliver primary and preventive care. In addition to serving more than 20 million patients at nearly 8,900 service delivery sites around the country, these centers are also an integral source of local employment and economic growth in many underserved and low-income communities. For more than 45 years, health centers have delivered comprehensive, high quality, cost-effective primary health care to patients regardless of their ability to pay. During that time, health centers have become an essential primary care provider for America's most vulnerable populations. Health centers advance the preventive and primary care medical home model of coordinated, comprehensive, and patient-centered care. They coordinate a wide range of medical, dental,

behavioral, and social services, often making all of these services available at one location. Important to note is that nearly half of all health centers serve rural populations. Recognizing that barriers to health care take various forms, as necessary, health centers also provide a variety of supportive and enabling services that promote access and quality of care, including patient case management, outreach, patient education, language translation, and transportation services. Many of these centers are involved not only in their primary mission of delivering patient care but also serving as sites where health care providers are trained.

The second health care service delivery program that I want to mention is the Ryan White HIV/AIDS Program. The Ryan White program supports 900 grantees that provide top-quality primary medical care, essential pharmaceuticals, and vital support services to more than half a million people impacted by HIV/AIDS; that is about half of the estimated total population in the U.S. living with the disease. In the United States, people living with HIV are, on average, poorer than the general US population, and Ryan White HIV/AIDS Program clients are poorer still. For these individuals, the Ryan White Program is the payor of last resort because they are uninsured or have inadequate insurance and cannot cover the costs of care on their own, and because no other source of payment for services, public or private, is available. Currently, HRSA is orienting our HIV/AIDS work to support the goals of the President's National HIV/AIDS Strategy, announced in July 2010. The Strategy has three primary goals: 1) reducing the incidence of HIV; 2) increasing access to care and optimizing health outcomes; and 3) reducing HIV-related health disparities.

In addition to our health center and HIV/AIDS programs, HRSA also considers our work with special populations and elimination of health disparities a top priority. A key piece of this work focuses on maternal child health programs are the Maternal and Child Health Block Grants

to States that help 6 out of every 10 women who give birth and their infants. The states use funds from the Block Grant to improve access to health care, promote care quality, provide care coordination for pregnant women, infants and children, ensure that children with disabilities and chronic conditions receive the special services they need, and support a wide range of targeted activities to improve maternal and child health in their states, such as reducing infant mortality. This effort has contributed to a steady decline in infant mortality in the U.S. for 4 years straight.

HRSA administers a number of other critically important health care programs that collectively touch the lives of millions of people across the country. These include supporting the 57 Poison Control Centers and national programs for Countermeasures and Vaccine Injury Compensation, and federal organ and blood stem cell transplantation, as well as efforts to promote awareness and increase organ donation rates.

Some of our programs specifically support health services delivery in geographically isolated communities. The HHS Office of Rural Health Policy, housed within HRSA, serves as the Department's primary voice on rural health issues. The Office funds a number of state and community-based grant and technical assistance programs to help meet the health care needs of rural communities.

As I noted earlier, in addition to focusing on health care services, HRSA also has a priority focus on supporting the education, training, and distribution of a highly skilled primary care workforce through health professions training, curriculum development, and scholarship and loan repayment programs. HRSA's efforts support a diverse and culturally competent primary care workforce that can deliver high quality, efficient health care. With respect to our efforts to improve distribution, I want to point out that HRSA also is expanding training in underserved areas, including rural areas. Because of the much higher proportion of primary care shortage

areas in rural compared to urban areas, for instance, HRSA supports grants focused on expanding rural residency training. We think these are important investments, in particular since studies have shown that high proportions of medical residents stay to practice in or very near the areas where they trained.

Across this country, the nearly 10,000 National Health Service Corps (NHSC) clinicians, are providing care to more than 10.4 million people who live in rural, urban, and frontier communities. The NHSC repays educational loans and provides scholarships to primary care physicians, dentists, nurse practitioners, physician assistants, behavioral health providers, and other primary care providers who practice in areas of the country that have too few health care professionals to serve the people who live there. Employed by local rural health clinics, community health centers, and other primary care sites, NHSC clinicians work every day to treat illness or injury, to keep people healthy and to prevent them from getting sick. As a result of historic investments by Congress and the Administration, the numbers of clinicians in the NHSC are at all-time highs. These investments in the NHSC make a lasting impact, with more than four out of five NHSC clinicians continuing to serve in high-need areas even after their obligation is over.

In addition to the NHSC, HRSA offers loan repayment and scholarships to nurses who work in community health centers, rural health clinics, hospitals and other types of facilities currently experiencing a critical shortage of nurses. As a result of these investments approximately 3,000 registered nurses, nurse practitioners, and other advance practice nurses are working in communities where they are needed most, compared with a nursing field in these areas of approximately 1,000 in 2008.

In addition to deploying these and a number of other programs, HRSA takes seriously our stewardship responsibilities for the funds awarded to grantees in communities across the nation. Over two years ago, HRSA began developing and implementing a number of new strategies to ensure the integrity of the programs we operate and use of tax dollars. For example, we have increased and optimized the use of site visits as tools for program and financial monitoring, and produced webcasts to educate grantees and staff on priority subjects such as identifying fraud, waste, and abuse.

What we do at HRSA is accomplished through collaboration with partners in each community and at all levels of government. The synergies between HRSA's activities and our many partnerships are leveraged between our programs – such as community health centers and HRSA workforce programs, state and community partners. To see what HRSA is doing in your state or district, you and your staff can visit HRSA.gov, a resource that allows you to see specifically the focus of HRSA's work in your state and your district.

HRSA will continue its efforts to strengthen the safety net by expanding and enhancing primary care services, the number and quality of primary care health professionals, services for low-income individuals and people with HIV/AIDS, health services for mothers and children, and targeted health professions training. HRSA will also continue to work in partnership with other federal entities, State and local governments, private organizations, and Members of Congress to strengthen access to care and thus improve the health and lives of millions of Americans. Thank you again for providing me the opportunity to share HRSA's mission with you today. I am pleased to respond to your questions.

POLIO ERADICATION

Mr. KINGSTON. Thank you very much, and I thank all of you for being prompt and quick.

The only thing I am very disappointed about is my friend, Tom Frieden, did not brag about the polio success, and if you know those stats off the top of your head or if you have somebody who can get them out, I think it would be good to share with the folks real quick. I think it is something that really is a modern miracle that we are taking for granted, and it is the work of CDC and Rotary International and so many other people.

Dr. FRIEDEN. In 1988, CDC and three other partners led an effort endorsed by the World Health Organization to eradicate polio forever. At that time, there were about 350,000 cases per year. That is about 1,000 a day. Polio eradication activities have benefited from the support from Rotary International which has generated more than \$1,000,000,000 in support, as well as supporting the programs around the world. UNICEF and WHO have been critical partners, and CDC has spearheaded this for the U.S.

What we have seen is that last year there were just a little over 200 cases, the fewest there have ever been in the fewest districts of those countries. And a couple of years ago, India got over the finish line through an enormous effort and has not had a case in more than 2 years. So we are closer than ever to polio eradication. Cases only remain spread in Nigeria, Pakistan, and Afghanistan.

Mr. KINGSTON. A great success story.

END OF LIFE CARE

Dr. Conway, I wanted to ask about—and I am not sure that this comes directly into your sphere of control and study, but on end of life, what percentage of the Medicare budget is spent in the last 3 months or 2 months of a patient's life? Do you know? I have heard it is very high.

Dr. CONWAY. So I will have to get back to you with an exact number. The percentage on end-of-life care is significant in the last 12 months of life. I believe around 20 to 25 percent. We will get back to you on an exact number on that. And other colleagues may jump in.

I think at CMS I would highlight that we are committed to high quality care. We are committed to engaging patients and families in decision-making. In our quality programs, we increasingly have quality measures around patient and family care just to make sure we meet the goals of patients and families.

Mr. KINGSTON. And I think what my question would be when you get back to me is the living will. What is the correlation between having a living will and not spending as much and spending a lot not having a living will and what are the impacts of it? So if that comes under your silo, that would be very helpful.

Dr. CONWAY. Yes, sir. We will have to get back to you with the specifics on that.

[The information follows:]

Dr. CONWAY: Yes, sir. In CY 2011, spending in the last six months of life represented about 17% of total spending in Medicare Parts A and B. CMS does not track utilization of living wills by beneficiaries.

Mr. KINGSTON. Okay.

HEALTH SERVICES RESEARCH

And then I have a general question for all of you. In terms of the health services research, NIH has that under its jurisdiction and has had about a 58 percent increase in budget authority since 2008 on it. And yet, AHRQ spends \$400,000,000 on it, and CMS Innovation Fund and CDC all have components of health services research in it. So there is overlap, and how much of it is duplicative? How well do you coordinate, and how committed are you in terms of, okay, if you are doing that, we will do this? We both can join in the middle. But for the time being, we do not all have to be on a parallel track spending dollars doing the same thing.

Dr. COLLINS. Thank you for the question. I will start and others, no doubt, will want to pitch in.

I do think you raise a very important question. Obviously we are critically interested in discovering which kinds of interventions are actually going to produce the best outcomes in real-world situations. NIH's role in this generally is to conduct large-scale, randomized clinical trials to assess what works and to be able to get that information in front of caregivers and the public.

So take, for instance, the question about atrial fibrillation, a common form of a cardiac arrhythmia where there have been serious questions about exactly what is the right approach. Is this something where you should try to convert this using some sort of electrical shock? Should you just basically treat with anticoagulants in order to reduce the risk of stroke? NIH is in the position to then conduct a randomized trial where individuals are assigned to one of those outcomes by their full informed consent and try to see on the large scale what the outcomes look like. But those are very carefully controlled situations. Patients need to be free of other kinds of complicated features, otherwise we are not sure we are getting a clear answer.

On the other hand, AHRQ—and Carolyn Clancy no doubt will want to talk about this—will conduct broad-scale analysis of all of the many studies that have been done in this space to try to see if you put those all together, many of those observational, not necessarily interventional, can you draw conclusions in that regard.

CDC has a critical role working with the States and the public health agencies to try to then implement whatever seems to be best practices.

We have been working closely with CMS in the last year and a half, meeting every quarter with their senior staff, to look at ways that the Innovation Center can also step in here.

So I think we are actually working pretty closely together. It is a very complicated landscape in terms of this kind of research.

Mr. KINGSTON. Dr. Clancy, unfortunately, we are running out of time. So we will get back to you on it.

Dr. CLANCY. If I could just make one point on our budget, if anyone is spending a nickel that we might have spent, we make sure that we find out about it.

Mr. KINGSTON. Good.

Ms. DeLauro.

Ms. DELAURO. Thank you very much, Mr. Chairman.

And I would just say to all of you, you just continue to—and I listened to your testimony—reinforce what my view was all along, that the agencies that you head up and what you are charged with, quite frankly, is giving the gift of life. And for that, we are so grateful for the work that you do.

SEQUESTRATION

As you know, the President implemented the sequestration order. He was required to do that by the Budget Control Act. What I would like to do is to ask the directors of NIH, CDC, and HRSA what actions will you be required to take as a result of the across-the-board budget cuts. What effect will there be on your ability to carry out your agency's missions? Dr. Collins, if you could begin.

Dr. COLLINS. Certainly. So the sequestration order results in a 5 percent cut to our fiscal year 2013 budget already now well into the fiscal year, total dollars, \$1,545,000,000 that are now not going to be available for support of research. And of course, we are concerned about that for this year. We are particularly concerned about that in the sense that there is a potential that this could go on for as long as a decade, and then you could compound the consequences of this.

There are many consequences, but if I could just mention the one that worries me the most. It is the impact on young scientists who are looking at this circumstance and wondering whether there is a career path for them. In a situation where your ability to get funded by the NIH, which is the main source of medical research in this country, has been already getting deteriorated over the course of the last 10 years so that now an applicant has only one chance in six of getting funded, that will drop further as a result of the sequester. And if you are a person in high school or college and you are looking at medical research as a career and you are seeing those statistics, how many of those folks will be able to stick it out? And how many of the ones that are already in training careers are going to get exhausted by the frustration and decide to do something else? That is our seed corn. It has been the strength of America. It is the biomedical research community, their creativity, their innovative instincts, and we are putting that at serious risk as we see this kind of downturn in the support for research.

Ms. DELAURO. Dr. Frieden.

Dr. FRIEDEN. The threats to our health are not decreasing by 5 percent. So the cut of 5 percent in CDC's budget means that we will have roughly \$300,000,000 less. About two-thirds of our dollars go out to State and local entities. They are already, as one health commissioner describes it, at the breaking point which through State and local reductions, there are 45,000 fewer staff working at that level. That means our support will be able to provide assistance to State and local entities to hire perhaps as many 2,000 fewer disease control experts, disease detectives. We will have less money for flu, less money for HIV, less money to protect our children through things like fluoridation, autism research, asthma prevention, and decreased ability to detect and respond to outbreaks. This will cut our outbreak control staff by more than \$12,000,000, and also a decreased ability to keep us safe from global threats be-

cause we will have to cut back on our work in other countries to find threats before they come to our borders.

Ms. DELAURO. Dr. Wakefield.

Ms. WAKEFIELD. So the overwhelming amount of money that HRSA receives is then used to support grants that go directly out to local communities and the States. We have 80-plus programs and that 5 percent cut will be taken across each of those programs, policies, and activities. That is the requirement. So each one will have a 5 percent cut.

You can look at the impact in any one program, but I will just give you one example. Our ADAP program, AIDS Drug Assistance Program, as part of our Ryan White Program, will see a cut to that program as a result of the rescission of about \$45,000,000. That will mean that the ADAP program can serve about 7,400 fewer patients.

We could not tell you right now, because we are still working on the numbers, what States would be impacted or where this might then drive up waiting lists. But what I can tell you is that since 2011, the fall of 2011, that was sort of our high water mark. The waiting list to get on the ADAP program across States had really peaked to about 9,300. And do you know just within the last couple of months, we have gotten that waiting list down to 63 people. That is it in two States. And so now what is going to happen is likely we will see that waiting list start to expand, go that direction again. What will happen then in local States? Well, States are going to have to scramble. Case managers will have to scramble to try and find patient assistance programs that will be able to accommodate those patients. And that means that those costs then will be shifted to manufacturing, drug manufacturing companies, et cetera to try and provide those resources, pharmaceutical resources, for those patients.

That is just one example. But cuts proportionate to each one of our programs.

Ms. DELAURO. Thank you very much for the time.

Mr. KINGSTON. Mr. Simpson.

Mr. SIMPSON. Thank you, Mr. Chairman.

And I thank all of you for being here today. This is the first time I have ever seen where we have five doctors. It is kind of intimidating for all of us to have all these doctors on the panel.

But I have several questions that, as you might expect, deal with dentistry to some degree but I am not going to ask most of those because they deal with the budget that is not out yet, so we do not have a chance to do that. I have been to most of these places, but I will tell you for any of the Members of Congress that want to see what Government does and does right, they need to get out to some of these agencies and see what goes on. I have been out to NIH several times. It has been a couple years since I have been there. I need to get back out there because it is just awe-inspiring what goes on in these programs.

And I would be remiss if I did not thank Dr. Frieden for maintaining the oral health division as we have talked about over the last couple years. It has been one of your smallest divisions, but they obviously play an important role in dentistry.

PHS EVALUATION FUNDS

Now, let me turn to a question with several statements to start with. The HHS Secretary is authorized to tax or as HHS refers to it, “tap” PHS Act-authorized programs up to 1 percent of their appropriation in order to conduct program evaluations. The administration has requested language to increase the tap over time.

The fiscal year 2013 budget we can talk about because it was last year—the budget request attempted to take tap to 3.2 percent, or \$1,300,000,000 of the resources. The House bill reduced tap to the authorized level of 1 percent last year.

The public perception is that NIH received \$30,600,000,000 in fiscal year 2012 and that NIH is using \$30,600,000,000 for biomedical research. But because NIH is subjected to the tap, over \$700,000,000 was shifted to other activities within HHS outside of NIH, in essence allowing HHS to count the funds twice. In fact, the fiscal year 2013 President’s budget request, once adjusted for tap increases, actually proposes to cut NIH by about \$250,000,000. So NIH would have only about \$29,600,000,000 last year to spend on biomedical research under the President’s proposal.

In addition, HHS recently began to expand its definition of what programs are subject to tap to include mandatory programs which effectively results in the conversion of mandatory funds to discretionary funds. The intent of this authority is to provide the support for program evaluations.

I know in fiscal year 2012, CDC received over \$370,000,000 of tap funding while AHRQ received \$400,000,000 in tap funds.

Can you explain to me how much of these funds are actually going to program evaluation and how much of them are going to expanded programs? And why does it need to be 3.2 percent, as requested by the administration, as opposed to the 1 percent which decreases the amount we are actually spending on research?

Dr. CLANCY. So it is my understanding, Mr. Simpson, that the actual tap is something that was a decision made by the Congress, which is why AHRQ is funded out of that tap. I am less familiar with—

Mr. SIMPSON. At 1 percent.

Dr. CLANCY. And AHRQ has had a significant proportion of its budget funded by that 1 percent tap since 2003 and even before 2003, since the agency was created in 1989, and since 2003, it has been all of the evaluation tap.

Frankly, this has not been our decision. Our commitment has been to make sure that American taxpayers get the best value and return on that investment.

Mr. SIMPSON. Could you tell me how much of those funds are actually in program evaluation?

Dr. CLANCY. Well, what I can tell you is that almost every study that we invest in—about 80 percent of the money goes out the door to universities, to research firms, and so forth—is actually evaluating various aspects of how health care is delivered and how we could make it better. So I think to some extent that depends on the definition of program evaluation.

Dr. FRIEDEN. The resources that are used from the evaluation funds at CDC include the National Institute for Occupational Safe-

ty and Health, the National Center for Health Statistics, and some of the basic surveys that all of HHS benefits from. So, for example, our National Health and Nutrition Examination Survey receives funds from many other parts of the Federal Government and coordinates that work so that we do not have to do it in multiple places but can get definitive information that the entire Government can use to evaluate programs.

Mr. SIMPSON. Is the 3.2 percent requested in the last budget request by the administration a necessary increase, or is the 1 percent sufficient? And will the sequestration affect the tap funds or not?

Dr. CLANCY. Yes, it will.

Mr. KINGSTON. The gentleman's time has expired.

We have now been joined by the ranking member, Ms. Lowey, and we would like to yield the floor to you.

Mrs. LOWEY. Well, thank you very much, Chairman Kingston and Ranking Member DeLauro. This is one of my most favorite places to be because of all the good work you do, and I have had the opportunity to interact with so many of you and I thank you. And I remember when we first were looking at the genome map and it was blank, and now it is just extraordinary. So thank you, thank you. I am in awe of your commitment and your hard work. Thank you.

As we listen to the testimony, I hope that all of the members contemplate the impact to our communities. Extramural grants fund groundbreaking research, and as Dr. Collins will testify, every \$1 of the NIH funding generates \$2.21 in local economic growth. In 2011, the CDC obligated more than \$473,000,000 in funds to public health initiatives throughout New York, nearly three-quarters of which was for vaccines for children and infectious disease programs. These are vital services that this subcommittee has responsibility to support.

But one of the best ways for me to illustrate the importance of the work that is led by our witnesses is to examine HIV programs. This weekend doctors announced that 2-year-old child born with HIV and treated with the antiretroviral drugs in the first days of life no longer has detectable levels of the virus, despite not taking HIV medication for 10 months. The two pediatric experts who led the research received funding from the NIH.

Dr. Frieden and I have had numerous conversations about CDC's significant efforts on HIV both at home and abroad.

HRSA is another leader through the Ryan White Program which provides medical care, pharmaceutical support services to more than 500,000 Americans living with HIV/AIDS.

And while AHRQ strives to improve health care for all, CMS—I know we get tired of these acronyms, but it saves a couple of minutes—

[Laughter.]

Mrs. LOWEY [continuing]. Provides coverage to tens of thousands of Americans with HIV/AIDS.

Each agency plays an important but distinct role in our fight against this terrible disease, and these are services that need greater investments, not cuts.

This is one of many reasons why I hope my colleagues and I will pass a balanced solution to prevent the full impact of sequestration.

Thank you. Thank you to our witnesses. I am so appreciative. And I just want to say in closing—oh, I have got 2 minutes. Okay. [Laughter.]

Mrs. LOWEY. I do want to say in closing I was in a meeting with several of our major hospitals in the New York metropolitan area, and they were talking to me about how critical are the hundreds of millions that they get in research. And I just want to emphasize again it is not just the research that is saving lives. Whether it is cancer, whether it is autism, whether it is Alzheimer's or heart disease—we can go on and on—these are jobs. And when you see what the sequester will do—it is estimated—and we cannot be fooled because it is a slope, not a cliff—that it will cost us 750,000 jobs. This research, these investments is economic development in our future. So I just wanted to emphasize that.

BIOMEDICAL RESEARCH

And perhaps it would be helpful if you share with us how we, the United States of America—and I always feel we are the beacon of hope to the world. How long have we been leaders and will we continue to be leaders? And what investments are other countries making in biomedical research? I apologize that I missed the statements. So I will go on to the next question if they answered that. Would you like to tell me about that in a minute, 20 seconds?

Dr. COLLINS. I will tell you a quick story. I am honored to serve as the chairman of a group, a rather informal one, called the Heads of International Research Organizations. It is the major supporters of biomedical research around the world. We get together every 6 months. It is sort of group therapy, but it is also an opportunity to talk about our dreams and our hopes and what our various countries are doing. And when we go and sit around the table and I hear from South Korea, and I hear from China, and I hear from India, I hear from Germany, I hear from the United Kingdom, from Brazil about how they are ramping up their support of biomedical research because they have read our playbook and then it comes to me and I say, well, I hope maybe we could be flat this year, they are shaking their heads. They are wondering what happened. You are supposed to be the country that leads us forward. We are learning from you. Surely you must be able to do something to support this kind of economic growth as well as health.

Mrs. LOWEY. Thank you.

Mr. KINGSTON. It is hard to stop you. We are just trying to stay on track.

Ms. Roybal-Allard, you are next. And I want to make sure everyone knows I am trying to do this in the order of arrival.

NEWBORN SCREENING

Ms. ROYBAL-ALLARD. Welcome to all of you.

I would like to direct my first question to Dr. Wakefield. Congressman Simpson and I have worked together for many years to promote strong standards in newborn screening, and we are cur-

rently preparing to introduce a bill to reauthorize the Newborn Screening Saves Lives Act that was signed into law in 2007.

As you know, the Newborn Screening Act codified the Advisory Committee on Heritable Disorders in Newborns and Children to help address the vast discrepancy between the number and quality of State screening tests. The committee's recommended standards of newborn screening has led to lifesaving treatments and interventions for at least 12,500 newborns diagnosed with genetic and endocrine conditions each year.

Congressman Simpson and I are very concerned by HRSA's plan to disband the Secretary's advisory committee in April. Pompe's disease was scheduled to be evaluated by the advisory committee in May. Including a treatable disease on the panel's list for newborn screening could save approximately 100 babies who otherwise would die before their first birthday.

Dr. Wakefield, I have a series of questions. I want to try and get them all in and see if you can respond to them.

First, as a nurse, can you briefly highlight the value of this advisory committee?

As Director of HRSA, can you tell us what will happen to the review of diseases such as Pompe's disease if the committee is disbanded in April?

Does HRSA have an alternative plan to address future lifesaving screening tests if the committee no longer exists to make recommendations?

And third, Congressman Simpson and I are working to pass a reauthorization bill this year, and in the meantime, will you use the authority of the Secretary of HHS under the Public Health Service Act to extend the committee charter?

Ms. WAKEFIELD. Sure. Thank you very much for that question.

As you indicated, the Newborn Screening Act needs to be reauthorized at the end of April, and the Secretary's Advisory Committee on Heritable Disorders sunsets without that reauthorization. So what we are doing is going ahead and moving up more quickly a meeting that will occur before that sunset in April so that they can continue their work on Pompe's disease, as you had mentioned that specific illness.

We highly value and hold in high regard the expertise of the national experts that come from across the United States to do that really important work of the Secretary's Advisory Committee on Heritable Disorders. So it is critically important.

What we are doing right now is to look at the options that we have available should that law not be reauthorized and should that committee be sunsetted. We are looking at our internal options and working through them right now.

Ms. ROYBAL-ALLARD. The question is as we are working to reauthorize the bill, will the Secretary use her authority under the Public Health Service Act to extend the committee at least until a decision has been made and we are able to pass that bill.

Ms. WAKEFIELD. We have had a lot of conversations about using that authority internally and we are absolutely looking at that option and looking at how that could be done. I could not give you specifics because we do not have them yet. But we are looking at that vehicle as a possibility to extend that committee. We abso-

lutely are exploring that option right now, working with counsel and so on. I have been involved in those meetings myself.

Ms. ROYBAL-ALLARD. I know you know this, and I understand that some of the decision is based on cost savings. But it would come at a cost of both human suffering, lives lost, and future costs that would be incurred in having to take care of those that are affected by these newborn diseases.

Ms. WAKEFIELD. To your point, we do not have another source of this type of information. It is a critically important source of experts to us.

Ms. ROYBAL-ALLARD. What I will do is I will just yield the rest of my time and ask my questions in the second round. We will have second rounds, Mr. Chairman?

Mr. KINGSTON. Yes.

Ms. ROYBAL-ALLARD. Yes.

Mr. KINGSTON. Thank you.

Mr. Joyce.

Mr. JOYCE. Thank you, Mr. Chairman.

I appreciate you all being here today.

BIOMEDICAL RESEARCH WORKFORCE

Dr. Collins, I have heard you express your concern about the future of biomedical scientists going forward. I was wondering what NIH is doing to ensure that we have an adequate supply in the next generation of biomedical scientists and what we are doing to ensure that we have advanced the translational and clinical research that they are doing.

Dr. COLLINS. Thanks. I appreciate the question.

We recently conducted, over a period of about a year and a half, a fairly detailed analysis of the state of the biomedical research workforce and particularly the way in which young scientists are coming to join us. It is clear that there is great interest out there in young people who are seeing that science right now is at a remarkable time of discovery and are interested in participating in it. But it is also clear that these are not easy times for people coming to join us. People who are, in fact, trained through graduate school and through post-doctoral fellowships often do not have an easy time finding the kind of dream job they were looking for. Over the last 10 years, the support for biomedical research through NIH, which is the largest supporter of universities, having lost about 17 or 18 percent of its purchasing power, many universities have cut back in terms of their hiring of new faculty. So many of these highly trained individuals find themselves taking other kinds of positions. That, of course, is good. We want to populate other situations in industry, in teaching, in science policy, and so on.

But clearly we are at a point where there is a bit of a crisis emerging as the ability to continue to support the number of individuals that I think would be good for our future is not quite clearly there anymore. If you are a young person looking at the situation, I think the consequence of that is increasing anxiety about whether this is a career path that is actually going to be one you want to choose.

Young scientists oftentimes, because of this, end up spending many, many years in training. The average age at which somebody

comes to NIH for their first independent grant and successfully gets it is age 42. That is not a good picture. We are basically keeping young talented scientists in less than independent positions for too long. We are working hard to try to do something about that. I started a new program that allows the most independent-minded scientists to go directly from their Ph.D.'s to an independent position instead of a long period of post-doctoral training.

The other area that we are very intensely looking at is the lack of diversity in our workforce. Despite many programs over many years, we have not achieved a situation where the best and brightest from all groups are coming to join us. We have a bold new set of programs to try to make that more appealing for individuals who traditionally choose other pathways, who do not have role models from their own communities. And we are optimistic that is going to change that dynamic, but it is going to be a long path to make that come true.

Mr. JOYCE. Thank you very much. I yield back.

Mr. KINGSTON. Ms. Lee.

Ms. LEE. Thank you very much.

First, let me just thank all of you so much on behalf of my constituents, on behalf of my family. On a personal level, my mother has COPD. My sister has multiple sclerosis. So I know your work very intimately and I just have to take this moment to thank you so much because all of you are doing life-affirming work.

And, Dr. Collins, I just have to say I remember your speech at the Prayer Breakfast in 2007. I think it was one of the most profound speeches that I have ever heard from a scientist.

Let me ask you, Dr. Frieden. First, I also thank you for your work on domestic and global efforts to prevent diseases, including cancer, hepatitis B, HIV and AIDS which all disproportionately affect minorities. Your agency is a leader in many initiatives such as—and I want to call one to your attention. It is the Racial and Ethnic Approaches to Community Health. I think it is called the REACH program, which really aims to eliminate racial and ethnic disparities in health. How do you anticipate sequestration affecting these programs and the populations that they serve?

And then secondly, let me just ask you about HIV criminalization laws. You know, we have 32 States and U.S. territories that have criminal statutes based on perceived exposure to HIV. These laws have been on the books since the 1980's and most of them need to be modernized to reflect current scientific advances in AIDS research. And last year the UN body which I sit on—we issued a report against these laws, and the President's Advisory Committee on HIV—you know, they cited a direct impact that these laws have on public health and the fear that they instill in people who seek HIV testing and counseling. And so I know you have been working on a review of these laws and the implications for public health, and I would like to find out the status of that and can you give us an update?

Dr. FRIEDEN. Thank you very much.

REACH AND SEQUESTRATION

In terms of the REACH program and sequestration, sequestration would affect virtually every program at CDC with a decrease

of approximately 5 percent. So it would be that much less that we would be able to do to address communities, that particular need for health programs that would reduce health disparities. We focused on trying to reduce disparities. We released for the first time what is called a surveillance summary or monitoring report on inequalities and disparities in health status in the U.S. We identified some of the leading disparities and some of the specific things that can be done to reduce them.

HIV CRIMINALIZATION LAWS

In terms of the HIV laws, we look at this very broadly. We found that many laws have been out of date, ranging from testing to monitoring to some of the criminal sanctions that are in existence. So what we have done working with other groups is to just survey what is the lay of the land out there. What are people doing? What are the laws that exist? And we believe that that should go through a peer review process and be published in the medical literature. So we can get back to you with the exact timeline of that, but I understand that the review is largely finished and we are now finalizing with the goal of ensuring that whatever laws are there at least address or are cognizant of the latest scientific information.

Ms. LEE. Okay. Are you looking at the impact, though, on public health of these laws, I mean, what it means, for instance, in terms of stigmatization, in terms of people willing to come forward to get testing knowing that they could be put in jail?

Dr. FRIEDEN. I would have to get back to you on that in terms of how that would be looked at and what they have done in that area.

Ms. LEE. Okay.

NIH WORKFORCE DIVERSITY

And, Dr. Collins, let me just follow up on the issue that was discussed earlier with regard to the whole inclusion of minorities. Specifically in the RO1 grants, can you kind of elaborate on that and how this will impact—how these RO1 grants and the whole effort to diversity will impact the health disparities issue?

Dr. COLLINS. I appreciate the question.

So a couple of years ago, there was a publication indicating that African American individuals who come to NIH seeking their first RO1 had a lower success rate than individuals from other groups, and you cannot account for that by the number of correlates that people would have assumed might have played some role in terms of previous training, publication record, and so on. We are continuing to look closely at that to try to understand it. It certainly sent a shock wave through our community.

I have organized an effort, through my advisory committee to the director led by Reed Tuckson and John Ruffin and Larry Tabak, to look at our whole area of diversity in our workforce. And they concluded that we have a problem which is beyond simply looking at success rates of investigators who have already made it into the position of applying to NIH for a grant, but also why are there so few of those individuals.

We have just begun and we will be spending substantial funds, even in very difficult budgetary times, on several new programs to

try to assist us. One is to try to make it possible for individuals from under-represented groups to have a real research experience as undergraduates, together with some tuition rebates to make this more financial possible. Another is to set up a national research mentoring network because it is clear that one of the problems that we see is that under-represented groups do not have that same network of support that the majority, folks do. We think that could be a very important part of it.

There are several other parts. I see my time is up. I would love to talk to you more about that.

Ms. LEE. Thank you very much.

Mr. KINGSTON. Dr. Harris.

Dr. HARRIS. Thank you very much.

First, I want to echo the ranking member with her comments, you know, thanking you all for being around to protect and improve the life and health of not only Americans but really people throughout the world. And I have taken a leadership role in that.

I do want to echo, though, the chairman because I do have some concerns about duplications that are occurring. You know, the GAO reports multiple duplications in the Federal Government. Our goal really in this time of contracting resources is to look for efficiency and effectiveness. So I am going to ask very specific questions. I just need a kind of a yes or no from Dr. Clancy, Dr. Collins, Dr. Conway.

PATIENT SAFETY RESEARCH

Do each of your entities fund patient safety research?

Dr. CLANCY. Yes.

Dr. HARRIS. Dr. Collins.

Dr. COLLINS. A very small amount.

Dr. HARRIS. Dr. Conway.

Dr. CONWAY. Only if it relates to payment and delivery system—

Dr. HARRIS. So it does. Okay.

Dr. FRIEDEN and Dr. Collins, do you fund obesity research?

Dr. FRIEDEN. We do surveillance on obesity and support communities in their work on that.

Dr. COLLINS. Yes.

Dr. HARRIS. Dr. Collins, Dr. Frieden, are there other areas of research in other disease processes, hypertension or whatever? So Dr. Frieden, do you also survey hypertension, other disease processes as well?

Dr. FRIEDEN. Surveillance, yes.

Dr. HARRIS. So you do. Okay.

And AHRQ and NIH fund telemedicine research?

Dr. CLANCY. Moderate, a little bit, yes.

Dr. HARRIS. You do. So there is a little bit of duplication.

Look, I have held grants from DOD health grants, worked on VA health grants. So I understand that there are multiple areas in the Government that actually look at very similar things, and that is some concern. So I just want to mention that again as we look toward effectiveness and efficiency.

VACCINES FOR CHILDREN

Now, I want to ask in the last remaining minutes, Dr. Frieden, I have a great deal of concern about a document my office got from the White House that talked about the cuts that were going to occur due to Republicans and affecting children. And I am going to read their quote about vaccines for children. It says, in Maryland, about 2,050 fewer children will receive vaccines due to reduced funding for vaccinations of about \$140,000. Did the CDC assist the White House in preparing that estimate?

Dr. FRIEDEN. I would have to get back to you on that.

Dr. HARRIS. You as the Director do not know if you assisted the White House in preparing an estimate that was distributed to every Member of Congress?

Dr. FRIEDEN. On that specific number, I would have to give you—

Dr. HARRIS. Okay. Let us forget the number. Let us forget the idea of how vaccines for children are going to be affected by the sequester. Is this the vaccine for children program?

Dr. FRIEDEN. No, it is not, sir.

Dr. HARRIS. Which program is it? Is it 317?

Dr. FRIEDEN. Yes, it is.

Dr. HARRIS. And what did the President's budget do to 317, the President's prospective budget for 2013?

Dr. FRIEDEN. The precise numbers I would have to get back—

Dr. HARRIS. Well, does a \$58,000,000 cut sound familiar?

Dr. FRIEDEN. Yes.

Dr. HARRIS. And what was the sequester cut?

Dr. FRIEDEN. Again, the precise—

Dr. HARRIS. Does \$30,000,000 sound familiar? Do you think that is around the ball park, is it not?

So actually the President cut the program twice as much in his budget. Can I assume that the President's proposed cut would have reduced the funding to 4,100 children in Maryland?

Dr. FRIEDEN. As per the justification that was published with that, we have looked at ways that we can run the program more efficiently by helping State and local health departments recoup dollars, for example, for—

Dr. HARRIS. And you cannot do that under a sequester, but you can do it under the President's budget? Is that my understanding of your testimony today?

Dr. FRIEDEN. I would have to get back to you on that.

Dr. HARRIS. So let me get it straight. Under the President's cut of \$58,000,000 to the 317 program, you think you could get around that to avoid cutting vaccines to children, but under a sequester that the President blames on Republicans, you do not know if you can do that?

Dr. FRIEDEN. We are going to do everything we can to limit any damage that occurs because of the across-the-board cut, but it reduces our flexibility significantly.

Dr. HARRIS. Is it your testimony that under the President's proposed cut of \$58,000,000 in his budget to the 317 program, you could have avoided cuts to vaccines to children in Maryland?

Dr. FRIEDEN. We believe that we could have maintained vaccination levels, yes.

Dr. HARRIS. Very interesting.

I yield back the balance of my time for now.

Mr. KINGSTON. Thank you.

Mr. Womack.

Mr. WOMACK. Thanks to all of the expert witnesses here today for your testimony and for your service to your country.

DUPLICATION

I have really one fundamental question. In my 2-plus years of serving in this capacity, not on this subcommittee, but as an appropriator and as a Member of Congress, I notice that so much of our Government is duplicative in nature. There is a lot of turf protection that goes on in our business throughout the Federal bureaucracy, but there is also a whole lot of—in the military we called it “mission creep.” I will stop short of that and just say there are a lot of things that we do from one agency to another that can be looked at as duplicative in nature. And I am going to ask this long question and then I will just leave it to the panel. And then I will yield back my time.

For example, all of your organizations fund activity or some do related to health care-associated infections, on prenatal care models, on issues involving biomedical research, tobacco cessation programs, and other similar related programs that come under a different title or a different theme from organization to organization.

Are we being efficient? Is there proper collaboration, and in your professional opinions, what are we doing to ensure that the Federal outlays, in a constrained resource environment as we operate today, are actually accomplishing the short-term and long-term goals and not involving a waste of resources? So I will just kind of throw that out on the table and let each one of you have a stab at it. Thank you.

Dr. CLANCY. Well, I will start with health care-associated infections because I made a big focus on that in my opening statement.

Our focus is on answering the question “how do we do that.” We have known about these infections for decades. My colleagues, Drs. Frieden and Collins, have done groundbreaking science and so forth, but meanwhile, it was accepted as disappointing but almost inevitable in health care settings that a very unacceptably high rate of these infections continued to occur. And we funded what turned out to be a groundbreaking study in the State of Michigan in 2003, and that led to dramatic improvements. And what was exciting about this was the focus on making it work in small rural access hospitals as well as ICU’s and so forth. So that is our unique focus.

We use every piece of information we can use from the CDC in doing this work. We do not reinvent definitions or anything like that. Anytime there is new biomedical science, we are there for it.

We play a minuscule or other role in the other areas that you delineated, but I think it is fair to say that both through a very short list of high priority goals for HHS, as well as through multiple components of her leadership, the Secretary herself insists on a great deal of collaboration so that we are at all times making

sure that we are getting the best value for every dollar that the taxpayers have invested in this work. And I will say that the return on investment for our investments in reducing HAI's has been quite wonderful. I will have to turn to my budget officer to get you the numbers, but we would be happy to do that.

Dr. FRIEDEN. Just health care-associated infections is a good example where research from AHRQ, policies from CMS, and monitoring support to States from CDC work really in close coordination. And we have had terrific partnerships in this and other areas.

Another area to think about is HIV where research at the NIH developed the drugs. Funding through HRSA gives people access to them, and support from CDC helps programs monitor what is happening and prevent HIV. And of course, through the Medicaid program as well, there is a lot of access to HIV care.

So there are many areas in which complex problems work. And I will say that we work very closely together.

One additional example is CMMI has some new programs to try things, and when they are in areas where CDC has expertise, rather than hiring their own staff to monitor those programs, they are paying us to make sure that we can put our staff on the case and do that without duplication.

Dr. CONWAY. Just HAI's I do think is an excellent example. We use the CDC measurement system and their expertise. We put it in payment and delivery system programs at CMS, and we have seen an over 40 percent reduction in central line infections. I personally as an intern took care of a family whose neonate passed away. So I think it is dramatic.

Mr. WOMACK. Thank you. I will yield back the balance of my time.

Mr. KINGSTON. Well, that was generous of you. [Laughter.]

Mr. Fleischmann, you came late. Are you up to speed on what we have been talking about?

Mr. FLEISCHMANN. Well, yes, Mr. Chairman. Sorry. I was in another subcommittee hearing.

Mr. KINGSTON. That is okay. You buy the coffee for everybody. No. You buy Tennessee Italian pastry. I think that is the penalty for coming late. [Laughter.]

Mr. FLEISCHMANN. We can call them Little Debbie's. [Laughter.]

Mr. KINGSTON. They do not have pastry but they have another fine product they brew in the mountains. [Laughter.]

Mr. FLEISCHMANN. Having said that with our good medical personnel here, I am a teetotaler for the record.

Thank you, Mr. Chairman.

INTERAGENCY COORDINATION

I will address this to all witnesses. HHS has many interagency coordinating committees and working groups. Could you please tell us how many interagency coordinating committees and working groups are in existence, and how are recommendations from these advisory groups handled at HHS?

Dr. COLLINS. So this is, I think, very much a follow-up to the question Mr. Womack was asking. You would want us to have a lot of these interagency working groups, I believe, because the ecosystem represented by the agencies at this table stretches from

very basic science trying to make discoveries about causes of illness and the means to prevent and cure all the way through understanding how that works in an epidemiological way across the country in terms of health services and quality of care in terms of issues that Medicare and Medicaid has to deal with all the time. So we all are engaged in this.

Take diabetes, for instance, an enormous threat to the health of our Nation. Each one of the agencies here has a particular role to play in that kind of a circumstance, but we need to be sure that we are together and we are not duplicating efforts, but we are actually being synergistic and complementary.

I could not tell you how many interagency working groups there are, but I suspect if we tallied them all up, there would be dozens. And that is a good thing. And we populate those with people at a high level who have the ability to know what their agencies are up to and have worked together quite closely.

And each of us at this table—we know each other really well. We talk to each other a lot. We have senior staff meetings shared between agencies in a bilateral sort of way. We get it. This is a time where budgets are extremely tight. We would not be happy about the idea of wasting a single dollar right now either.

Mr. FLEISCHMANN. All good? Okay, thank you.

DISSEMINATION OF HEALTH INFORMATION

A follow-up. In the area of health information, could you each please take about 30 seconds to educate us on how your organization spends on dissemination of health information?

Dr. FRIEDEN. So CDC often is the lead for monitoring of the health status of Americans and that information is provided to individual researchers. It is provided through our website. It is provided through grantees who get information to the public in a wide variety of areas. We also coordinate across HHS on issues like vaccine safety where we want to make sure that all information is present so there is not a partial view.

Dr. CLANCY. So I am going to make a quick statement. You know, we all know, all of us, that it takes too long for scientific information to benefit patient care. The statistic is that it takes 17 years for 14 percent of funded research to benefit patients. 14 percent. I do not know if that is good or bad. Research can be risky business in terms of what is going to pay off. We all think 17 years is too long. So I think it is fair to say that each of us is trying to exploit and take advantage of all kinds of new opportunities.

We have a particularly big role in getting health information out to the public, both by virtue of how our authorizing statute is written to get information out to the public and to health professionals and also through a new authority in the Affordable Care Act for getting information about patient-centered outcomes research out there. We think we are really cheap and efficient.

And we rely a lot on partners because particularly for clinicians, many of them would much rather hear from the College of Cardiology than even wonderful AHRQ in the Federal Government, even NIH. They like hearing from their professional organizations. So we utilize those partnerships very effectively.

Ms. WAKEFIELD. And I could just add, just to give you an example, we would use from CDC their guidelines for screening and treatment around heart disease, take those guidelines and push them out to the community health centers across the United States, of which there are about 9,000 sites. So that is a good utilization of pulling it in very rapidly and pushing it out through the infrastructure that we support across the country in every State and territory.

Dr. COLLINS. NIH sees a major part of our role is distributing information about the results of research, clinicaltrials.gov, a place where anybody who is interested in a clinical trial can find out what is going on anywhere in the country, both publicly and privately supported. The PubMed database, which is where people go to look at the public literature, downloaded 40,000,000 pages on an average day by people who are interested in that information, and MEDLINE, which is perhaps one of the most trusted resources for the public looking for medical information that is well-based on evidence.

Dr. CONWAY. So we share our quality information, including the private sector companies that utilize that information, to build technology to support choice by Medicare beneficiaries and their families.

Mr. KINGSTON. Okay. We are going to go to a second round, and we will try to limit it to 4 minutes each, if everybody is in agreement, and we will just keep going. We will try to talk fast.

Dr. Frieden, we are probably looking at—I do not know—low side 675, high side maybe 900 in IQ at the collective table here at the moment. [Laughter.]

Ms. LEE. Your table. [Laughter.]

Mr. KINGSTON. I know I am not adding to the average.

COMMUNITY TRANSFORMATION GRANTS

But, Dr. Frieden, I want to talk to you about it specifically. I am troubled and very unimpressed with community transformation grants. I would ask you as a really smart scientist who has earned his stripes, pseudo-science, public relations, real serious stuff, good politics?

Dr. FRIEDEN. The community transformation grants, which were authorized and directed by Congress—

Mr. KINGSTON. That should tell you right there. [Laughter.]

Dr. FRIEDEN [continuing]. Are an opportunity to allow communities to work in specific areas with specific outcomes, healthier school food, better control of blood pressure, reduced exposure of children to tobacco and other cancer-causing chemicals.

Mr. KINGSTON. I am going to kind of move along on a clip here. It just strikes me that the only thing we are getting out of them is a bunch “me too” stuff of kind of, oh, yeah, the tobacco. Oh, well, that is an original thought. Sugary beverages. Oh, that is an original thought. I mean, I do not see much coming out of community transformation grants that show, hey, you know what, this is a really good investment.

It disturbs me when tax dollars are used to fund government to single out food rather than educate people on what you should be doing for your exercise. It seems that there is a real slant towards

let's tax certain food items and make it harder for people to get in as opposed to talking about the broader picture of obesity. I do hope to have a hearing on obesity.

But I am very concerned that what we are seeing now—for example, CDC gets \$825,000,000 in PPH funds, and \$226,000,000 are used in community transformation grants. If we are talking about not immunizing children so we can get a bunch of people in Los Angeles to say, oh, we should have less tobacco, I do not think that is a good investment of tax dollars.

LOBBYING

I just need assurances from you that these grants are not going to be used to just continually lobby for more taxes, more bans, and more restrictions on particular food.

Dr. FRIEDEN. We take very seriously the restriction on lobbying by grantees. We have a rigorous process in place to monitor and oversee grantees and provide training, technical assistance and guidance on this topic. And if we identify a potential issue, we address it immediately.

Mr. KINGSTON. I am going to look forward to working with you on that.

SODIUM

And I want to ask you about sodium because we get mixed signals on sodium. You have said in the past that—and there was a New York Post article that you said too much sodium raises blood pressure which is a major risk factor for heart disease and stroke. These diseases kill more than 800,000 Americans each year and contribute to the estimated \$273,000,000,000 in health care costs. But when pressed for specifics, Karen Hunter of the CDC says that the CDC does not have data on the number of heart attacks and strokes that are caused by excess sodium.

So what specific data do you have on the number of deaths caused by sodium? And this is a computer-generated number or has it been peer-reviewed? Is it solid data or not? And does a low-sodium diet lead to health problems in certain populations? And I see you have 7 seconds. [Laughter.]

So I tell you what if we have a third round, I will let you answer that. If not, let's do it for the record. Thank you.

Ms. DeLauro.

VACCINES FOR CHILDREN

Ms. DELAURO. Thank you. Just a quick comment on the \$58,000,000 in the immunization effort. I too would be opposed to that cut. I think it is important to recognize as well, though, that the administration made a presumption that the Affordable Care Act would be implemented and that in fact would accommodate immunization.

Let me move on and, Dr. Clancy, let me ask you a couple of questions if I can. I will just tick them off very, very quickly.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Last year, the subcommittee would have eliminated AHRQ. What would we lose? And secondly, you began to mention one of the arguments for eliminating AHRQ was that it is duplicative of other agencies. You made a response. I do not know if you would want to add to that response about whether there is overlap with other agencies.

And last, AHRQ and the Patient-Centered Outcomes Research Institute, which is set up by the Affordable Care Act. Some have suggested that we should stop providing an appropriation to AHRQ to do the patient-centered outcomes research because that research can now be supported by PCORI. Is PCORI in a position to take over the support of all of AHRQ's patient-centered outcomes research?

Dr. CLANCY. So thank you very much for your question. I think that you probably got from my earlier statement my passion for this work, and given the opportunities for improving quality and safety and given what I think is sort of a new day among health professionals in terms of their excitement about improving health care, I think we would lose a lot if AHRQ were to go away.

Quite specifically, the question I hear from health professionals all the time is "I want to be part of this transformation. How do I do that? How do I get on board with a variety of policy initiatives? How do I know what is right for my practice? How do I do that?" And we are the agency that actually gives them evidence-based tools to make it easy for them to do the right thing. And the excitement and enthusiasm among health professionals—you cannot buy it. The payment policies are really important, but the professional commitment to providing the best possible patient care. So it is HAI's. It is the work in team work. It is the work in communication. It is information for the public. Dr. Frieden mentioned being a disease detective. In our world, being a disease detective often involves trying to find out precisely what medications this patient is taking now and how can we make sure that we are helping them to avoid potentially deadly interactions. So that is the work in patient safety.

The second question was about duplication. I think the unique area that we focus on is the "How do I do that." Dr. Conway referred to it as "improvement science," which is a slightly more glamorous sounding label. I do not care what you call it. What I see is that we have got a health care system that is not equipped to provide high quality, safe, affordable care, and we have developed and generated practical solutions for doctors, hospitals, nurses, pharmacists, and so forth to be able to do that. And I cannot tell you how excited they are, and we hear from them all the time. The words I hear are they are "game-changing." This approach to HAI's—that is what really turned the corner for us, and we thought we were trying really hard before.

In terms of patient-centered outcomes research, that is a program we are phasing out. You probably know we think and are very proud of the work we have done to date, particularly with the Recovery Act funding as a foundation for the Patient-Centered Outcomes Research Institute. Dr. Collins and I are both on the board

of that institute. So we have both, I am just going to say, been quite generous both with our own time and with sharing lessons learned. We have a unique and exciting opportunity because 16 percent of the allocation from the PCORI trust fund comes to AHRQ to support two vital areas. One is dissemination of the findings to the patients, to families, to health professionals, and so forth so that they have got good information when they need it to shorten that 17-year time frame. The other is building capacity, training future researchers, training people who can understand how to use this information.

Sorry for going over.

Ms. DELAURO. Thank you, Mr. Chairman.

Mr. KINGSTON. Dr. Harris.

Dr. HARRIS. Thank you very much.

Again, I want to thank you for all you do for protecting and improving life and health.

VACCINES FOR CHILDREN

Dr. Frieden, I do look forward to your answer about who was the source within the CDC for the information that I got concerning Maryland. So I look forward to your answer.

[The information follows:]

Dr. FRIEDEN: CDC provided data that was used in developing the report.

Let me just follow up one more thing for you. A concern I have is the ATSDR which apparently has issued reports on Dimock and one other place where hydraulic fracturing was alleged to have contaminated drinking water. And I read through the reports. It is actually good that the ATSDR actually pointed out that the EPA sampling was improper, you know, quality control samples. I mean, I like that idea. But I would urge you to keep it to science and leave the politics aside. That is the one good thing I think we should insist upon, medicine, medical research, public health research, is that we leave the politics aside. Let's concentrate on science.

NIH RESEARCH FUNDING

Now, Dr. Collins, I have got to ask you a couple of things here, and I did not think I was going to except that it popped across one of my local, online—I guess you would call it a blog—yesterday—2 days ago. It says, NIH study claims link between the Tea Party and the tobacco industry. Are you aware of this? I mean, again this popped across one of my local—let me ask you. The only comment says—so it is a study. I guess it was—was it University of California? Are you aware of it?

Dr. COLLINS. UC San Francisco.

Dr. HARRIS. UC San Francisco. So they allege that somehow the Tea Party had its origin in the 1980's with tobacco funding, which is pretty incredible because, I mean, I am a Tea Party guy. I was there when it was established in 2009. I know the origins. I find it incredible that NIH funding is funding this because the one comment says, what may I ask does this article have to do with Chertown, which is the local community. Of course, it has nothing to

do with Chestertown and everything to do with a partisan political agenda. I could not agree more.

Dr. Collins, what methods does the NIH have when this kind of research takes dollars from cancer research and other important, vital research—what does the NIH do to universities that waste Federal tax dollars this way?

Dr. COLLINS. Dr. Harris, I appreciate your question, and I too am quite troubled about this particular circumstance. Dr. Stanton Glantz, who is the author of that article, has been a funded grantee of the National Institutes of Health, the Cancer Institute, for 14 years and has done some very important work in terms of tobacco control over those years and is considered by peers to be among the best in the field.

Dr. HARRIS. If I might just interrupt, you do not consider this among his most important work in tobacco research. [Laughter.]

Dr. COLLINS. No, I would not.

Dr. HARRIS. Okay. Thank you.

Dr. COLLINS. If you look carefully at the acknowledgements at the end of this particular paper, which came as a surprise to us as well—

Dr. HARRIS. I am looking at them, but go on.

Dr. COLLINS [continuing]. It does cite two different grants from the NCI. There is also wording there—and maybe you could read it off to us—which says that this particular work and this particular paper was not suggested or encouraged by the NIH. He did this on his own.

Dr. HARRIS. Correct. And that drills down exactly to my question. This was the use of Federal dollars on a clearly partisan political agenda. I mean, look, we are going to come to agree—clearly partisan political agenda. What is the NIH going to do to make sure that we do not fund this research, we fund the real medical research as we go forward in a time of constrained resources?

Dr. COLLINS. Of course, we thought we were funding a different kind of research when those grants were awarded.

Dr. HARRIS. So what is within the NIH's abilities to, shall we say, make sure that this researcher of this institution does not play fast and loose with taxpayer money in this kind of research?

Dr. COLLINS. So it is a very appropriate question and I am struggling with it, to be honest.

Dr. HARRIS. Could you get back to me about what plans the NIH is going to have to be certain that this kind of research is not funded?

Dr. COLLINS. The tension here is both to recognize that this is an unfortunate outcome but also not to put NIH in the position of basically playing a nanny over top of everything that our grantees do because a lot of what they do, which is more appropriate, ends up being quite innovative.

Dr. HARRIS. Thank you very much.

Thank you, Mr. Chairman.

Mr. KINGSTON. This is a very good discussion, but we are out of time.

Ms. Lowey.

Mrs. LOWEY. Thank you very much, Mr. Chairman.

And I just want to say to Dr. Collins and my colleagues, since I got on this committee, which I love, many years ago I have always tried to figure out how you can legislate excellence consistently. And that is the challenge that we all have because we are so committed to the important work that you are all doing. So I thank you for your comments and maybe you can come back with some good advice.

DIABETES PREVENTION PROGRAM

I would like to focus for a moment on the diabetes prevention program because we know that between 1980 and 2010, the number of Americans diagnosed with diabetes more than tripled. I understand that some of you are involved with an effort to alter that trend called the Diabetes Prevention Program which helps people at risk make the kinds of modest life changes that can substantially reduce their chances of developing diabetes. The program originated with a large study by the NIH that demonstrated the potential of modest lifestyle changes in reducing risk of type 2 diabetes, and CDC is now leading the implementation of these findings in partnership with organizations throughout the country using funding from the Prevention and Public Health Fund.

Now, before I ask the question, I just want to associate myself with the chairman's comments before about sodium because there have been recent reports on the Mediterranean diet and another report, no salt, no sugar, no fat. And at some point maybe we can have a hearing or a discussion of all these diets because it is so important, Dr. Frieden, to your work and to everyone's work. I would be interested in that.

But my question today to Dr. Collins and Dr. Frieden, can you tell us how the Diabetes Prevention Program works, about the respective role of your agencies in developing and carrying out this effort, and are we seeing some results?

Dr. FRIEDEN. So the Diabetes Prevention Program is a great example of partnerships where the NIH funded research that shows that for people with pre-diabetes, if they participate in this program, their risk of developing diabetes falls by 58 percent. We then took that and worked with the YMCA, now called the Y, to come up with a lower cost way of doing that, and now we are working with providers throughout the country and insurers throughout the country to identify ways to get patients access to these programs. What we have done is to essentially verify that a provider is doing the program with fidelity to the model and require them to provide aggregate reporting periodically to us, and then United Health Care and other insurers are going to pay those providers because there is a great return on investment here. A single person with diabetes costs on average \$6,600 more to care for per year than someone without diabetes. So if we can prevent a few of these cases, we can save a lot of money for the health care system.

One of the areas that this is addressing is how do you get the health care system to pay for lower cost, high value preventative services. And that is something that I think all of us are learning and understanding more of.

Dr. COLLINS. Yes. I think this is a great example of our agencies working together in terms of conducting the original study, which

has now been extended out over 10 years, a follow-up, showing that the benefits of this lifestyle change, which is diet and exercise, are sustained over long periods of time, especially for people over 60, which is also an interesting part of the discovery, and then CDC picking this up in terms of implementation in the real world to see how this works out.

We have been talking now a lot with CMS about how we could see a path forward here for a proven, successful enterprise here to prevent diabetes to be more broadly available to people who have Medicare and Medicaid coverage.

It was a challenge because a lot of the delivery of the health care depends upon non-traditional providers, coaches, lifestyle coaches who are successful in being able to maintain people's exercise and diet abilities.

Mrs. LOWEY. Well, thank you, Mr. Chairman. My time is up.

I would like to add this discussion to the one that we are going to have because we have known a lot of this for a long time. Whether it is Weight Watchers or Over-Eaters Anonymous how do you really get people to change behavior with all the advertisement for sugar, starches, etc.? But this is a longer discussion. Thank you very much.

Mr. KINGSTON. It is a great discussion, and I do hope to have some hearings on it.

Ms. Roybal-Allard.

TB OUTBREAK IN LOS ANGELES

Ms. ROYBAL-ALLARD. Dr. Frieden, before he went into politics, my father was a public health educator responsible primarily for educating the Latin communities in California about the spread and prevention of TB. So I grew up with a healthy respect for the dangers of that disease.

I have been closely following the rising number of TB cases among L.A.'s skid row homeless population which has been called the largest TB outbreak in a decade. Equally concerning are other communicable disease outbreaks such as last year's TB outbreak in Florida and last year's whooping cough outbreak in the State of Washington.

Given that CDC's budget has been significantly cut over the past several years and sequester is expected to take an additional \$300,000,000 from CDC's budget, will the CDC have adequate funding and resources to control and prevent the spread of communicable diseases in all States? And if not, will some communities be hit harder than others? And what risks, if any, will this pose to the rest of the population at large?

Dr. FRIEDEN. We will do the best we can to mitigate the damage that sequestration cuts will do, but the reality is that about two-thirds of our budget goes out to State and local entities. Those entities have already absorbed about 45,000 fewer staff because of State and local reductions in funding. And so this comes at a very difficult time for State and local governments, and there is always the risk that an outbreak will be undetected or detected more slowly or controlled more slowly with fewer resources.

With respect to the Los Angeles tuberculosis outbreak, we have a team that arrived yesterday at the request of the State. We only

go places where we are requested. They requested assistance and we have sent a team there. But some aspects of the investigation will be difficult to do in this budgetary climate.

For example, we are increasingly using what is called whole genome sequencing of bacteria and viruses to understand the transmission, where they spread and how they spread. It is a costly and difficult study to do. They are getting cheaper, but the bioinformatics needs are great. And this is an area where we need to continue to grow our capacity.

Just to give you an example a couple of years ago when cholera hit Haiti, we were able to do sequencing of the genome of that bacteria, but we were not able to interpret the results because we did not have the bioinformatics capacity. And I am ashamed to say we had to send the information to Canada for them to interpret it for us. I never want to have that happen again on my watch at CDC. So we will do everything we can to respond as effectively as we can to outbreaks that occur.

On average, we start an investigation about every day. So which of those we may be able to address less well I cannot predict.

Ms. ROYBAL-ALLARD. And if you are not able to address them, what communities do you think will be hit the hardest and how will that impact the population at large?

Dr. FRIEDEN. I think the spread of infectious diseases knows no boundaries around the world and also can spread in hospitals from food. There are populations at higher risk, people who chose not to get vaccinated, for example, or communities that have low vaccination rates. But ultimately because we are all connected by the air we breathe, the spread of communicable disease is a potential risk to everyone.

Ms. ROYBAL-ALLARD. It will affect all of us. Thank you.

VIOLETIONS OF ANIMAL WELFARE REGULATIONS

Dr. Collins, in January I sent a letter asking about violations of Federal animal welfare regulations in NIH-funded research laboratories. Since I have not received a response to date, I want to follow up on that issue.

It is my understanding that NIH requires federally funded animal research laboratories that violate animal welfare regulations to return the funds used for the noncompliant activities. There was a well publicized case several years that a noncompliant lab was ordered more than \$65,000.

My questions are, are the FDA and USDA notifying NIH about noncompliant projects funded by NIH, and what is NIH doing in response to these reports? For example, over the last 5 years, how many incidents requiring grant repayment have been reported to NIH? What actions have been taken, and how much in taxpayer money has been returned to the NIH?

Mr. KINGSTON. And, Dr. Collins, you will have to answer on the record.

Dr. COLLINS. Okay. I will be glad to answer on the record. I am sorry you did not get a response to your letter, and I will be sure you get one.

[The information follows:]

DR. COLLINS: The NIH, FDA, and USDA have a Memorandum of Understanding that describes the process for information exchange concerning animal welfare issues. Each agency, operating under its own authority, has specific and differing responsibilities for stewardship of the care and welfare of animals. The three agencies meet semiannually to discuss issues of shared concern, to formulate new regulatory initiatives, and to coordinate ongoing collaborative activities.

The NIH Office of Laboratory Animal Welfare (OLAW) Division of Compliance Oversight is in regular contact with the Eastern and Western Regional Offices of the Animal Care, Animal and Plant Health Inspection Service, USDA. NIH and USDA work closely to coordinate joint responses, including educational outreach activities and site visits when concerns involving PHS-funded activities at USDA-registered research facilities are raised.

OLAW's interactions with FDA are less frequent because FDA's inspections for compliance with the Good Laboratory Practice Regulations (GLPR) have less direct involvement with animal welfare issues. During 2012, and continuing this year, OLAW and USDA have been actively participating in the FDA's working group tasked with modifications to the GLPR to ensure its consistency with each agency's directives concerning animal welfare.

The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges for the conduct of live vertebrate animal activities to grant awards during periods in which terms and conditions of the NIHGPS are not upheld. The specific situations under which charges are not allowable are:

- The conduct of animal activities in the absence of a valid Animal Welfare Assurance with OLAW; and
- The conduct of animal activities in the absence of a valid IACUC approval of the activity.

Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval.

Not all noncompliance reportable events that OLAW investigates meet the requirements for reconciliation of charges. For example, individual incidents involving accidental animal deaths, natural disasters or mechanical failures, although reportable, do not meet the requirements for return of funds. During its investigation of each case, OLAW provides guidance to the institution on the requirement for reconciliation of unallowable charges. Institutes and Centers (IC) are directed to report noncompliant situations to the NIH IC Grants Management Officer (GMO) managing the award. During the last five years, in seven percent of cases reported to OLAW, the institution has been advised by OLAW to contact the GMO concerning possible reconciliation of charges, as required by the NIH Grants Policy Statement.

The individual NIH ICs administratively manage noncompliant activities that require grant award reconciliation. IC grant files indicate that 26 animal welfare noncompliance incidents were self-reported by NIH grantees or discovered by NIH during the period from January 3, 2008, through January 4, 2013. During this time, NIH recovered \$592,796 in unallowable charges made to NIH grants for unauthorized animal research activities.

In summary, NIH investigates all reported allegations of suspected noncompliance with animal welfare requirements received from any source, including from Congress, our federal partners, the media, animal welfare organizations, and the public concerning inappropriate animal care or use involving PHS-supported activities. The Institutional Animal Care and Use Committees and the institutional official who

has signed the Animal Welfare Assurance are the key contacts at a grantee institution with whom OLAW interacts when investigating animal welfare concerns. OLAW advises the institution to report to GMO of the NIH funding component when the requirement for reconciliation of unallowable charges is applicable. GMO determines if the institution's adjustment of charges to the project is proper and initiates reconciliation if indicated.

Ms. ROYBAL-ALLARD. Okay. Thank you.

Mr. KINGSTON. Ms. Lee.

Ms. LEE. Thank you very much.

DIABETES IN INDIVIDUALS WITH SICKLE CELL TRAIT

Dr. Collins, let me ask you if you could give us—and you may not have it here—an update on an effort that actually was through this committee we mounted as it relates to the whole issue of diabetes with individuals who have the sickle cell trait and the A1C test. Several years ago, I just happened to stumble upon the fact that the A1C test is not valid if in fact one has the sickle cell trait, which primarily are in population of African American and Southeast Asian populations. We raised this with the National Institute of Diabetes and Digestive and Kidney Disease and also worked with NIH to develop a public awareness campaign.

I want to know how that is going. Do physicians now and labs know that—because there were many, many people who were being treated for diabetes who did not have the disease because they had the sickle cell trait, and they were never tested for the sickle cell trait. And so it was a real problem throughout many communities. And so I am wondering if you could give us an update on that, if we know what has happened. Are labs and physicians fully aware now that they need to be very careful in administering that test?

Dr. COLLINS. So, Congresswoman Lee, you were right to raise this. This is an important issue because it was leading to confusion and misdiagnosis. And there has been attention paid to this by the National Institute of Diabetes, Digestive, and Kidney Diseases with Dr. Griff Rodgers as the director of that effort. And there has been, although I do not have the details on the tip of my tongue, a recent workshop looking at this trying to figure out how best to distribute the information that you refer to.

All of this I think is being assisted—and it is an important thing to bring up at this hearing—by a much closer relationship across the Department in terms of sickle cell disease and other things that need to be looked at more closely. The CDC is now engaged in a surveillance effort so that we have much better record availability in terms of sickle cell disease across many States, which has been something we have not previously had access to, and Tom and his team have taken that on.

Susan Shurin, who is the former acting director and now deputy director of NHLBI, has made it a personal priority to bring together various parts of HHS in the sickle cell agenda.

We have two new, very exciting approaches therapeutically to sickle cell disease, one of which has already gone into phase I trials at our clinical center, the sort of first really new ideas about drugs since hydroxyurea, which has been almost 20 years.

So there is an increased focus on this first molecular disease, this disease that very much deserves attention and advances all across the board, from basic science to clinical issues such as the one you raised. I could give you a more thorough report on that for the record.

[The information follows:]

DR. COLLINS: As you note, there have been previously reported examples of problems associated with the measurement of hemoglobin A1C due to the presence of some hemoglobin genetic variants (hemoglobinopathies) such as sickle-cell trait. Unfortunately, in the case of sickle cell, the gene is more common in some populations that are also at a high risk for type 2 diabetes. These problems are not an issue with the newer, more reliable testing methods now utilized by most laboratories. The National Glycohemoglobin Standardization Program (NGSP), which is funded by NIH and has an advisory committee chaired by the Centers for Disease Control and Prevention, works to improve the quality and reliability of A1C tests, and emphasize the importance of employing methods that are accurate for all people. NGSP's website (<http://www.ngsp.org/>) has information on problems associated with certain hemoglobin variants and which test methods are appropriate for people with hemoglobin disorders.

In addition, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has developed a public awareness campaign for patients and providers in response to these concerns; with the hopes of increasing attention on this issue and the complications that may result. A key example of the impact of this campaign is in a recent statement from the American Diabetes Association relating to the use of the A1C test for diagnosing diabetes, which explicitly notes the importance of using an appropriate A1C assay for patients with certain hemoglobin variants (http://care.diabetesjournals.org/content/35/Supplement_1/S11.full). Efforts to increase awareness continue in the development of educational materials. NIDDK recently developed a fact sheet on the A1C test, which includes a discussion of potential problems with result accuracy in people with variant forms of hemoglobin (www.diabetes.niddk.nih.gov/dm/pubs/A1CTest/). More information on HbA1c and hemoglobin disorders is available on NIDDK's website in pdf form: (www.diabetes.niddk.nih.gov/dm/pubs/traitA1C/SickleCell-Booklet.pdf and www.diabetes.niddk.nih.gov/dm/pubs/hemovari-A1C/SickleCell-Fact.pdf).

Ms. LEE. I would appreciate that because I hope this committee realizes the importance of this and the seriousness of this because there are many people who are being treated and mistreated because they were not properly diagnosed. And I think it is a really important issue that I am going to stay on until no one is being mistreated.

Dr. COLLINS. You have been very effective in drawing attention to that. Thank you.

Ms. LEE. Thank you.

IMPACT OF SEQUESTRATION ON MEDICARE & MEDICAID

And finally, if I have a couple more minutes, you probably will not have to answer this on the record, Dr. Conway. The budget cuts, as it relates to the sequestration, the impact on administering Medicare and Medicaid services because of the fact that these payments are going to be cut to doctors and hospitals and health plans and providers who provide services to Medicaid and Medicare patients—what is going to happen to the patients and the doctors?

Dr. CONWAY. So as the agency has said publicly, on April 1st there will be a 2 percent cut to all doctors, hospitals, as well as health plans in terms of the sequestration cut. So as you alluded to, that is a major cut in terms of payments. Administratively we also will need to look at our operations and prioritize work to try to deal with the cuts as best as possible.

Mr. KINGSTON. Mr. Honda.

Mr. HONDA. Thank you, Mr. Chair.

HEPATITIS B AND C

My question will be around hep B and C. It is directed to Dr. Frieden. We have seen hep B and C rise to alarming levels to a point where the new prevalence rates for hep C now overshadow those of other major diseases. This is not a problem that is going to go away. And yet, we find that we continue to fund CDC's division on viral hepatitis at a very meager level. So in an ideal world, what is an appropriate funding level that the CDC should have, and then what kind of sacrifices have you had to make due to the insufficient funding put towards combating hepatitis B and C?

Dr. FRIEDEN. As you point out, Congressman, hepatitis B and C are a major problem. And we do have new treatments available through work that NIH and others have funded which are effective at achieving long-term viral suppression, essentially a cure.

Last year, CDC published guidance on encouraging doctors to test everyone born in a certain cohort, I believe 1945 to 1965, at least once for hepatitis C and to get people into treatment because we know that many people who are infected are not aware that they are infected and therefore cannot get the treatment that they would benefit from. And we work closely with CMS, with AHRQ, with HRSA to increase access to testing.

In terms of the exact funding level of the program, I would have to get back to you. But as with every program, it would face roughly a 5 percent budget cut. It is funded at a very low level currently relevant to other programs. Our major effort here, in addition to trying to come up with better ways to diagnosis the acuteness of hepatitis C infection, is to scale up the treatment throughout the

country by supporting State and local governments and health providers to do that.

Mr. HONDA. In the area of public and private funding, that cooperation, what kinds of partnerships have you been able to leverage and what kind of leverage has been realized through this relationship?

Dr. FRIEDEN. We have had an excellent relationship with many of the professional societies and nongovernmental organizations that have been advocating for better prevention and treatment of people living with hepatitis B and hepatitis C. We have also worked closely with many of the providers in thinking about how to scale things up and with State and local governments in terms of how to affect the practice of care in their communities and identify parts of their community that may be at highest risk and ensure that they get the services they need.

Mr. HONDA. What kind of attention is being focused towards screening of hep B and C in the public? Is that a question for yourself?

Dr. FRIEDEN. We have released a public education campaign called No More Hepatitis, encouraging people to know more about their status. We have reached out to health care—

Mr. HONDA. Oh, know, k-n-o-w. Okay.

Dr. FRIEDEN. And also no. [Laughter.]

Dr. FRIEDEN. And so this is one of the efforts that we have had. We also find that working closely with health care providers, people are seeing a doctor. So through electronic health records, through CMS, HRSA, and others, we are looking at how to ensure that people get the test, and then if they are positive, follow up in care. And we are seeing many gaps in that cascade. We are working with different groups to try to close them.

FUTURE IMPACTS OF SEQUESTRATION

Mr. HONDA. Through the chair, if I may ask, the members here, the panelists, we are looking at sequestration. We are looking at cutbacks. You said 2 percent in your arena. If we look at the cutbacks and we get a funding level that has been cut, is there a way you could project what it is that we are going to suffer in the future? What are the future impacts on our society? What is the cost of that? If you can come up with something like that, I would like to be able to share that so that we can let people know how shortsighted some of our actions are right in this country. And so if that information can be shared, I would be very appreciative of it.

Mr. KINGSTON. Mr. Alexander.

Mr. ALEXANDER. Mr. Chairman, if you will, just three short questions to read into the record, if you would allow me.

FOOD-BORNE ILLNESS

The CDC has a key role in investigating food-borne illness and helping identify suspect foods. The outbreak of listeria in cantaloupes was the example. How can you assure us that we are able to detect such outbreaks quickly?

CDC FUNDING AT STATE AND LOCAL LEVEL

And why is CDC's funding so focused on supporting public health agencies at the State and local level?

CDC'S UNIQUE ROLE

And number three, in an era of reductions, we cannot afford to have agencies tripping over themselves. What makes CDC unique and deserving of our support?

Thank you, sir.

FOOD-BORNE ILLNESS

Dr. FRIEDEN. Thank you very much. CDC's role in terms of food-borne infections is to identify outbreaks when they occur and then work with State and local governments to stop them.

We coordinate very closely with both the Food and Drug Administration and the USDA. Our top scientists meet weekly. There are 30 to 40 clusters of infections that we are investigating at any one time, and with that interagency coordination, we are able to prioritize those and take rapid action.

CDC FUNDING AT STATE AND LOCAL LEVEL

It is State and local governments that monitor whether infections are spreading. They track the laboratory results. We coordinate a network called PulseNet. PulseNet takes the infections that occur and subjects them to a DNA test to see if they are related. It is an old technology, and actually we need to replace it in the coming years with something that works even better based on whole genome sequencing. That is going to take a while, but that will allow us to find outbreaks sooner and stop them quicker.

CDC'S UNIQUE ROLE

But CDC's role is fundamentally to identify and stop outbreaks. We handle the illness part of it. FDA and USDA handle the food part of it. And often it is our investigations that will identify a new way that food became contaminated so that the manufacturers can reduce the risk. And we emphasize the entire food chain from farm to table. At every step, there are responsibilities and things that can be done to make our food safer.

Mr. KINGSTON. Thank you, Mr. Alexander.

And that is the end of the second round, and what we are going to do is ask members to submit the rest of their questions for the record. There will be a lot of questions like that.

Mr. KINGSTON. I do want to say this and I think Ms. DeLauro is just going to make a statement or two right now.

NIH LOGO

About every other campaign, somebody comes to me and says you have to change your logo because you have had it the same. And I always say, you know, I understand there is always somebody new who wants to tell you why something that is tried and true does not work. And I have said, you know, if you guys want to

change the logo, fine, but I am not paying for it because this logo was designed by my wife and good friend on my kitchen table.

But I heard you guys are looking at a new logo. And so my question is to you for the record, you know, whose idea is that? Why is it necessary? Is this a good time for it? And how much are we talking about? And I see you are prepared to answer this question. [Laughter.]

All new logos take a while to get used to.

Dr. COLLINS. This is one old, ugly logo. So this is basically what we have had for the NIH logo for the last 34 years.

When I came to the NIH——

Mr. KINGSTON. Well, let me do this in fairness and consistency. Could I get that for the record?

Dr. COLLINS. Sure. If I could just say, the point of this was actually to save money. We have proliferation of way too many logos. We are going to focus on just one.

[The information follows:]

DR. COLLINS: For many years, NIH leadership has heard from voluntary organizations, patient groups, professional societies, its own advisory committees, and even members of Congress, that NIH should do more to strengthen and modernize its communications efforts. Despite its \$30 billion budget and support of research in more than 2,500 colleges, universities, medical centers, and research institutions in every state of the Union, public awareness of the role of NIH in advancing science and health has been low. Outside polling by Research!America (February 2010), for example, showed that only 9 percent of the American public knew about NIH. As a government agency funded by tax dollars to advance biomedical research, it is incumbent upon NIH to communicate clearly to the public how their investment in NIH research is helping to improve people's health—and that it is a primary source of trusted, reliable health and science information. Historically, NIH communications has been largely localized—at the agency's Institute, Center, or program level with minimal or no connection to NIH, the home agency. As a result, NIH communications has been extremely fragmented. This made it very difficult, if not impossible, for the public to grasp the full scope of NIH's impact on health and medicine, or that information they may seek comes from the same, reliable source. It also resulted in duplication of effort and costs.

Over the last several years, there has been an internal effort to strengthen NIH communications. In the spring of 2011, the Associate Director for Communications and Public Liaison, John Burklow, began putting together elements of a new NIH communications plan. He brought together a sub-group of IC (Institute and Center) communication directors to discuss how best to go about strengthening and modernizing NIH communications. Several strategies were discussed, including ways to communicate more clearly to the public about NIH. Other strategies included bolstering communications with grantee institutions, patient, voluntary, and professional organizations, and investing additional resources into new media. For example, it is a little-known fact that NIH funding is almost always behind the latest biomedical research results coming out of the nation's preeminent universities because the connection is not made back to NIH. Efforts to establish better communication and collaborations with grantee institutions, which are a priority, are under way.

At the outset, the proliferation of logos across NIH, estimated to be at least several hundred, was deemed problematic, counter-productive, and an inefficient use of resources. It was clear that the fragmented approach to communications across NIH needed to be addressed in order for NIH to be able to communicate with maximum impact. Tackling the multiplicity of logos was a natural place to start.

KINGSTON

Is this a good time for it? And how much are we talking about?

DR. COLLINS:

Yes. The move toward a single logo, with clear implementation guidelines, was an effort to eliminate duplication of efforts and costs, and maximize NIH communications efforts. Currently, there are several hundred logos in operation at NIH with no link or visual connection to NIH. Each time a logo was developed—whether it is for a new research initiative or office—money was spent to hire contractors and designers and make all the necessary graphic changes, electronic and print. The ICs also regularly update or change their IC logos, incurring costs each time. It is a less costly and more efficient means of doing business.

The costs have been minimal for such an undertaking and nobody has been hired specifically to work on the logo switches. Over the past two years, contractor costs for developing the logo design total are approximately \$150 thousand, which includes the development of the NIH logo, suite of IC logos, and logo use guidelines. In addition, estimated staff time to make the changes to the IC web sites: the

amount of time it takes for an IC to change over depends on the content management system they use. On average, it would take five hours to make changes to all the different components of an IC web site, depending on the number of sites. If they use FTEs, it would cost about \$3,000. If they used a contractor, it would cost approximately \$5,000. This is the job of the staff that is currently employed by NIH—they work on web site maintenance and development, whether it is about the logo or any other aspect of the web site.

Mr. KINGSTON. Okay. And I do want you to know—well, let me yield to my friend, Ms. DeLauro, and then I will conclude.

Ms. DELAURO. I do not have any closing statements, but I want to very quickly get three answers.

NATIONAL CENTER FOR ADVANCING TRANSLATED SCIENCES

Dr. Collins, we gave you money for NCATS. What has been accomplished? There was a question about duplication there. How are we preventing that?

MATERNAL AND CHILD HEALTH BLOCK GRANT

Dr. Wakefield, return on child health block grant. It has been cut back in appropriations. What is its role? What kind of efforts does it deal with in terms of prenatal care and infant health?

FOOD-BORNE ILLNESS

And Dr. Frieden, just to piggyback on Mr. Alexander's comment on food-borne illness, how do we modernize your capability to implement the Food and Safety Modernization Act? What is your concern about sequestration and food safety?

Mr. KINGSTON. Those are for the record?

Ms. DELAURO. No. Quick answers.

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

Dr. COLLINS. So NCATS, the National Center for Advancing Translational Sciences, has been I think in its course of its just 1 year and 3 months actually embraced by virtually all the sectors that are touched upon, academics, universities, and industry.

I would like to maybe send for the record an editorial written by Bernie Munos who is sort of seen as a really authoritative view about the intersection between public and private who has ringingly endorsed the way in which NCATS has provided an opportunity to tackle bottlenecks in the pipeline that were otherwise not being attended to for the benefit of industry as well as academia. This is turning out to be a really wonderful enterprise.

MATERNAL AND CHILD HEALTH BLOCK GRANT

Ms. WAKEFIELD. So in terms of the Maternal and Child Health Block Grant, a couple of comments I think could be made. First of all, the money that we receive is distributed based on a formula using the number of children that are in poverty in a State compared to national poverty rates. It is a matching program, so it is really important in that respect too. So the States match. We match 4 Federal dollars for every \$3 that are invested by the States. The resources of that program go to care for Nation quality improvement, State infrastructure, special attention to children with special needs, for example.

In terms of infant mortality, it is an extremely important investment to help drive down rates of infant mortality, and we have actually been fairly successful on that front over the last few years. But we have very large disparities between African American infants and white children, and that is an area where we need to continue to do our work.

FOOD-BORNE ILLNESS

Dr. FRIEDEN. And we do need to modernize our laboratory testing so that we can go to methods that are quicker and more sensitive for detecting outbreaks.

I would also like to mention that as we understand how our health departments work to collect money from insurers, we are realizing it is much harder than we had anticipated. And that is one of the things that we are dealing with with many of our programs, including the immunization program, and the reason why we are less optimistic now about the ability to modulate the impact of cuts than we were a year ago.

Ms. DELAURO. Can you let me know just what sequestration would do to the food safety area?

Dr. FRIEDEN. It would reduce our funding by about 5 percent which would limit our ability to develop new tools as well as better use the existing tools that we have now to find and stop outbreaks.

Ms. DELAURO. And PulseNet will not be able to be upgraded.

Dr. FRIEDEN. We will do everything we can to manage through it.

Ms. DELAURO. Thank you.

COMMUNITY TRANSFORMATION GRANTS

Mr. KINGSTON. You know, there is \$226,000,000 in these pseudo-science community transformation grants that we could probably get you. I am just thinking that that is going to be a source of discussion.

I want to say this, Dr. Collins. While you and I have talked about that Tea Party tobacco study privately, I did not know that other committee members were monitoring it as well. And I think that is where we can find some common ground as we grapple with this issues, is just the straight allocation of resources to what makes sense and what does not.

And I do, Dr. Frieden, have a lot of questions on BARDA. We had a bill on the floor yesterday. It is very important to all of us in terms of stockpiling and chemical, biological attacks and everything else that are of national security. I am going to submit those to you for the record.

Mr. KINGSTON. So there is so much here and I know that Rosa and I could probably sit here till 5 o'clock, but at some point we may need to vote and eat. [Laughter.]

But with that, this hearing is adjourned. We meet again tomorrow at 10 o'clock.

[The following questions were submitted for the record.]

Department of Labor, Health and Human Services and Education and Related Agencies

Oversight Hearing: Health Agencies Core Mission

March 5, 2013

**HHS
QFRs from Chairman Kingston**

1) What process is used to ensure all HHS organizations routinely work together to review and coordinate research activity prior to funding?

Answer: HHS coordinates activities and promotes collaboration through its strategic planning process, annual performance reporting and budget processes, and working groups that connect experts from across the Department to address complex, multifaceted, and ever-evolving health and human service issues. The budget process provides the broad framework to assure research efforts are coordinated. At NIH where much of this research takes place, Institutes and Centers collaborate closely with many federal agencies to facilitate the broad dissemination of research findings generated by NIH-funded investigators. These efforts occur both at the IC level of NIH and at the level of the NIH Office of the Director.

2) How does the process ensure there is no duplication of efforts before you make funding decisions?

Answer: HHS coordinates activities and promotes collaboration through its strategic planning process, annual performance reporting and budget processes, and working groups that connect experts from across the Department to address complex, multifaceted, and ever-evolving health and human service issues. The budget process provides the broad framework to assure agencies' efforts are coordinated. In addition, agencies engage in various working groups, councils and advisory committees in an effort for agencies to prioritize funding efforts and avoid duplication.

3) How often do your agencies get together to examine the results of this activity to measure progress toward common public health or research goals and objectives?

Answer: The annual budget process is the Department's primary method to review and coordinate activities prior to funding. The process begins in the spring of each year, when HHS operating divisions are required to submit budget justifications to the Assistant Secretary for Financial Resources. Those justifications undergo rigorous examination, which includes review by the Secretary's Budget Council. Once Departmental decisions are finalized, revised justifications are submitted to the Office of Management and Budget. The result is a streamlined budget request to Congress, which provides critical investments in health care, disease prevention, social services, and scientific research.

In addition, HHS staff communicate frequently through informal channels as well as through interagency working groups, advisory councils, and social media platforms. One example is the

National Alzheimer's Project Act, which convenes an Interagency Group on Alzheimer's disease and Related Dementias (ADRD). This working group includes ASPE, OASH, NIA, CMS, CDC, ACL, HRSA, AHRQ, SAMHSA, FDA, IHS, and ACF to measure progress towards a common public health goal of preventing ADRD and addressing the challenges faced by people with these conditions and their caregivers. Through efforts like the National Alzheimer's Project Act, the Department supports, coordinates and implements performance management efforts across HHS.

- 4) Does HHS or do any of your organizations have a system in place to routinely conduct process evaluations to improve your organization's administrative or operational activities?**
- a. What were the results of the last round of reviews?**
 - b. Please explain any efficiencies, cost avoidance, or waste these types of review have resulted in over the past four years?**

Answer: HHS is always looking to improve administrative and operational activities. For example, consistent with the Administration's executive order on efficient spending, we are on track to reduce FY 2013 spending on a variety of administrative costs by 20% below FY 2010 levels. In addition, the Department accepted 190 quality and management improvement recommendations from the Office of Inspector General (OIG) in FY 2012 alone. One of the best ways the Department improves its activities is through the elimination of fraud, waste, and abuse in Medicare and Medicaid. The most recent Health Care Fraud and Abuse Control (HCFAC) Report (FY 2012), which details the programs detection and displayed the highest three-year return-on-investment (\$7.9:\$1) the program's history, with no evidence of diminishing returns, and \$4.2 billion in actual savings returned to the Medicare Trust Funds and the Treasury.

- 5a) The CMS Innovation fund is conducting comparative effectiveness research on prenatal care models to reduce elective deliveries. PCORI is also looking at this same research area. What is the specific process that was used to coordinate with PCORI to ensure efforts complement rather than duplicate each other?**

Answer: The Strong Start for Mothers and Newborns initiative, a joint effort between the CMS Innovation Center, the Health Resources and Services Administration (HRSA), and the Administration on Children and Families (ACF), aims to reduce preterm births and improve outcomes for newborns and pregnant women. On February 8, 2012, CMS announced the two strategies of this initiative to achieve these goals. The first is a public-private partnership and awareness campaign to reduce the rate of early elective deliveries prior to 39 weeks for all populations. The other component is a funding opportunity to test the effectiveness of specific enhanced prenatal care approaches to reduce the frequency of premature births among pregnant Medicaid or Children's Health Insurance Program (CHIP) beneficiaries at high risk for preterm births.

The Strong Start effort to test new approaches to prenatal care is a four-year initiative to test and evaluate enhanced prenatal care interventions for women enrolled in Medicaid or CHIP who are at risk for having a preterm birth. The goal of the initiative is to determine if these approaches to care can reduce the rate of preterm births, improve the health outcomes of pregnant women

and newborns, and decrease the anticipated total cost of medical care during pregnancy, delivery, and over the first year of life for children born to mothers in Medicaid or CHIP.

The Innovation Center seeks to ensure that our efforts build, strengthen and complement, not duplicate, other federal grant programs and initiatives. Reducing adverse outcomes for maternal and prenatal populations is a priority across several of our agency programs to ensure that we can provide quality care while lowering costs and improving overall health and outcomes for the populations we serve. As directed by statute, the Innovation Center consults with other federal agencies when appropriate.

5b) NIH uses biomedical research funds to study the effectiveness of smoking cessation programs while the CDC has spent close to a billion dollars in the last few years funding and evaluating tobacco control programs across the country. What is the specific process that was used to coordinate to ensure efforts complement rather than duplicate each other?

Dr. Frieden:

Answer: The smoking cessation activities at NIH and CDC are fundamentally different. NIH primarily funds research on nicotine addiction and the effectiveness of smoking cessation interventions (among other types of tobacco control research). CDC primarily funds state tobacco control programs to implement cessation interventions that have been shown to be effective. CDC's tobacco control work also includes preventing smoking initiation among young adults and youth, reducing nonsmoker exposure to secondhand smoke, and reducing population-level tobacco-related disparities.

CDC-funded cessation activities are built on the evidence base that NIH research helps create. CDC supported state evaluations of these activities further contribute to building and refining that evidence base. CDC's focuses on cessation surveillance research and evaluation of existing state tobacco cessation programs. CDC and NIH engage in frequent conversation about goals, funding initiatives, and new research to ensure the efforts are well coordinated and complementary, rather than duplicative.

Dr. Collins:

Answer: The scope of activities related to smoking cessation at NIH and CDC are fundamentally different and complementary to each other. NIH primarily funds investigator-initiated research on nicotine addiction and the effectiveness of smoking cessation interventions. CDC primarily funds state tobacco control programs to implement cessation interventions that have been shown to be effective based in part on the evidence base coming from NIH-funded research. CDC-supported state evaluations of these activities further contribute to building and refining that evidence base.

CDC and NIH recognize the importance of coordination and collaboration. Both CDC and NIH engage in frequent conversations and serve together on a number of working groups and committees to collaborate around goals, initiatives, and priorities for new research.

6) HHS has many interagency coordinating committees and working groups –

- a. How many interagency coordinating committees and working groups are there?**
b. How are recommendations from these advisory groups handled at HHS?

Answer: HHS has many interagency working groups and coordinating bodies that cover topics ranging from Racial and Ethnic Health Data, to food safety, to the Department's IT infrastructure. Working groups are designed to connect experts from across the Department to address complex, multifaceted, and ever-evolving health and human service issues. There is no one set way that recommendations are handled; some groups are formally structured while others are informal. Most working groups meet regularly to discuss plans in each of these areas and actions they are taking to implement recommendations and provide advice to leadership.

- 7) Fetal alcohol syndrome research examines potential developmental issues in a baby when a mother drinks alcohol during pregnancy. It is funded in all of your organizations, except the Innovation Fund but maybe you do research there as well.**

NIH spends about \$36 million a year on this syndrome. It also puts out guides or manuals for the public. CDC spends about \$10 million a year on fetal alcohol syndrome and also makes guidance available to the public. Further HRSA, AHRQ, and Substance Abuse and Mental Health Services Administration also fund this activity in their budgets.

- 7a. How does NIH work with the other agencies to decide what activities to fund in the area of fetal alcohol syndrome?**

Answer. NIH coordinates with other agencies on this topic primarily through the Interagency Coordinating Committee on Fetal Alcohol Spectrum Disorders (ICCFASD), established in 1996. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) chairs this committee with significant contributions from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) as well as agencies from the Department of Health and Human Services (HHS) (including the Administration for Children and Families (ACF), the Centers for Disease Control and Prevention (CDC), the Indian Health Service (IHS), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Health Resources and Services Administration (HRSA), the Agency for Healthcare Research and Quality (AHRQ), the Department of Education, and the Department of Justice (DOJ). The ICCFASD was established to improve communication, cooperation, and collaboration among federal agencies that address issues relevant to fetal alcohol spectrum disorders (FASD), including Fetal Alcohol Syndrome (FAS), caused by prenatal alcohol exposure. The ICCFASD meets regularly; the most recent meeting of the ICCFASD was on April 4, 2013. Through the ICCFASD, agencies share their current activities, program advances, and future plans. The ICCFASD includes special focus work groups on education issues, justice issues, diagnostic issues, and a special work group on women, pregnancy, and drinking. These special subgroups help ensure coordination across more specific areas. More information on the ICCFASD is available at <http://www.niaaa.nih.gov/ICCFASD>.

- 7b. How do you coordinate the funding plan and goals?**

Answer. The ICCFASD meetings help agencies exchange information and coordinate general funding strategies, plans, and goals. Each agency's funding plan is directed by their specific mission, although guided by the overall goals established through the ICCFASD. Within NIH, NICHD and NIAAA work closely together to coordinate FAS research activities. An important portion of the NIH research activity on FAS is conducted through the Prenatal Alcohol in Sudden Infant Death Syndrome (SIDS) and Stillbirth (PASS) research network, jointly funded by NIAAA, NICHD, and the National Institute on Deafness and Other Communication Disorders (NIDCD).

7c. What actions do you take to reduce duplication, and ensure the scientific gaps across the various agencies are effectively addressed

Answer. Although several agencies fund activities related to FAS and related disorders, each agency's unique mission guides its activities and funding priorities. NIH focuses on basic and clinical research to prevent FAS and to treat affected children to minimize the damage caused by FAS and related disorders. Within NIH, NICHD's major interests in this area are stillbirth, SIDS, and alcohol's role in these outcomes; NIAAA supported research is focused on identifying the biological mechanisms that underlie FASD, improving FASD diagnosis and prevention, and developing behavioral and/or pharmacological interventions to ameliorate the symptoms of FASD. Officials in ICCFASD agencies stay in close touch and exchange information on new, planned and ongoing activities to prevent duplication of effort. The ICCFASD's special focus groups allow agencies to work together to address research and program gaps. In addition, the ICCFASD conducts workshops and joint activities to address gaps across the various agencies and to allow agencies to work collaboratively to inform the public about FAS issues. For example, in 2012 the ICCFASD held a special workshop entitled "Alcohol-Related Birth Disorders and the Law: How Should Attorneys & Judges Respond to Fetal Alcohol Spectrum Disorders?". Held in collaboration with the American Bar Association, this meeting educated the legal community on FAS with presentations by NIH-funded researchers, program officials from ICCFASD agencies, public health officials, local district attorneys, and other experts.

7d. How do you measure success and develop measures that build on each organization's strength?

Answer. The activities conducted by different federal agencies are diverse in their ultimate goals and objectives. Because the goals and activities of agency programs are so diverse, measures of success will also differ across programs and organizations. Within NIH, research success is assessed at the level of the individual project and also by assessing the impact of the overall research portfolio. NIH Institutes and Centers commonly assess FAS projects and portfolios through publication reviews, science advances, and the career development of early stage investigators.

7e. How and how often do you conduct program evaluations?

Answer. NIAAA's FASD portfolio is evaluated annually by the Program Officer serving as NIAAA's representative to the ICCFASD. This evaluation is undertaken shortly after the close of each fiscal year to ascertain the number of FASD grants comprising this portfolio, overall dollars spent on this research, and the distribution of these projects addressing prevention, diagnosis, treatment, and mechanistic research. Information from this analysis is presented to the ICCFASD as well as to the FASD Study Group which is comprised of FASD researchers. FASD projects are also reviewed in the larger context of the NIAAA grant portfolio to ensure a balance of research projects across the entire spectrum of NIAAA-supported research.

8) Please explain how you coordinate items posted on your website on various overlapping health topics to ensure they are not in conflict or duplicative with information on other HHS or federal government web sites?

Answer: The development, review and daily operation of the main HHS/OS public website (www.hhs.gov) is managed by the Office of the Assistant Secretary for Public Affairs (ASPA). ASPA also manages the Department's priority websites, including several cross-federal topic websites, such as FoodSafety.gov and Flu.gov, Secretary-level web pages, and the HHS intranet. ASPA works across the Department to ensure that agency staff review news releases and other public affairs announcements to ensure that the information is coordinated.

Websites for individual operating divisions within the Department are managed by their own staff. For example, at NIH leadership and guidance on internet-based communication is provided by the Office of Communications & Public Liaison to NIH's 27 Institutes and Centers. Operating divisions cross-reference related health topics, like obesity or tobacco, to ensure websites are aligned and complimentary to efforts at each agency.

9) How many office of communications to each of you have and how much is spend on all your communications activity across your organizations?

Answer: HHS operating divisions are responsible for promoting transparency, accountability and access to critical public health and human services information to the public, media, and constituency groups. Many of the Department's communications efforts are embedded in agency operating budgets and program operations, so a breakout of HHS-wide communications activity is not available in the format requested.

HHS operating divisions have centralized offices of communications to manage efforts such as public affairs activities, internal communications efforts, as well as digital, print, and broadcast media. The National Institutes for Health has a communications office for each of its 27 Institutes and Centers, as well as an Office of Communications & Public Liaison located in the Office of the Director. The Centers for Medicare & Medicaid Services has one Office of Communications. The Health Resources and Services Administration has an Office of Communications that provides leadership and general policy and program direction for, and conducts and coordinates communications and public affairs activities of the Agency. The Agency for Healthcare Research and Quality has an Office of Communications and Knowledge Transfer (OCKT) that promotes the communication of information to both internal and external

customers. The Centers for Disease Control and Prevention has an Office of the Associate Director for Communication, whose mission is to further customer-centered, science-based and effective communication to support CDC's public health work.

10) I assume you are familiar with process evaluations, as they can identify ways to eliminate inefficiencies in programs operations, such as duplication within your agency and across agencies where overlapping activities exist.

- a. Does HHS or do any of your organizations have a system in place to routinely conduct process evaluations to improve your organization's administrative or operational activities?
- b. What were the results of the last round of reviews?
- c. Please explain any efficiencies, cost avoidance, or waste these types of review have resulted in over the past four years?

Answer: The annual budget process is the Department's primary method to identify and eliminate redundancy and duplication across programs. The process begins in the spring of each year, when HHS operating divisions are required to submit budget justifications to the Assistant Secretary for Financial Resources. Those justifications undergo rigorous examination, which includes review by the Secretary's Budget Council. Once Departmental decisions are finalized, revised justifications are submitted to the Office of Management and Budget. The result is a streamlined budget request to Congress, which provides critical investments in health care, disease prevention, social services, and scientific research in order to create healthier and safer families, stronger communities, and a thriving America.

In addition, as part of the Administration's Executive Order on efficient spending, HHS reviewed categories of administrative spending to find ways to improve efficiency and lower cost. For example, HHS was able to achieve savings in printing and reproduction by shifting printed material to digital and online access, and reducing hard copy printing.

11) How do you coordinate your portfolio to ensure it aligns and is approved with the National Agenda created by the Patient-Centered Outcomes Research Institute (PCOR)?

Answer: HHS is keenly interested in the work of PCORI, and works to make sure that each organization's role is complementary rather than duplicative. With funding from the American Recovery and Reinvestment Act of 2009, the Department established a foundation for the field of patient-centered outcomes research (PCOR) efforts. Both Dr. Clancy, the Director of AHRQ, and Dr. Collins, the Director of NIH, sit on PCORI's board, providing for a flow of information between PCORI and HHS research agencies. The organizations discuss upcoming projects as well as lessons learned, in order to better align activities between PCORI and HHS. For example, since PCORI is primarily conducting research, AHRQ is focusing instead on dissemination of PCOR information to health professionals and patients, and training researchers who understand how to conduct and use that information to improve care.

12) NIH uses biomedical research funds to study the effectiveness of smoking cessation programs while the CDC has spent close to a billion dollars in the last few years funding and evaluating tobacco control programs across the country. What is the specific process that was used to coordinate to ensure efforts complement rather than duplicate each other?

Dr. Frieden:

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CDC and NIH recognize the importance of coordination and collaboration. Both CDC and NIH engage in frequent conversations and serve together on a number of working groups and committees to collaborate around goals, initiatives, and priorities for new research.

13) Please update all the tables and dates provide in the fiscal year 2013 HHS Secretary hearing questions for the record for the questions under the title "Continued Excessive Use of Special Title 42 Pay Authority." The update should add a column for fiscal year 2012 and projected for fiscal year 2013.

Answer: The following tables provide information from the HHS Office of Human Resources' Business Intelligence Information Systems (BIIS), which included Capital HR (CapHR) data and the Defense Finance and Accounting Services (DFAS) payroll data for FY 2007 through FY 2012.

OPWAV	2007	2008	2009	2010	2011	2012	2013 (Projected)
ACF							
Total FTE used	1,229	1,283	1,238	1,331	1,338	1,302	1,379
Total Title 42 FTE	-	-	-	-	-	-	-
Total Title 42 209 F Staff Count	-	-	-	-	-	-	-
Total Title 42 209 G Staff Count	-	-	-	-	-	-	-
Total # Title 42 Recruitment Bonus	-	-	-	-	-	-	-
Total # Title 42 Retention Bonus	-	-	-	-	-	-	-
AHRQ							
Total FTE used	295	297	288	312	313	308	320
Total Title 42 FTE	53	38	35	28	12	14	14
Total Title 42 209 F Staff Count	5	3	3	3	6	3	3
Total Title 42 209 G Staff Count	48	35	32	25	16	18	18
Total # Title 42 Recruitment Bonus	-	-	-	-	-	-	-
Total # Title 42 Retention Bonus	-	-	-	-	-	-	-
ACL							
Total FTE used	112	106	101	100	115	119	119
Total Title 42 FTE	-	-	-	-	-	-	-
Total Title 42 209 F Staff Count	-	-	-	-	-	-	-
Total Title 42 209 G Staff Count	-	-	-	-	-	-	-
Total # Title 42 Recruitment Bonus	-	-	-	-	-	-	-
Total # Title 42 Retention Bonus	-	-	-	-	-	-	-
CDC							
Total FTE used	8,569	8,944	9,567	10,179	10,674	10,877	10,823
Total Title 42 FTE	702	796	922	991	1,100	1,225	1,225
Total Title 42 209 F Staff Count	94	97	105	104	127	138	138
Total Title 42 209 G Staff Count	747	879	1,009	995	1,002	686	686
Total # Title 42 Recruitment Bonus	5	5	14	5	11	2	2
Total # Title 42 Retention Bonus	8	5	3	4	4	2	2
CMS							
Total FTE used	4,526	4,483	4,381	4,537	5,195	5,416	6,160
Total Title 42 FTE	15	13	9	8	6	-	-
Total Title 42 209 F Staff Count	1	1	1	1	1	-	-
Total Title 42 209 G Staff Count	-	-	-	-	-	-	-
Total # Title 42 Recruitment Bonus	-	-	-	-	-	-	-
Total # Title 42 Retention Bonus	-	-	-	-	-	-	-
FDA							
Total FTE used	9,618	9,909	11,310	12,522	13,331	13,538	14,572
Total Title 42 FTE	535	551	795	870	858	853	853
Total Title 42 209 F Staff Count	251	249	232	223	215	940	940
Total Title 42 209 G Staff Count	394	496	698	800	795	864	864
Total # Title 42 Recruitment Bonus	1	65	55	5	0	3	3
Total # Title 42 Retention Bonus	114	95	120	18	26	26	26

Agency	2007	2008	2009	2010	2011	2012	2013 (Projected)
HRSA							
Total FTE used	1,708	1,484	1,481	1,609	1,869	1,894	1,894
Total Title 42 FTE	3	3	4	4	4	6	6
Total Title 42 209 F Staff Count	-	-	-	-	3	4	4
Total Title 42 209 G Staff Count	-	-	-	-	2	2	2
Total # Title 42 Recruitment Bonus	-	-	-	-	1	-	-
Total # Title 42 Retention Bonus	-	-	-	-	1	1	-
IHS							
Total FTE used	15,062	14,985	15,267	15,830	15,509	15,587	15,587
Total Title 42 FTE	2	2	1	4	3	-	-
Total Title 42 209 F Staff Count	-	-	-	-	-	-	-
Total Title 42 209 G Staff Count	-	-	-	-	-	-	-
Total # Title 42 Recruitment Bonus	-	-	-	-	-	-	-
Total # Title 42 Retention Bonus	-	-	-	-	-	-	-
NIH							
Total FTE used	16,986	17,241	17,785	18,351	18,569	18,497	18,497
Total Title 42 FTE	4,234	4,348	4,537	4,766	4,792	4,771	4,771
Total Title 42 209 F Staff Count	2,334	2,458	2,530	2,580	2,533	2,565	2,565
Total Title 42 209 G Staff Count	2,432	2,541	2,609	2,729	2,854	2,859	2,859
Total # Title 42 Recruitment Bonus	59	72	62	53	32	12	-
Total # Title 42 Retention Bonus	75	68	55	26	16	15	-
OS							
Total FTE used	3,850	4,069	4,118	4,706	5,416	5,456	5,550
Total Title 42 FTE	10	11	11	11	12	14	14
Total Title 42 209 F Staff Count	5	2	7	8	10	12	12
Total Title 42 209 G Staff Count	3	4	1	5	7	8	8
Total # Title 42 Recruitment Bonus	-	-	-	1	1	-	-
Total # Title 42 Retention Bonus	-	-	-	-	-	-	-
PSC							
Total FTE used	1,126	1,132	1,199	985	826	764	677
Total Title 42 FTE	1	-	-	-	-	-	-
Total Title 42 209 F Staff Count	-	-	-	-	-	-	-
Total Title 42 209 G Staff Count	-	-	-	-	-	-	-
Total # Title 42 Recruitment Bonus	-	-	-	-	-	-	-
Total # Title 42 Retention Bonus	-	-	-	-	-	-	-
SAMHSA							
Total FTE used	511	533	519	530	542	590	631
Total Title 42 FTE	10	11	7	6	0	2	2
Total Title 42 209 F Staff Count	-	-	-	-	-	1	1
Total Title 42 209 G Staff Count	-	-	-	-	-	1	1
Total # Title 42 Recruitment Bonus	-	-	-	-	-	-	-
Total # Title 42 Retention Bonus	-	-	-	-	-	-	-

Annual Number of Title 42 FTE with an Annual Salary equal to or above the Executive Level III for the year	Fiscal Year						
	2007	2008	2009	2010	2011	2012	2013
ACF	-	-	-	-	-	-	-
AHRO	5	4	4	4	6	2	2
ACL	-	-	-	-	-	-	-
CDC	99	90	89	91	92	81	81
CMS	-	-	-	-	-	-	-
FDA	70	89	94	105	104	124	124
HRSA	-	-	-	-	-	3	3
IHS	-	-	-	-	-	-	-
NIH	885	1,040	1,024	1,085	1,115	1,046	1,046
OS	5	3	8	9	9	6	6
PSC	-	-	-	-	-	-	-
SAMHSA	-	-	-	-	-	-	-

Annual Number of Title 42 Employees who received both a Recruitment and Retention Bonus	Fiscal Year						
	2007	2008	2009	2010	2011	2012	2013
ACF	-	-	-	-	-	-	-
AHRO	-	-	-	-	-	-	-
ACL	-	-	-	-	-	-	-
CDC	-	-	-	-	-	-	-
CMS	-	-	-	-	-	-	-
FDA	-	-	-	-	-	-	-
HRSA	-	-	-	-	-	-	-
IHS	-	-	-	-	-	-	-
NIH	1	-	-	-	-	-	-
OS	-	-	-	-	-	-	-
PSC	-	-	-	-	-	-	-
SAMHSA	-	-	-	-	-	-	-

Annual Maximum Recruitment Bonus	Fiscal Year						
	2007	2008	2009	2010	2011	2012	2013
ACF	-	-	-	-	-	-	-
AHRO	-	-	-	-	-	-	-
ACL	-	-	-	-	-	-	-
CDC	\$67,500	\$35,089	\$37,400	\$53,750	\$53,359	\$10,728	\$31,424
CMS	-	-	-	-	-	-	-
FDA	\$19,800	\$33,750	\$20,492	\$40,000	-	\$75,000	-
HRSA	-	-	-	-	\$22,375	-	-
IHS	-	-	-	-	-	-	-
NIH	\$51,250	\$57,250	\$50,000	\$45,000	\$62,500	\$85,000	\$25,000
OS	-	-	-	\$20,097	\$25,000	-	-
PSC	-	-	-	-	-	-	-
SAMHSA	-	-	-	-	-	-	-

Annual Maximum Recruitment Bonus	Fiscal Year						
	2007	2008	2009	2010	2011	2012	2013
ACF	-	-	-	-	-	-	-
AHRO	-	-	-	-	-	-	-
ACL	-	-	-	-	-	-	-
CDC	\$46,602	\$38,196	\$25,877	\$20,973	\$25,367	\$22,776	-
CMS	-	-	-	-	-	-	-
FDA	\$32,608	\$17,980	\$26,492	\$14,606	\$13,630	\$5,459	-
HRSA	-	-	-	-	\$4,975	\$44,600	-
IHS	-	-	-	-	-	-	-
NIH	\$49,831	\$68,999	\$44,681	\$45,001	\$45,845	\$45,842	-
OS	-	-	-	-	-	-	-
PSC	-	-	-	-	-	-	-
SAMHSA	-	-	-	-	-	-	-

Annual Maximum Recruitment Bonus	Fiscal Year						
	2007	2008	2009	2010	2011	2012	2013
ACF	-	-	-	-	-	-	-
AHRO	-	-	-	-	-	-	-
ACL	-	-	-	-	-	-	-
CDC	\$46,602	\$38,196	\$25,877	\$20,973	\$25,367	\$22,776	-
CMS	-	-	-	-	-	-	-
FDA	\$32,608	\$17,980	\$26,492	\$14,606	\$13,630	\$5,459	-
HRSA	-	-	-	-	\$4,975	\$44,600	-
IHS	-	-	-	-	-	-	-
NIH	\$49,831	\$68,999	\$44,681	\$45,001	\$45,845	\$45,842	-
OS	-	-	-	-	-	-	-
PSC	-	-	-	-	-	-	-
SAMHSA	-	-	-	-	-	-	-

Annual Number of Title 42 Hires	Fiscal Year						
	2007	2008	2009	2010	2011	2012	2013
ACF	-	-	-	-	-	-	-
AHRO	5	2	3	4	1	6	6
ACL	-	-	-	-	-	-	-
CDC	169	192	183	198	179	143	143
CMS	-	-	-	-	-	-	-
FDA	197	178	322	165	168	479	479
HRSA	-	-	-	4	2	1	1
IHS	-	-	-	-	-	-	-
NIH	650	699	667	648	575	500	500
OS	1	1	5	3	5	9	9
PSC	-	-	-	-	-	-	-
SAMHSA	0	-	-	-	-	1	1

Annual Number of Title 42 Conversions	Fiscal Year						
	2007	2008	2009	2010	2011	2012	2013
ACF	-	-	-	-	-	-	-
AHRO	14	11	12	2	5	6	-
ACL	-	-	-	-	-	-	-
CDC	142	145	182	142	164	166	-
CMS	-	-	-	-	-	-	-
FDA	94	214	151	187	167	250	-
HRSA	-	-	-	0	0	2	-
IHS	-	-	-	-	-	-	-
NIH	513	694	581	463	489	960 *	-
OS	-	-	-	-	-	9	-
PSC	-	-	-	-	-	-	-
SAMHSA	2	-	-	-	-	1	-

* These conversions also include the number of employees converted in FY 2012 to correct policy compliance issues.

The below table identifies the number of employees that could be paid at levels above executive level III if HHS were restricted at any of the varying levels indicated in your question.

Title 42 Employees	Total Title 42 FTE
Total Title 42 Employees end of FY 2012	6885
Above Exec Level III at 1%	69
Above Exec Level III at 0.5%	34
Above Exec Level III at 0.25%	17

14) For each HHS OPDIV, please provide a description of its OPDIV fiscal management process with a specific discussion on hard funds control systems to ensure the agency does not violate any reprogramming, anti-deficiency, or acquisition rules.

Answer: HHS OPDIVs take financial management very seriously, and our financial leadership is vigilant in its efforts to ensure that financial and budget staff are aware of the rules and regulations pertaining to reprogramming, acquisitions, and the Anti-Deficiency Act. Staff trainings on appropriations law, HHS Acquisition Regulation and internal HHS acquisition guidance, appropriation law decision tree, and the updated Acquisition Plan template are used to ensure that program, contracting, and budget officials fund our acquisitions properly.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

QFRs from Chairman Kingston

1) I understand CDC has encouraged States to consider using the National Public Health Performance Standards (NPHPS) as a mechanism to improve the quality of public health practice and performance of public health systems by providing systems-focused standards for performance.

a. Please describe how CDC has implemented these tools and standards within to improve the quality of public health practice and performance at CDC.

CDC-KINGSTON1a Response:

The national public health system performance standards and assessment tools (NPHPS) are available for state and local public health agencies as well as for local boards of health. The NPHPS is a valuable tool for state and local jurisdictions. NPHPS is a collaborative effort of seven non-Federal national public health organizations, engaging multiple cross sector partners involved in community health assessment, planning, and identification of strengths and weaknesses to drive improvement efforts. As such, the NPHPS results are often a key part of state or community health improvement planning efforts.

NPHPS was developed by workgroups comprised of the very state and local constituencies specifically for use at the state and local level. Although CDC has not used instruments specifically at the federal level, many of the NPHPS standards and processes have been routinely applied to the work of CDC. This work centers on federal initiatives that foster broad cross sector engagement, strategic planning and goal setting, routine monitoring of performance, and implementation and evaluation of improvement initiatives. For example, Healthy People 2020, the Government Performance Results Act (GPRA) and the National Prevention Strategy represent concrete initiatives that include development of performance measures, tracking performance against benchmarks and targets, and establishing health improvement planning activities for the nation as a whole. Within CDC, the Office of the Director leads a quarterly program review process of center, office, and division level programs to track and manage performance and make improvements. In the same way that the NPHPS stimulates broad engagement of stakeholders, CDC receives input and guidance on how to improve CDC's operations, programs, and support to jurisdictions via the Advisory Committee to the CDC Director and its State, Tribal, Local and Territorial Workgroup. Recommendations from this workgroup have led to improvements in high-priority areas, such as streamlining and standardizing CDC's funding opportunity announcements and improving program development and project officer competencies and customer service to state, local, tribal, and territorial health agencies.

b. Does CDC have a transparent criteria-based budget process that uses sound scientific data to create measurable public health and preparedness goals with specific goals for each program?

CDC-KINGSTON -1b Response:

Yes, in addition to the Government Performance and Results Act (GPRA) and the recent Modernization Act (GPRAMA) which require that HHS and other cabinet-level Departments provide annual program performance data and targets for the public, CDC has a proven track record of ensuring measurable public health outcomes and has established accountability systems and specific measures to track investments and to set clear standards for performance and monitoring progress.

Programs establish all CDC performance measures in consultation with CDC leadership, HHS, and OMB. The performance measures represent the key activities and accomplishments of CDC programs for which sound data are available. To ensure data quality, CDC requires all programs to provide data validation statements annually. Should an issue with data quality arise, CDC provides a brief explanation in the President's budget to ensure transparency.

CDC regularly reviews the GPRA measures to identify programs with performance issues. CDC provides these programs with various forms of assistance, including program review and consultation on program strategy and redesign. In some cases, programs are elevated for discussion with senior leaders as potential candidates for budget increases, decreases, or elimination.

c. If yes to above, please describe the process and provide the measurable objective for each program, project, or activity listed in the FY 2012 Appropriations Act and Statement of Managers.

CDC- KINGSTON-1c RESPONSE:

The FY 2014 President's Budget submission for CDC and ATSDR lists 173 performance measures capturing the ongoing activities of our priority programs and their impact. In addition to the measures listed in the budget, CDC sets additional goals for several priority areas, known collectively as the "winnable battles." Winnable Battles were chosen to achieve measurable impact in a short timeframe (one to four years) in a few targeted areas. They address high impact health problems where evidence-based, scalable interventions exist to make significant improvements and have formed the basis of CDC's budget formulation.

Lastly, in collaboration with HHS and other HHS operating divisions, CDC plays a critical role in three federal High Priority Goals (reducing cigarette smoking, improving patient safety, and reducing foodborne illness in the population). These high priority goals are actionable and achievable. They aggregate the resources of HHS operating divisions to work toward and achieve common outcomes. CDC uses these clear and aggressive performance metrics and program evaluation data to monitor performance and effectiveness and to ensure these goals can be achieved.

Examples of performance successes at CDC

- CDC is better protecting Americans from illness and harm from contaminated food through improved tracking. In the 2011 Listeria outbreak, health officials warned the public four times faster than ever before.
- A higher percentage of Americans with HIV know they are infected, enabling them to protect themselves and their partners and to live longer, healthier lives. Awareness of HIV infection

among men who have sex with men (MSM) testing positive for HIV in a 20-city study has increased in recent years, and the proportion of MSMs testing positive that were already aware of their infection increased from 56% in 2008 to 66% in 2011.

- Americans are less likely to get a life threatening infection in healthcare settings. In 2010, CDC helped reduce these infections--a 32% reduction in central-line associated blood stream infections and an 18% reduction in healthcare associated MRSA from year to year.
- CDC developed a new diagnostic test to detect the presence of dengue virus in 2012. This is the first FDA-approved molecular test for dengue that detects evidence of the virus itself. It can be performed using equipment and supplies many public health laboratories already use to diagnose influenza.
- CDC is projecting that 100,000 smokers in the United States are likely to quit smoking as a result of the first-ever national paid anti-tobacco media campaign, *Tips from Former Smokers*.
- 90% of the U.S. population now lives within 100 miles of a CDC Laboratory Response Network member laboratory, ensuring broad access to testing during public health emergencies.

2) Please provide a list of all the programs, projects or activities that required or voluntarily collect data from State, counties, or other municipalities?

CDC-KINGSTON-2 RESPONSE

CDC surveillance systems are driven by the nature of the specific public health area each is designed to track, and there are a variety of sources and collection methods for the data being collected and reported. The design and functionality of these systems are driven by the type of data and how the data are used for decision-making. Data collection efforts that involve health care records, for example, focus on diagnosis and care issues, and information from these health records is routinely extracted and reported by almost every state. Others systems collect data through surveys that are telephone based, which have a specific at-risk population and require unique sampling and survey methods.

Current surveillance systems and registries that receive data relevant to human health from state, local, county, or territorial health departments are:

- Behavioral Risk Factor Surveillance System
- BioSense Surveillance System
- Birth Defects Surveillance, Autism and Developmental Disabilities Monitoring Network including data on Fetal Alcohol Syndrome and early hearing detection and intervention; the Metropolitan Atlanta Congenital Defects and Developmental Disabilities Surveillance Programs
- Emerging and Zoonotic Infectious Diseases Surveillance including foodborne diseases and outbreaks, laboratory subtyping network for foodborne diseases, listeria, botulism, cholera and other vibrio illnesses, rabies, Lyme disease, dengue, arboviruses, the Arctic investigations program and emerging infections program

- Influenza Surveillance Program including data on influenza associated pediatric mortality, hospitalization, outpatient influenza-like illnesses, 122 cities mortality reporting, geographic spread, novel influenza A and WHO collaborating laboratories
- Medical Monitoring Project (related to schools)
- National ALS Registry (will receive 2009-11 data on one time basis only)
- National Environmental Public Health Tracking Network and the National Voluntary Environmental Assessment Information System including data on healthy homes and lead poisoning prevention
- National HIV Surveillance System including the HIV Behavioral Surveillance System
- National Notifiable Diseases Surveillance System
- National Program of Cancer Registries and US Cancer Statistics
- National Respiratory and Enteric Virus Surveillance System including data for calicivirus, enteroviruses, legionella, meningococcal disease, pertussis and the active bacterial core surveillance system
- National Toxic Substance Incidents Program
- National Tuberculosis Surveillance System including the Tuberculosis Indicators Project
- Occupational Health Surveillance including data on work-related asthma, silicosis, pesticide poisoning, adult blood-lead, occupational mortality and occupational injury (Alaska)
- Oral Health Tracking and Data Resource Center Programs including the National Oral Health Surveillance System and water fluoridations reporting
- Perinatal Hepatitis B Prevention data and reference laboratory data
- Pregnancy-related conditions surveillance including data on mortality, risk assessment, abortion and stillbirth
- Public Health Research, Epidemiology, Surveillance and Registry for Hemoglobinopathies
- Sexually Transmitted Diseases Surveillance Network including the Gonococcal Isolate Surveillance Project
- State Injury Indicators and National Violent Death Reporting System
- Travelers Disease Notification including quarantine activity reporting and the border disease surveillance project

3) What is the total cost of to operate all CDC information technology activities in fiscal year 2012?

CDC-KINGSTON-3 RESPONSE

The total cost to operate all CDC information technology activities in fiscal year 2012 was \$464.6 million.

4) Does CDC require States hire employees in order to receive certain federal funds? If so, please list the specific programs that include such requirement.

CDC-KINGSTON-4 RESPONSE:

CDC does not require States to hire employees in order to receive federal funds. States submit a detailed budget proposal when applying for funds, and they determine how to spend those funds to implement activities. The roles and responsibilities are outlined in the FOAs, and States have the discretion on how to fulfill the requirements. Some FOAs require a state coordinator, but this requirement may be filled with current staff. States may decide to hire employees if they do not have adequate staff to meet the requirements in the FOA.

5) Please identify how much CDC funds on all research activities?

CDC-KINGSTON-5 RESPONSE:

CDC spent \$407,524,000 on research and development in FY 2012.

6) Please identify how much CDC funds on all surveillance activities?

CDC-KINGSTON-6 RESPONSE:

CDC estimated funding of \$508,228,757 for surveillance activities for FY 2012.

7) Please explain why CDC proposes to change the ratio for purchases of adult and children?

CDC-KINGSTON-7 RESPONSE:

Our assumption is that this question is referring to the purchase of vaccines for adults and children by the Section 317 Immunization Program. Since September 2010, new health plans are required to cover vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) without charging a deductible, copayment, or coinsurance when services are provided in-network. In 2014, expansion of immunization coverage through the implementation of the Affordable Care Act will further decrease the number of uninsured and underinsured individual served by the Section 317 program. Further, uninsured children are served through the mandatory Vaccines for Children program. However, there will continue to be a need for Section 317-purchased vaccines to serve uninsured adults and to provide rapid vaccination response to disease outbreaks and other urgent public health needs. As part of the new five year funding cycle that began in FY 2013, CDC adopted a vaccine use policy that Section 317-purchased vaccines cannot be used for routine vaccination of fully insured individuals. Assuring that public funds are not subsidizing insured benefits allows CDC to target its resources more effectively to meet public health priorities.

8) In the FY 2013 budget request, CDC proposed to reduce funding for the Section 317 program based on assumptions related to the number of child who will have insurance from other programs. Please explain how CDC is working with the States to develop a plan to transition States out of CDC provided federal funding for vaccine activities and the assumed timeline for this transition.

CDC-KINGSTON-8 RESPONSE:

CDC is not transitioning States out of CDC provided federal funding for vaccine activities. The Section 317 Immunization Program is an essential public health program that provides the majority of federal funding for immunization infrastructure at the national, state, and local levels. Although modest in comparison to the vaccines purchased by the Vaccines for Children (VFC) program, Section 317-purchased vaccines are a critical resource for providing vaccines to individuals who are unable to receive them through other means and responding to disease outbreaks and other urgent public health needs. However, FY 2011 and FY 2012 funding supported activities to assist States with the transition to full implementation of the Affordable Care Act, such as enhancing Immunization Information Systems, expanding third-party billing for immunization services provided in public health clinics, strengthening vaccine storage and handling, and improving capacity for vaccinating school-age children and adults (FY 2013 CJ, page 44).

CDC issued a program policy that beginning October 1, 2012, Section 317-purchased vaccine may no longer be used to provide routine vaccinations for fully insured individuals. To help awardees prepare for implementation of this program policy, CDC has provided and continues to offer technical assistance to Section 317 awardees. Examples of the technical assistance provided includes: communicating the change to the public, providers, and other immunization partners; and identifying possible solutions for ensuring access for insured individuals, such as improving in-network access (e.g., rural areas and other areas where there may not be adequate in-network providers) and addressing issues related to high-deductible health plans.

9-10) Dr. Frieden – Last week the NY Times reporter Gina Kalata wrote articles dealing with the Mediterranean diet and diets in general. In one of the articles, Rachel Johnson, spokesperson for the American Heart Association said; “(the information is) Really impressive,” “And the really important thing — the coolest thing — is that they used very meaningful endpoints. They did not look at risk factors like cholesterol of hypertension or weight. They looked at heart attacks and strokes and death. At the end of the day, that is what really matters.”

Dr. Frieden, when you and the CDC look at sodium, it appears from your press releases and comments that you tend to only look at the risk factors such as hypertension, and pay little attention to studies that say otherwise?

In fact, you said in a 2012 NY Post article, “Too much sodium raises blood pressure, which is a major risk factor for heart disease and stroke,” “These diseases kill more than 800,000 Americans each year and contribute an estimated \$273 billion in health care costs.” However when pressed for specifics, Karen Hunter of the CDC said, “CDC does not have data on the number of heart attack and stroke deaths that are caused by excess sodium”

Are you stating that 800,000 deaths and \$270 billion in health care costs is attributable to sodium.

- a. What specific data do you or the CDC have on the number of deaths or illnesses caused by sodium? Is this a computer generated number or do you have peer reviewed studies that provided that data?**

CDC-KINGSTON-10a-RESPONSE

Excess sodium intake is a major contributor to hypertension (IOM, 2010) and hypertension is a major risk factor for cardiovascular disease (Heidenreich, *Circulation*, 2011). Dr. Frieden's remarks correctly refer to estimates of costs and deaths attributable to cardiovascular disease available in the scientific literature. The latest published data indicate nearly 800,000 people die in the United States each year from cardiovascular diseases, accounting for about 1 in every 3 deaths (Kochanek, *National Vital Stat Rep*, 2011). The \$270 billion estimate is from a 2011 *Circulation* article which projected direct medical costs of cardiovascular disease (Heidenreich P., et al, <http://circ.ahajournals.org/content/early/2011/01/24/CIR.0b013e31820a55f5.full.pdf+html>)

- b. Are you aware of studies that suggest, using patient observational data that a low sodium diet leads to health problems and even death in certain populations? What are your views of those studies?**

CDC-KINGSTON-10b RESPONSE

According to the Dietary Guidelines for Americans (DGA), 2010, "sodium is an essential nutrient and is needed by the body in relatively small quantities, provided that substantial sweating does not occur. A strong body of evidence in adults documents that as sodium intake decreases, so does blood pressure. Moderate evidence in children also has documented that as sodium intake decreases, so does blood pressure. Keeping blood pressure in the normal range reduces an individual's risk of cardiovascular disease, congestive heart failure, and kidney disease. Therefore, adults and children should limit their intake of sodium." The DGA recommend that Americans "reduce daily sodium intake to less than 2,300 milligrams (mg) and further reduce intake to 1,500 mg among persons who are 51 and older and those of any age who are African American or have hypertension, diabetes, or chronic kidney disease. The 1,500 mg recommendation applies to about half of the U.S. population, including children, and the majority of adults."

- c. Finally, please provide details on the funds CDC has spent funding anti-sodium activities and studies over the past 2 years. One example of such a CDC funded activity is the current IOM review on sodium. Another example is the computer modeling study recently conducted by the American Heart Association and published in its Hypertension Journal.**

CDC-KINGSTON-10c RESPONSE

Sodium reduction is one component of a larger portfolio of CDC work to help Americans consume diets consistent with the Dietary Guidelines for Americans 2010 and to help prevent cardiovascular disease. Sodium reduction efforts for FY 2011 and FY 2012 at CDC totaled \$3,088,115 and \$5,101,123 respectively. The modeling project, "Mortality Benefits from US Population-wide Reduction in Sodium Consumption: Projections from 3 Modeling Approaches" was published in the journal *Hypertension* and was funded in FY 2010 at \$100,026.

Extramural funding related to sodium reduction in FY 2011-2012 is in the following table:

FY11	Sodium Reduction in Communities Program	1,924,956
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d.	Monitoring and Surveillance*	825,580
e.	Evaluation, Dissemination and Communications	337,579
f.		
g.	<i>FY11 Total</i>	<i>3,088,115</i>
h.		
i.	Sodium Reduction in Communities Program	1,924,956
j.	Monitoring and Surveillance*	792,608
k.		
l.	Salt Sources Study	997,770
m.	Evaluation, Dissemination and Communications	420,789
n.		
o.	24 hour urinary excretion pilot*	365,000
p.	IOM report - Consequences of Sodium Reduction in Populations	600,000
q.		
	<i>FY12 Total</i>	<i>5,101,123</i>

r. *activities and data encompass more than just sodium

12) I understand CDC's Advisory Committee on Immunization Practices (ACIP) is considering moving toward offering "permissive" rather than "routine" recommendations for vaccines. It is important to keep children's health a priority with support for proven immunization initiatives, such as routine recommendations for infant vaccines and the change could result in lower vaccination rates. Please explain why and how the CDC's ACIP has shifted priorities in its deliberations of vaccine recommendations?

CDC-KINGSTON-11-RESPONSE:

The Advisory Committee on Immunization Practices (ACIP) makes evidence-based recommendations for vaccines licensed for use in the United States. The ACIP has not shifted priorities in its deliberations nor is it considering moving toward offering "permissive" rather than "routine" recommendations for vaccines. The ACIP makes routine immunization recommendations for children, adolescents, and adults that are population-based (e.g., age-based), risk-based (e.g., underlying medical conditions, work-related, or other special circumstances that increase risk of illness), or are catch-up recommendations. In some circumstances, such as a lack of evidence for a population, the ACIP makes a recommendation that health care providers and patients determine on an individual basis whether a vaccine should be administered.

12) Please provide an update on the activities CDC has taken to consider expanding activities related to developing sensitive and more accurate diagnostic tools and tests for Lyme disease, including the evaluation of emerging diagnostic methods and improving utilization of adequate (validated) diagnostic testing to account for the multiple clinical manifestations of Lyme disease; to expand its epidemiological research activities on tick-borne diseases to include an

objective to determine the frequency and nature of the long-term complications of Lyme disease; to improve surveillance and reporting of Lyme and other tick-borne diseases in order to produce more accurate data on their incidence; to evaluate the feasibility of developing a national reporting system on Lyme disease, including laboratory reporting; and to expand prevention of Lyme and tick-borne diseases through increased community-based public education and physician and healthcare provider programs based on the latest scientific research on the diseases.

CDC-KINGSTON-12 RESPONSE:

To expand activities related to developing sensitive and more accurate diagnostic tools and tests for Lyme disease, CDC is funding two cooperative agreements aimed at developing diagnostic tests that would be simpler and more sensitive in detecting infection in Lyme disease cases, compared to current two-tiered testing. CDC will continue efforts aimed at identifying unique diagnostic biomarkers of active infection and will work with the National Institutes of Health and the Food and Drug Administration to facilitate development and approval of improved Lyme diagnostic tests.

CDC continues to support a 5-year research study aimed at identifying and characterizing long-term and potentially chronic complications associated with Lyme disease infection to expand epidemiological research activities on tick-borne diseases, including determining the long-term course of illness for Lyme disease and to improve surveillance and reporting of Lyme and other tick-borne diseases in order to produce more accurate data on their prevalence..

Lyme disease has been a nationally notifiable disease since 1991, and cases are reported to CDC each year through the National Notifiable Diseases Surveillance System or NNDSS. Thus, the principal challenge for surveillance is not the lack of a reporting system but rather assuring that cases are captured and entered into the system. To this end, CDC is funding health departments in over a dozen high incidence states to improve surveillance and reporting for Lyme and other tick-borne illnesses. This funding supports improved reporting by both physicians and laboratories. In addition, through our Emerging Infections Program, CDC is funding research studies in three states to better determine why and to what degree Lyme disease cases are under-reported. This work is designed to yield better estimates of the national burden of Lyme disease and to identify fundamental ways in which reporting can be made more complete and accurate (e.g., through use of electronic medical records).

CDC continues to fund and conduct research to validate the most effective prevention methods and approaches for use by individuals and communities, to distribute newly developed prevention resources and toolkits for prevention education, and to develop a healthcare provider education program based on validated, scientifically proven research.

13) Please identify how CDC is supporting prion disease. Specifically, explain how any reductions are directed to intramural and travel rather than overly burdened on the extramural activity?

CDC-KINGSTON-13 RESPONSE:

The Centers for Disease Control and Prevention (CDC) monitors the occurrence of human prion diseases in the United States through several surveillance mechanisms that include:

- Follow-up of spontaneous case reports to CDC, usually from clinicians, either directly or through state and local health departments;
- Regular analyses of national Creutzfeldt-Jakob disease (CJD) mortality data routinely submitted to CDC from all 50 states;
- Regular review of available medical records of CJD cases under 55 years of age in collaboration with state health departments, as this is the age group primarily affected by variant CJD (vCJD);
- Funding and promoting diagnostic neuropathological testing of all clinically suspected cases of human prion disease at the National Prion Disease Pathology Surveillance Center (NPDPS) at Case Western Reserve University;
- Collaborative surveillance studies focused on subpopulations of special public health concern including human growth hormone recipients, CJD donor blood recipients, and hunters in the Chronic Wasting Disease (CWD)-endemic states of Colorado and Wyoming.

CDC intramural funding supports staff that maintains the human prion disease surveillance system described above. Historically, the majority of CDC's prion disease funds are awarded extramurally, including NPDPS and state/local health departments as recipients.

14) In the past several years, CDC proposed to Consolidated Chronic Disease Prevention and Health Promotion that we not supported by Congress as the proposal was not been fully developed. I do not expect CDC not to make any administration adjustment or make internal grants management consolidations to implement the purpose of the policy not accepted by Congress. Please provide your assurance that no such effort have been implemented or are planned to ignore Congressional intent.

CDC-KINGSTON-14 RESPONSE:

CDC has not consolidated any chronic disease prevention activities. In February 2013, CDC posted a common funding opportunity announcement to reduce administrative burden for States and improve coordination across Heart Disease and Stroke Prevention; Nutrition, Physical Activity, and Obesity; School Health; and Diabetes – separate chronic disease activities that share common risk factors. CDC's strategy is to capitalize on the complementary nature of the respective program strategies to develop cross-cutting strategies and expertise to achieve measurable impact; provide core funding to all states to support heart disease, diabetes, school health and nutrition, physical activity and obesity program activities; provide competitive funding to approximately 25 states to support the implementation of enhanced chronic disease prevention and health promotion strategies; and maintain fidelity to current categorical appropriation funding levels and performance targets. Funded activities will result in measurable impacts to address school health, nutrition and physical activity risk factors, obesity, diabetes, and heart disease and stroke prevention. States will advance the goals of categorical funding lines, while tracking funding and performance accordingly. The short-term outcomes of the program will be to: (1) Improve state, community, worksite, school, and early childhood education environments to promote and reinforce health and healthful behaviors across the life span related to diabetes, cardiovascular health, physical activity, healthful foods and beverages,

obesity, and breastfeeding (2) Improve effective delivery and use of quality clinical and other preventive services aimed at preventing and managing hypertension and diabetes (3) Increase community-clinical linkages to support prevention, self-management, and control of diabetes, hypertension, and obesity. The program's long-term goals will be improved prevention and control of hypertension, diabetes, and overweight and obesity.

15) I understand CDC partnered with the National Heart, Lung, and Blood Institute (NHLBI) to develop a national action plan to address Chronic Obstructive Pulmonary Disease (COPD). The CDC should work with NHLBI to jointly ensure NHLBI's research portfolio for COPD supports scientific gaps that are ready opportunities to accelerate prevention and disease understanding, which can improve outcomes and foster implementation of the of this plan. Please describe the process CDC uses to coordinate on the identification of research activities with NHLBI to address meaningful scientific gaps.

CDC-KINGSTON-15 RESPONSE:

Response: CDC and NIH have a successful collaboration that uses surveillance to inform the NHLBI research agenda. CDC collects and analyzes COPD surveillance data, which reveal gaps in scientific knowledge that should be prioritized for research. For example, in November 2012, CDC and NHLBI co-authored the first report of state-specific prevalence of COPD among adults in all 50 states, DC, and Puerto Rico (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6146a2.htm?s_cid=mm6146a2_e) CDC will continue to partner with NHLBI on respiratory measures in the National Health and Nutrition Examination Survey (NHANES) and the Behavioral Risk Factor Surveillance System (BRFSS) to address scientific gaps in knowledge of COPD.

16) Please provide a list of all the Community Grants CDCs supports from any funding source. The list should include the source of funding, annual and total project levels, grant title; and summary of grant activity for fiscal year 2011 and 2012 and projected spending level for fiscal year 2013.

CDC-KINGSTON-16 RESPONSE:

The following are CDC's largest community-based grant programs, with total funding for FY 2011, FY 2012 and projected for FY 2013.

Program	FY 2011	FY 2012	FY 2013 (projected)
Community Transformation Grants	\$145,000,000	\$226,000,000	\$146,340,000
HIV Community-based Organizations	\$138,059,000	\$137,314,000	\$130,131,000
Racial and Ethnic Approaches to Community Health	\$39,018,000	\$53,940,000	\$13,215,000

17) On the National Diabetes Prevention Program (NDPP), please provide an update on the NDPP on how the funding supported diabetes. Plus, explain how data is used to help prevent new cases with specific performance measures.

CDC-KINGSTON-17 RESPONSE:

CDC's National Diabetes Prevention Program (National DPP) was authorized in 2010 by the Affordable Care Act. The program was authorized and established in FY 2010 through a public-private partnership with the Y of the USA and United Health Group, and was focused on building a system of trained coaches to deliver a lifestyle change program aimed at reducing participants' weight in order to prevent new cases of type 2 diabetes. Based on findings from the clinical trial, adherence to the lifestyle change program reduced the risk of developing type 2 diabetes by 58 percent in people at high risk for diabetes.

In FY 2012, \$10 million from the Prevention and Public Health Fund (PPHF) was used to expand the National DPP from 22 to 47 states. With the PPHF allocation, six awardees were funded to establish a network of structured, evidence-based lifestyle change programs. As part of this expansion, funded organizations will encourage employers to offer the lifestyle change program as a covered health benefit for employees and will work with third-party payers, including public and private health insurance companies, to facilitate reimbursement directly to organizations delivering the lifestyle change program. Over the life of the award, grantees are expected to achieve the lifestyle change program as a covered benefit for a minimum of 500,000 employees. CDC's initial efforts have resulted in five insurers and over 280 self-funded employers who provide coverage and access for the lifestyle change program.

A key component of the National DPP, CDC's Diabetes Prevention Recognition Program (DPRP) assures quality of the program by recognizing programs that have shown they can effectively deliver a lifestyle change program to prevent type 2 diabetes. Grantees funded through PPHF will offer a lifestyle change program consistent with DPRP's Standards and Operating Procedures including training coaches to deliver the lifestyle intervention. Data collected through the DPRP will measure performance towards the goal of increasing the number of participants in the National Diabetes Prevention Program who achieve a minimum weight loss of 5 percent, a key measure of success for reducing or delaying the onset of type 2 diabetes.

18) Please explain the systematic process CDC programs uses to jointly work with NIH Institutes and Centers to identify scientific research gaps and coordinates with NIH on portfolio analysis to coordinate gaps in basic science that if addressed could improve CDC's ability to improve public health.

CDC-KINGSTON-18 RESPONSE:

While CDC and NIH do not have a common research agenda, our respective programs work directly (and many very closely) with each other on specific topics (disease/illness/condition) to identify research priorities and avoid funding overlaps; these collaborations include identifying the gaps, developing specific goals (agency specific or shared), and executing the actions.

We also have scientists (subject matter experts) representing our agencies on numerous scientific bodies (Agency Advisory Committees and Review Panels, HHS Advisory Committees, Work Groups, and ad hoc bodies) that cover such topics (disease/illness/condition), or on bodies that are more broader in nature (e.g., dual use research, scientific oversight, research on human subjects).

19) Please identify how CDC, FDA, and NIH jointly develop, coordinate, plan, and prioritize Global Health Strategy goals. Further, explain how the CDC request is link to any coordinated effort.

CDC-KINGSTON-19 RESPONSE:

CDC recognizes the importance of coordinating with U.S. government (USG) counterparts. CDC and our partners support cutting-edge global health programs and research, addressing over 400 diseases, health threats, and conditions that are major causes of death, disease, and disability. Through these activities, CDC improves health globally and protects the American people from health and security threats that cross international borders. CDC is committed to collaboration, and actively pursues input and collaboration from USG counterparts to set strategy and implement programs.

In 2011, CDC released our *CDC Global Health Strategy: 2012-2015*¹, to articulate the agency's role in global health, to communicate the vision for global health work at CDC, and to identify CDC's global health goals. The strategy was created with input from USG partners including the Department of Health and Human Services (HHS), the United States Agency for International AID (USAID), and the U.S. Department of State.

HHS also has its *Global Health Strategy: 2011-2015*². CDC's and HHS's global goals and objectives are closely aligned. For example, both CDC and HHS strategies emphasize critical roles in global health security. Both documents also align in terms of disease specific research, surveillance, and health systems strengthening.

CDC actively pursues strategy-level coordination with USG partners including the Food and Drug Administration (FDA) and the National Institutes of Health (NIH). For example, under the Global Health Initiative, CDC and NIH, USAID, and others work together to achieve targets with an emphasis on an AIDS free generation, ending preventable child deaths, and reducing maternal mortality. To support collaboration within HHS, CDC recently hosted FDA and NIH global health seminars to discuss new agency initiatives and identify ways to coordinate our work. Also, for the past three years, CDC has served on the review board of the Fogarty International Center. The Center is dedicated to advancing the mission of NIH and facilitating global health research conducted by the U.S. and by international investigators.

CDC, NIH, FDA, and other USG partners within and outside of HHS also collaborate at the program level. For example, The Federal Tuberculosis Task Force, which includes NIH, FDA, USAID, the Health Resources and Services Administration, the Office of the Global AIDS

¹ <http://www.cdc.gov/globalhealth/strategy/>

² <http://www.globalhealth.gov/global-programs-and-initiatives/global-health-strategy/>

Coordinator, and others, meets two times each year to coordinate federal efforts to eliminate tuberculosis (TB). CDC and NIH have a memorandum of understanding outlining roles and responsibilities for the Joint U.S. Partnership in TB Elimination Research (JUPITER). Through JUPITER, CDC and NIH have collaborated on multiple clinical trials and studies³. Also, CDC works with FDA, NIH, and USAID to develop and implement new tools to improve diagnosis and treatment of tuberculosis. NIH conducts basic and clinical research; FDA reviews and approves products that are introduced in the U.S., and CDC and USAID support implementation and evaluation of new tools in TB programs globally.

20) Please describe how CDC works with NIH and U.S. schools of tropical medicine to develop improved diagnostics and vaccines.

CDC-KINGSTON-20 RESPONSE:

The following are examples of how CDC works with NIH and the U.S. schools of tropical medicine to develop improved diagnostics and vaccines:

- CDC works with NIH and schools of tropical medicine on several projects related to improved diagnostics and vaccines. Currently, NIH has provided product development support for an inactive rotavirus vaccine developed by CDC. In addition, CDC has collaborated with the GAVI-funded Vaccine Implementation Technical Assistance Consortium (VITAC), which works with the Program for Appropriate Technology—commonly known as PATH, and the Johns Hopkins Bloomberg School of Public Health on evaluating the performance of new vaccines against rotavirus and pneumococcal disease in developing country settings.
- CDC is collaborating with NIH-supported researchers at Harvard University on advanced, informatics-based, real-time surveillance systems, including the dengue HealthMap program.
- CDC collaborated with NIH and FDA in the establishment and distribution of a comprehensive serum repository that can be used for validating new diagnostic tests for Lyme disease for FDA clearance.
- Since June 2010, CDC has been engaged in the following TB initiatives that bridge the complementary work of CDC and NIH:
 - Establishment of an FDA and NIH co-sponsored Consortium for TB Biomarkers to aid in TB biomarker discovery
 - NIH-sponsored TB Diagnostics Research Forum which focuses on research needed to ensure that development of diagnostics is aligned with new drug regimens
 - Bilateral CDC-NIH joint activity on improvements to diagnostic testing for pyrazinamide resistance in *Mycobacterium tuberculosis*
 - CDC and NIH coordination with the World Health Organization on moving research and development to field demonstrations for the molecular detection of drug resistance in *M. tuberculosis*

³ For example, co-enrollment of children and HIV+ in TBTC S26; quantitative bacteriology studies in Kampala through NIAID's TB Research Unit; co-enrollment in US in ACTG 5295 (Cepheid Gene Expert)

- CDC's Tuberculosis Trials Consortium (TBTC) performs clinical trials in tuberculosis. Patient specimens from these trials are provided to several different university-based investigators who are pursuing development of biomarkers for TB trials and diagnostics for tuberculosis.
- CDC staff have served as members of the advisory group for the NIH-funded Tuberculosis Clinical Diagnostics Research Consortium.
- CDC shares epidemiologic and representative strains and serologic specimens with NIH for basic STD research and product development.
- CDC has collaborated with NIH to test new combinations of existing antibiotics to treat gonorrhea in the absence of new approved antibiotics.
- CDC's Advisory Committee on Immunization Practices, Human Papillomavirus (HPV) Vaccine Workgroup includes representatives from NIH. This workgroup informs development of U.S. vaccine policy.
- CDC worked with NIH on the development of HPV serologic tests and is working with NIH on evaluation of the serologic response to different HPV vaccine schedules.
- CDC has members on the following NIH groups:
 - STD Clinical Trials Group / Scientific Review Group – deal with diagnostics treatment, and vaccines
 - Microbicide Trials Network / HIV Prevention Trials Network – interventions to expand testing and treatment and microbicide use
- CDC collaborates with the BASTA consortium (Battling Antenatal Syphilis – A Team Approach) - which includes representatives from the global health/tropical disease programs from NIH-supported Washington University (St. Louis), University of North Carolina, University of Washington (Seattle), University of California San Francisco, and Johns Hopkins - on improved STD diagnostics, including rapid diagnostics for congenital syphilis.
- CDC has conducted collaborative research with the NIH-funded University of Washington Global Health Program on molecular testing/diagnostics for congenital syphilis in Mozambique.

21) Please describe how CDC works with the Department of Homeland Security to align preparedness grant programs for state and local health departments. Specify how any alignment seeks to achieve convergence of goals and outcomes, as well as efficiencies in applications, reporting and data collection.

CDC-KINGSTON-21 RESPONSE:

CDC and the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) meet regularly, with the Department of Homeland Security's Federal Emergency Management Agency to coordinate preparedness grant programs for state and local health departments. CDC drafted an analysis of how the HHS public health and healthcare preparedness capabilities align with and support the National Preparedness Goal's core capabilities. This work will help state and local awardees mutually support each other and leverage DHS and HHS capabilities to promote program efficiencies, improve coordination among preparedness programs and related funding investments, reduce duplication, and strengthen the value of preparedness investments. CDC, ASPR, and FEMA made significant progress aligning common language in our funding

opportunity announcements and continuation guidance documents to promote awareness of and use of consistent concepts, definitions, and terminology.

22) I understand CDC has begun work on a Public Health Emergency Preparedness Index. I anticipate CDC will work with the States to develop an index based on critical factors to measure the preparedness of the States with a National Index to monitor State and National critical emergency preparedness capabilities that take into account appropriate geographical risk factors. Please provide an update progress of this effort. Please explain how CDC is coordinating with other federal agencies on the measure. Please provide an update on the steps and timeline needed to fully implement the index and how the tool would be used in future resource allocations for public health emergency preparedness and strategic national stockpile funding in fiscal year 2014.

CDC-KINGSTON-22 RESPONSE:

With input from many stakeholders, the Association of State and Territorial Health Officials (ASTHO), under a cooperative agreement with CDC, is coordinating development of the National Health Security Preparedness Index (NHSPI), an annual measure of health security and preparedness at the national and state levels. This developmental draft will be distributed to state health officials, preparedness directors, and related association partners for the purpose of gaining feedback and strengthening the index. After this early development phase is complete, the NHSPI will be released more widely with the goal of generating much broader stakeholder engagement. As with other major indices, the NHSPI will evolve through an ongoing process of rollout, testing, application, and revision. The NHSPI will give objective, evidence-based measures to policymakers and practitioners. Policymakers will be able to use the NHSPI to assess the progress in preparedness to date and to guide inquiries needed to inform decisions about investments. Practitioners will be able to use the NHSPI to help understand the interdependencies of the health security preparedness system and help benchmark and facilitate quality improvement at the state and local levels.

23) The 2013 budget request included a reduction to the Strategic National Stockpile that was concerning. It did not fully justify how CDC would mitigate against the resource shift. Any future change should fully explain the mitigation strategy and identify the method used to measure the SMNS (sic) readiness. In addition, please answer the following questions:

- a. Do any of the current SNS supply contracts have a provision to allow the SNS to re-sell or re-place items prior to expiration with the manufacturer to maintain a fresh stock of medical countermeasures or medications?**

CDC-KINGSTON-23a RESPONSE:

CDC has implemented some contracts with manufacturers to allow for storage of a fixed quantity of product with the manufacturer in their warehouse. Such contracts are termed vendor managed inventory (VMI) arrangements, and the manufacturer receives ongoing payments to maintain the specified amount of product in reserve and make it available to SNS for shipment within

prescribed time frames. This arrangement does allow for stock rotation and re-sale of product approaching expiration, as indicated in the question. However, such arrangements are costly to the government, and the management costs for CDC to hold purchased medical countermeasures (MCM) products in SNS storage is significantly lower than the management costs charged under such VMI contracts. Additionally, as the formulary has grown, the majority of SNS requirements are too large for manufacturers to be able to store and rotate the full amount through their commercial supply chain. Finally, as existing SNS VMI contracts have expired, very few proposals have been submitted to replace them, and even fewer have proven to be cost effective for the government to implement. As such, VMI contracts currently comprise a very small portion of SNS holdings. SNS will continue to examine the cost vs. benefit of such relationships.

- b. If not, we understand is done with some other stockpiles – has been HHS or CDC considered such a logistics method to reduce ensure a ready stock, reduce waste, and reduce taxpayer costs?**

CDC-KINGSTON-23b RESPONSE:

See response to question 23a above.

- c. How SNS does ensure is supply distribution system is tests and used routinely?**

CDC-KINGSTON-23c RESPONSE:

SNS conducts routine drills of inventory management and transportation functions, ranging from exercises with federal, state, and local partners as well as annual no notice exercises to test and evaluate the capability to activate SNS sites and ship SNS assets within required time and quality control parameters.

- d. If a contract mechanism existed to allow appropriate expiring stock to be exchanged for new stock, how would it help the distribution chain?**

CDC-KINGSTON-23d RESPONSE

Product rotation of expiring stock would not directly affect SNS distribution capabilities, depending on the mechanism and regulatory authorities involved. To analyze such a proposal, several variables would have to be specified and accounted for, including: amount of remaining shelf life required for product to be resold, transportation and distribution requirements and responsibilities for the expiring product, quality control validation requirements for the expiring product, and management responsibilities and costs for the product rotation requirements. Absent new information or proposals for such a contract, it is unlikely that any company would take on such a stock rotation or reverse logistics project on the scale required by SNS at a price that would offset or reduce the management costs under current SNS processes for most requirements.

- e. Please describe how SNS manages medical countermeasures for appropriate shelf life and policies are in-place to account for countermeasures to protect children.**

CDC-KINGSTON-23e RESPONSE:

CDC manages SNS assets in accordance with Current Good Manufacturing Practice (cGMP) regulations promulgated by the Food and Drug Administration. CDC works within those regulations to ensure the government receives the maximum value for medical countermeasure (MCM) investments. CDC participates with DOD in the joint Department of Defense/FDA Shelf Life Extension Program for all products where it is possible and cost effective. Through participation in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) managed by the Department of Health and Human Services Assistant Secretary for Preparedness and Response, CDC works to ensure all MCM licensed for use in pediatric populations are accounted for in SNS requirements and procurements. The Department of Defense (DOD), Department of Homeland Security (DHS), Veterans Administration (VA), and United States Department of Agriculture (USDA) also are interagency partners that help to inform decision making in the PHEMCE process.

24) The Committee rejected CDC's proposed changes to the Public Health Emergency Preparedness Cooperative Agreement Program as state and local health departments rely on the Public Health Emergency Preparedness Cooperative Agreement Program to support their work with federal government officials, law enforcement, emergency management, health care, business, education, and religious groups to plan, train, and prepare for emergencies so that when disaster strikes communities are prepared. Plus, the Committee rejected the Administration's proposal to cut the cooperative agreements to pay for CDC programmatic operating costs. Please provide assurances that these polices are not being implemented directly or indirectly.

CDC-KINGSTON-24 RESPONSE:

CDC's 2013 funding for Public Health Emergency Preparedness Cooperative Agreement will reduce funding only for Congressional changes, such as the rescission and the sequestration.

25) Last year, the Committee included specific language on facility stewardship for CDC that included funding for necessary mine explosive and mine safety research capacity that CDC has let lapse. Plus, the lack of stewardship over the Taft and Hamilton facilities, which are becoming obsolete due to non-support through the Administration's budget request. Please explain the steps CDC has taken to ensure appropriate resource allocation and stewardship of facility buildings over the past year. Plus, explain what CDC has done to ensure the capacities highlighted in the Committee's 2013 mark are being supported?

CDC-KINGSTON-25 RESPONSE:

CDC is moving forward to replace the mine safety research facility. CDC has finalized program requirements for a replacement facility, and is conducting initial searches to identify existing properties or potential sites that meet the criteria on which to procure or construct a replacement facility. CDC will provide an update to staff once the initial assessment is complete.

CDC is in project planning phase of options to address the condition of the Cincinnati Research Facilities (Taft, Taft North, and Hamilton buildings) -- including exploring the possibility of consolidating the facilities into one central location.

26) Please describe how CDC has worked to share guidelines related to Maternal Mortality Reviews with States to improve inconsistent and incomplete data. Plus, describe any actions that be taken to consolidate the data collection tool and how it could include voluntary data fields to allow States and CDC to calculate more accurate maternal mortality rates.

CDC-KINGSTON-26 RESPONSE:

CDC began the maternal mortality initiative in 2012 to assist states in their efforts to improve data collection and conduct maternal mortality reviews. The purpose of the initiative is to develop guidelines for the comprehensive identification and review of maternal deaths in states. To date, fourteen states (CA, FL, GA, IL, IA, LA, MA, MD, MI, NJ, NY, UT, VA, WI) and one city (Philadelphia) are participating in the initiative. In addition, CDC is working with the Health Resources and Services Administration's Maternal and Child Health Bureau and key national partners such as the American College of Obstetricians and Gynecologists and the National Association of Public Health Statistics and Information Systems to finalize the guidelines. Once finalized, states can use the guidelines to improve their current efforts or to develop new maternal review processes. While the maternal mortality initiative has the potential to result in some standardization of processes, it also allows for meeting the individual needs of states.

27) Last year the Committee rejected the elimination of the Preventive Health and Health Services Block Grant (PHHSBG) as proposed by the budget request. For over 30 years, the PHHSBG's have been a vital source of funding, allowing each State to address its most critical public health needs. For example, in approximately one-third of all States, the PHHSBG is a significant source, or the only source, of funding to support emergency medical services and trauma systems. The PHHSBG also is an important source of funding for activities such as poison control, the provision of emergency medical services for children, suicide prevention, school health activities, violence prevention, and chronic disease prevention. This unique source of funding gives States the autonomy and flexibility to solve problems, while still being held accountable for demonstrating the impact of supported programs. Please the justification as to why CDC believes this vital program should be eliminated?

CDC-KINGSTON-27 RESPONSE

Through CDC's existing and expanding activities, there is substantial funding to state health departments. When the PHHSBG was first authorized in 1981, there were minimal resources within CDC's budget allocated for categorical programs such as heart disease, diabetes, immunizations, and obesity, and many states did not receive funding from CDC to support prevention of chronic disease. However, since 1981, categorical programs at CDC have grown, and the PHHSBG now represents a much smaller percentage of state budgets when compared to total available CDC funding.

28) What activities and efforts does CDC have planned and ongoing to support adoption and implementation of Section 911 of the Tobacco Control Act MRTP's?

CDC-KINGSTON-28 RESPONSE:

CDC's Office on Smoking and Health and FDA's Center for Tobacco Products have an established collaborative relationship. Specifically, CDC lends its scientific expertise to the Center for Tobacco Products to explore the public health implications of tobacco control, including the implication of potentially issuing marketing orders for modified risk tobacco products. This work includes sharing CDC's surveillance findings with FDA and the public. CDC also provides technical assistance to FDA—and other federal agencies, such as NCI, NIDA, and SAMHSA—to interpret the latest scientific research and better understand the public health implications of possible modified risk products. CDC's Division of Laboratory Sciences is also working with FDA. The Tobacco Exposure Biomarkers Laboratory measures biomedical effects of tobacco exposure (e.g., cotinine blood levels). The Tobacco Products Laboratory is currently conducting specific analyses of tobacco products, including those with potential claims of modified risk. Findings from the lab are shared with FDA.

29) Please identify by year for each year the Community Transformation Grants have been funded the annual funding by funding source obligated, total expended, and how the results of each year's funds were measured with quantitative results for each year funded.

CDC-KINGSTON-29 RESPONSE:

Community Transformation Grants (as of March 2013)		
	2011	2012
Obligations	\$146,248,909	\$225,212,412
Expenditures	\$104,866,947	\$60,606,788
Approximate number of days funds available to grantee	545	180

Measure	Description	Year 1 Results	Year 2 Results
1	Number of people with increased access to smoke-free or tobacco-free environments in settings such as workplaces, restaurants, and bars; multi-unit housing; schools and campuses; and outdoor places (e.g., parks, beaches).	1,684,006	Due 12/31/2013
2	Number of people with increased access to environments with healthy food or beverage options in schools, afterschool programs, early childcare settings, workplaces, and other community settings.	214,551	Due 12/31/2013
3	Number of people with increased access to physical activity opportunities in schools, afterschool programs, early childcare settings, workplaces, and other community settings.	81,822	Due 12/31/2013
4	Number of people with increased access to systems or	161,461	Due

opportunities that support control of high blood pressure and of high cholesterol in health care and other community settings.		12/31/2013
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CDC developed a comprehensive evaluation and performance monitoring plan for Community Transformation Grants (CTG) that addresses the evaluation requirements in the Affordable Care Act. The plan was designed to assess the impact of activities that are part of the five-year CTG program, funded in FY 2011, and the two-year CTG Small Communities program, funded in FY 2012. The plan addresses all five strategic areas of CTG, which include: (1) Tobacco-Free Living, (2) Healthy Eating and Active Living, (3) Clinical and Community Preventive Services, (4) Social and Emotional Wellness; and (5) Healthy and Safe Physical Environments. The overall five percent reduction goals for 2016 are to reduce death and disability due to tobacco, obesity through nutrition and physical activity interventions, and death and disability due to heart disease and stroke by five percent.

The components of the national evaluation plan include:

- *Performance monitoring*
- *Population-level surveillance*
- *Enhanced evaluation studies*
- *Context scan*
- *Cost studies*
- *Simulation modeling (PRISM)*

30) It has come to my attention that CDC, in violation of the direct intend of Congress to not consolidate the Chronic Disease programs, that CDC is in fact taking direct steps to consolidate these programs through a RFA on CDC's Public Health Actions to Prevent and Control Diabetes, Health Disease, Obesity, and Associated Risk Factors and Promote School Health. Please provide assurances that this is not the case.

CDC-KINGSTON-30 RESPONSE:

CDC has not consolidated any chronic disease prevention activities. In February, CDC posted a common funding opportunity announcement to reduce administrative burden for States and improve coordination across Heart Disease and Stroke Prevention; Nutrition, Physical Activity, and Obesity; School Health; and Diabetes – separate chronic disease activities that share common risk factors. CDC's strategy is to capitalize on the complementary nature of the respective program strategies to develop cross-cutting strategies and expertise to achieve measurable impact; provide core funding to all states to support heart disease, diabetes, school health and nutrition, physical activity and obesity program activities; provide competitive funding to approximately 25 states to support the implementation of enhanced chronic disease prevention and health promotion strategies; and maintain fidelity to current categorical appropriation funding levels and performance targets. Funded activities will result in measurable impacts to address school health, nutrition and physical activity risk factors, obesity, diabetes, and heart disease and stroke prevention. States will advance the goals of categorical funding lines, while tracking funding and performance accordingly. The short-term outcomes of the program will be to: (1) Improve state, community, worksite, school, and early childhood education environments to promote and reinforce health and healthful behaviors across the life

span related to diabetes, cardiovascular health, physical activity, healthful foods and beverages, obesity, and breastfeeding (2) Improve effective delivery and use of quality clinical and other preventive services aimed at preventing and managing hypertension and diabetes (3) Increase community-clinical linkages to support prevention, self-management, and control of diabetes, hypertension, and obesity. The program's long-term goals will be improved prevention and control of hypertension, diabetes, and overweight and obesity.

31) CDC has a role in investigating foodborne illness, and helping identify suspect foods. The outbreak of listeria in cantaloupes was a disturbing example. Please explain how CDC works with other federal and local agencies and provide suggestions on what can be done to reduce duplication of effort and speed up the process to identify the source of the illness.

CDC-KINGSTON-31 RESPONSE

CDC's unique role in foodborne illness is that we focus on people. More specifically we conduct national surveillance for foodborne illnesses, detect and investigate foodborne illness outbreaks to identify the contaminated foods and their sources, and provide information about illnesses in people to help guide food safety policy (e.g., the pathogens and foods causing most illnesses, hospitalizations and deaths). CDC works closely with state and local public health agencies that provide the surveillance data from their jurisdictions. CDC coordinates across jurisdictions in the investigation of multistate outbreaks to identify the source, which may or may not be a food. When a contaminated food is suspected, the appropriate regulatory agency is continuously involved. CDC is a non-regulatory science agency. In contrast, FDA and USDA/FSIS focus on safe food production, distribution, and handling, and in outbreak investigations, their key responsibilities include conducting product tracebacks, conducting facility and farm investigations, helping manage product recalls and taking other regulatory actions. CDC works closely with FDA and USDA, hosting permanent liaisons from each agency and holding frequent direct communications concerning developments and progress during outbreak investigations. CDC's work with partners in investigating foodborne illnesses is collaborative, not duplicative. Since 1996, the capacity and technology to conduct surveillance and detect and investigate foodborne outbreaks has advanced dramatically. CDC uses its unique and strong partnerships with state and local public health agencies, as well as with FDA and USDA, to coordinate, fund and lead critical networks in food safety, such as tracking trends with FoodNet (Foodborne Diseases Active Surveillance Network) for and detecting outbreaks with PulseNet (the National Molecular Subtyping Network for Foodborne Disease) that provides DNA "fingerprinting" of pathogens, such as *E. coli*, *Salmonella*, and *Listeria*. PulseNet has revolutionized foodborne outbreak detection and response- detecting approximately 150 potential outbreaks each year which would not be otherwise recognized.

In 2011, CDC confronted one of the deadliest foodborne outbreaks in the United States in nearly a century. The outbreak killed 33 people and caused one miscarriage. However, a coordinated public health response— built on rapid detection and investigation— likely prevented many more illnesses and deaths from the bacteria *Listeria*, found in cantaloupes from Colorado. The outbreak was detected, its source was identified, and a national warning was issued, all in just 10 days, as compared with weeks that it took to respond to previous *Listeria* outbreaks. The rapid response was due to the work of many government agencies and healthcare professionals, in

addition to PulseNet laboratories that identified the illnesses through DNA “fingerprints.” PulseNet labs identified outbreak strains in Colorado patients, then connected them with illnesses in 27 other states. (<http://www.cdc.gov/ncezid/2011-2012-report/index.html>) Notwithstanding prior advances, there is more needed to speed the process to detect, investigate, stop and prevent foodborne outbreaks. Priority areas of investment include:

- 1) Preserving the capacity of our public health laboratory network to track infections and detect outbreaks in the next few years, as new diagnostic technologies are adapted in the medical laboratories to diagnose infections.
- 2) Expanding the number of states participating in the Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE) which work together to develop, assess and implement model public health practices and tools for rapid and efficient outbreak detection and response.
- 3) Funding fully the Integrated Food Safety Centers of Excellence to serve as a resource for local, state and federal public health professionals to respond to outbreaks of foodborne illness.
- 4) Increasing funding support for all state public health agencies to maintain critical capacity to enhance the national foodborne surveillance, outbreak detection and response systems through the CDC Epidemiology and Laboratory Capacity cooperative agreement program.
- 5) Intensifying efforts to provide information for policy by determining which foods make us sick. CDC works closely with FDA and USDA/FSIS to create advanced models that attribute illnesses to food categories so the regulatory agencies and food industries can better focus their efforts to prevent contamination of food where it is most effective.

For the longer term, CDC needs to speed up the detection, tracking and control of many infectious illnesses to protect the nation’s health. This means CDC and its public health partners need to keep pace with scientific advances in rapid reading and decoding of large blocks of DNA from germs. Decoding DNA for public health depends on advanced bioinformatics technologies and skills. CDC has started a few pilot bioinformatics projects that provide some initial data, but investing in this new technological capacity is critical to improve detection and response for many infections, including foodborne ones.

32) CDC has often pointed out that obesity is a complex issue, but it appears that CDC is placing excess focus on one of many solutions and public health interventions. The Committee understands that at CDC there is a Division of Nutrition, Physical Activity and Obesity. In reviewing CDC prevention grant funds related to obesity, it appears that CDC places little emphasis on the promotion of daily physical activity within its spending priorities. Would you provide the Committee with a detailed breakdown of expenditures showing investment in the promotion of daily physical activity within the overall grants funding? How does this funding investment compare to that invested on the calorie intake side of the energy balance equation?

CDC-KINGSTON-32 RESPONSE:

CDC recognizes that there is strong evidence on the health benefits of physical activity including: improved cardiorespiratory and muscular fitness; improved bone health; improved

cardiovascular and metabolic health biomarkers; and favorable body composition. For this reason, promotion of physical activity is a core, required strategy for all of CDC's obesity prevention initiatives in states and communities, as well as other settings such as worksites, early care and education settings, and schools. Evidence-based strategies to increase physical activity are a key focus of Community Transformation Grants, REACH, and state-based School Health and Nutrition, Physical Activity, and Obesity programs. Grantees are required to include a mix of evidence-based strategies to prevent obesity including strategies to increase physical activity and to increase healthy eating.

33) States and localities often look to CDC for guidance in implementing effective disease prevention and health promotion programs. However, I have noted that in some of the CDC guidance to states and localities, the CDC references NHANES data from 2003-2004 as opposed to the most current data (2009-2010). Could you provide justification as to why CDC would not keep pace using current NHANES data, particularly with respect to reductions in consumption of added sugars and sugared sweetened beverages, when giving guidance to states and localities?

CDC-KINGSTON-33 RESPONSE:

Data from the National Health and Nutrition Examination Survey (NHANES) are released in a number of ways including on public use files – allowing users to work with the data for their own inquiries - and in published reports. Given the complexity of the NHANES data collection, not all data are released at the same time. Public use files containing 2009-2010 dietary data were released in June 2012 and analyses and reports being developed now will include these updated data, sometimes combined with data from earlier time periods.

34) What is the status of implementing the recommendations from the HHS Inspector General letter dated June 29, 2012 on the CPPW program? In addition, explain what mechanisms have been established since this letter to allow the CDC Director to routinely track and monitor that violation of the anti-lobbying statutes do not occur?

CDC-KINGSTON-34 RESPONSE:

CDC is committed to ensuring the proper use of federal funds, and to ensuring awardees' compliance with all applicable restrictions on lobbying. Over the course of the CPPW program, CDC has worked hard to ensure the proper use of appropriated funds, and to ensure awardees' compliance with all applicable regulations and statutes related to lobbying activities.

CDC's policy prohibits lobbying at the federal, state, and local levels. These restrictions apply to all CDC grants, including the CPPW program (initiated in 2009 with funding from the Recovery Act, with nearly all activity completed). All CDC awardees are informed at multiple junctures about the federal laws relating to use of federal funds, including applicable anti-lobbying provisions. CDC's *Additional Requirement 12, "Lobbying Restrictions"* (AR-12) stated CDC's policy at the time of CPPW awards prohibiting awardees from using any appropriated federal funds for "any activity designed to influence action in regard to a particular piece of pending

legislation” As noted below, we have revised the AR-12 to reflect new language in the FY 2012 appropriations law.

In addition to making these restrictions part of grant awards, for the CPPW program CDC staff has provided numerous reminders and conducted trainings for CPPW awardees on these prohibitions in order to ensure awardees understood the limits on use of the awards. These steps included an initial pre-award teleconference; presentations at the CPPW Communities kick-off meeting in April 2010; and multiple training sessions during the grant period of performance, including a mandatory meeting for all program managers and principal investigators to review the prohibitions outlined in AR-12.

In addition to educating awardees, CDC has regularly monitored awardee performance in order to ensure that federal funds are used effectively and appropriately. CDC staff have interacted with awardees every month to ensure that they were implementing the activities and strategies set forth in the awardee’s work plan and that awardees were adhering to administrative requirements, including provisions relating to lobbying prohibitions. In addition, CDC staff has monitored the use of federal funds by awardees using tools such as onsite reviews and risk mitigation plans.

The HHS Inspector General’s June 29, 2012 letter proposed a set of recommendations that CDC could take to clarify guidance for grantees and to clarify misleading statements about activities by grantees. The HHS Inspector General recommended that CDC:

- Review its guidance and other posted materials on CDC’s website;
- Clarify any misleading statements about lobbying activities by grantees under the CPPW program;
- Train employees, as necessary, and
- Provide updated and more detailed guidance to grantees describing how to avoid violating these statutory provisions. Such guidance should also advise grantees concerning new restrictions on lobbying contained in the FY 2012 HHS appropriations.

CDC has fully implemented each of the HHS Inspector General recommendations. These steps have included:

- Developed more detailed anti-lobbying guidance for CDC staff, which was broadly disseminated to senior leadership, management and policy officials, and CDC project officers. This guidance updated and expanded upon previously available material to reflect changes in the FY 12 appropriations law and to provide more detailed examples to help clarify restricted activities.
- Initiated a new training program for CDC project officers, to provide more specific information about restrictions on lobbying by CDC grantees, and provided more specific guidance to CDC program officials on anti-lobbying restrictions to be included in all CDC funding opportunity announcements.
- Revised CDC’s conditions of award for grantees (Additional Requirements-12), posted at www.cdc.gov/od/pgo/funding/grants/additional_req_shtm#ar12, to reflect new language enacted with the FY 2012 appropriations law.

- Communicated directly with all of our grantees about the new requirements included in the FY 2012 appropriations law, including transmittal of the new AR-12 restrictions. The grantee information included examples of restricted and allowable activities.
- Communicated the importance of compliance with lobbying restrictions and the need for accurate reporting of only those activities undertaken that were supported by CDC funding. This effort was accomplished through multiple direct communications and conference calls with grantees and organizations that represent them.

35) The CDC plays an important national security role: managing and distributing emergency medical supplies in the Strategic National Stockpile. We must be prepared for the unthinkable – a terrorist attack using a biological weapon, or a naturally occurring disease pandemic. President Obama’s National Strategy on Countering Biological Threats confirms “the effective dissemination of a lethal biological agent within an unprotected population could place at risk the lives of hundreds of thousands of people. The economic cost could exceed \$1 trillion for each such incident.”

- (a) It is my understanding that CDC handles the procurement of licensed products whereas BARDA is responsible for the procurement of unlicensed products through the Special Reserve Fund. Please describe how CDC works with BARDA to prioritize budgets for drugs, vaccines, and diagnostics in the SNS?**

CDC-KINGSTON-35a RESPONSE:

Both CDC and BARDA participate in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) process, through which the requirements for MCM development and procurement are identified and presented for action. As BARDA development contracts reach production of licensed products, the finished MCMs are delivered to SNS for stockpiling and maintenance under SNS appropriated funds. The PHEMCE Annual Report on the SNS provides prioritized corrective actions to ensure procurement and replacement of the critical MCM assets required to protect the National Health Security. DOD, DHS, VA, and USDA also are interagency partners that help to inform decision making in the PHEMCE process.

- (b) How will CDC ensure the stockpile of new products developed over the last 10 years under Project Bioshield will remain available to the American public in the event of an emergency?**

CDC-KINGSTON-35b RESPONSE:

CDC will continue to maintain all MCM assets in the SNS in accordance with the PHEMCE approved priorities, pending the availability of funds.

- (c) Can you assure Congress that for threats where HHS has established formal medical countermeasure requirements and developed appropriate medical countermeasure the CDC will ensure that those minimal requirements are met?**

CDC-KINGSTON-35c RESPONSE:

CDC addresses the prioritized PHEMCE goals for product procurement each fiscal year, and will continue to do so, as PHEMCE requirements are adjusted and reprioritized based on the latest available scientific and risk information (which is informed by DHS and DOD). CDC continues to execute the PHEMCE prioritized procurement plan while working to inform future requirements and ensure strategic investment in critical countermeasures is maintained. CDC will continue to maintain all MCM assets in the SNS in accordance with the PHEMCE approved priorities, pending the availability of funds.

36) On the winnable battles? You have identified “HIV” as one of your winnable battles; please explain what you are doing to decrease the number of new infections, which has stood at 50,000 every year for the past several years?

CDC-KINGSTON-36 RESPONSE:

CDC programs have contributed to U.S. HIV prevention successes, including reductions in HIV among certain risk groups, reductions in HIV transmission rates, and increases in individual knowledge of HIV status. CDC’s most recent analysis of HIV incidence data reveal signs of an encouraging decrease in new HIV infection among heterosexual black women from 7,700 new infections in 2008 to 6,100 in 2010 – a reduction of 21 percent -- and among females generally by 21 percent as well. In addition, HIV cases attributed to injecting drug use have continued to decline among both male and females over this same time period. Rates of HIV transmission, which is the number of new infections per year per 100 persons with HIV, have also declined. Nevertheless, much remains to be done.

CDC has undertaken a comprehensive approach to HIV prevention efforts that will move the United States beyond stabilizing to reducing the number of new HIV infections diagnosed each year. In 2011, CDC and its partners began pursuing a High-Impact Prevention (HIP) approach to reduce new HIV infections. By using combinations of scientifically proven, cost-effective, and scalable interventions targeted to the right populations in key geographic areas nationwide, HIP will increase the impact of HIV prevention efforts. HIP strategies include HIV testing and linkage to care, adherence of persons living with HIV to antiretroviral therapy, and prevention programs for persons living with HIV and their partners. CDC also implements various HIV testing campaigns to encourage HIV testing and knowing one’s HIV status. While the testing campaigns carry wide appeal, certain campaigns are specifically tailored for a targeted audience, consisting of persons with demographic characteristics that are associated with a higher risk of HIV infection. In recent years, CDC has realigned funding opportunities to increase the effectiveness of reducing the number of HIV infections in the United States and to support the HIP approach. CDC’s funding to health departments to support HIV prevention activities is now aligned so that funding to states and localities correlates with the prevalence of HIV in those geographic areas. In addition, CDC has provided funding to support HHS’ Minority Health Initiative Care and Prevention in the United States (CAPUS) awards in eight jurisdictions. These awards are designed to promote partnerships between health departments and communities with a high prevalence of HIV to increase testing and linkage to and retention in care, particularly among racial and ethnic minority communities.

37) Regarding the Community Preventive Services Task Force. As this committee provides oversight of the CDC and its' funding I am interested in the activities undertaken by the Community Preventive Services Task Force and the work it carries out. Very little light is shed on the operations of the Task Force, who oversees their work, what their mandate is and how they are funded. The only sources of insight into the Task Force is found on the CDC website and from the Community Preventive Services Task Force 2012 Annual Report which describes it as an "independent, nonfederal, unpaid panel of public health officials" that meets 3 times a year, and is completely supported by CDC staff in terms of administration, research and technical needs. The Task Force has issued over one hundred policy prescriptions – some of them controversial – as if it were acting on behalf of the United States Government itself rather than of an unpaid panel whose recommendations do not undergo review or approval by CDC . It seems to walk an awfully fine line between independence and total alignment with CDC's own policy biases.

a. Can you explain what the Task Force's role really is?

CDC-KINGSTON-37a RESPONSE:

Section 399U of the Public Health Service Act establishes the Task Force to "review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the Guide to Community Preventive Services (referred to in this section as the 'Guide'), for individuals and organizations delivering population-based services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, schools, governmental public health agencies, Indian tribes, tribal organizations and urban Indian organizations, medical groups, Congress and other policymakers."

The Act establishes the Task Force as an independent, expert group, and specifies the role of CDC to "provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations."

b. Are you aware of any other panel or entity, not just in CDC, that has such wide latitude in making policy recommendations yet has as little oversight of its activities and does not undergo any review or approval mechanisms such as this Task Force?

CDC-KINGSTON-37b RESPONSE

The Task Force does not make policy recommendations. The Task Force's charge is similar to that in Section 915 of the Public Health Service Act, establishing the U.S. Preventive Services Task Force (USPSTF) with a parallel legislative mandate to the Community Preventive Services Task Force, except that the USPSTF reviews the clinical effectiveness of preventive services delivered in the health care system. To make the USPSTF recommendations clear and its

processes transparent, the USPSTF posts online all draft Research Plans, Evidence Reports, and Recommendation Statements for public and stakeholder comment. . To make Community Preventive Services Task Force (CPSTF) recommendations clear and to ensure that its processes are transparent, all CPSTF meetings are open to the public and announced in the federal register 60 days prior to each meeting. Publically open meetings allow CPSTF to solicit feedback from the public and stakeholders on systematic review findings, Task Force recommendations, prioritization proposals, proposals for upcoming reviews, and methods development.

c. What are the Task Force’s funding sources and how much did it receive in each fiscal year beginning with 2004 through fiscal year 2013?

CDC-KINGSTON-37c RESPONSE

The Task Force is an independent panel. Section 399U of the Public Health Service Act specifies the role of CDC to “provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.” In support of those efforts, Community Guide funding allocations from FY 2004 to FY 2013 are below:

Fiscal Year	Funding Allocation
FY 2013	Budget not yet finalized
FY 2012	\$10,500,000
FY 2011	\$8,177,000
FY 2010	\$6,630,000
FY 2009	\$1,737,000
FY 2008	\$1,831,000
FY 2007	\$1,796,000
FY 2006	\$1,886,000
FY 2005	\$1,587,000
FY 2004	\$1,400,000

i. How much has been provided via discretionary appropriations?

CDC-KINGSTON-37ci RESPONSE:

Since FY 2010, the Community Guide has been funded in part through the mandatory Prevention & Public Health Fund (PPHF). All other funds are discretionary. See below for PPHF funding levels.

ii. How much mandatory funding has the Task Force received since its inception by fiscal year? A factsheet on Healthcare.gov indicates \$49 million was committed to the Task Force in FY 2011 under Title 4 of the ACA, the Prevention and Public Health Fund.

CDC-KINGSTON-37cii RESPONSE:

Prevention and Public Health Fund allocations to Community Guide

FY 2012	\$10,000,000
FY 2011	\$7,000,000
FY 2010	\$5,000,000
Total	\$22,000,000

iii. Is the PPHF an additional, ongoing source of Task Force funds in FY 2013?

CDC-KINGSTON-37ciii RESPONSE:

CDC has not received its allocation for the Prevention and Public Health Fund for FY 2013. The Community Guide received PPHF in FY 2010 through FY 2012 as shown in the above table.

iv. Do you anticipate additional funding for the Task Force in the President’s budget request for FY 2014? If so, at what dollar levels?

CDC-KINGSTON-37iv RESPONSE:

The FY 2014 Budget has not yet been released.

37d) How does this independent, unpaid Community Preventive Services Task Force allocate its budget? Please specify amounts for overhead (staff and expenses), research grants, program support, outreach to stakeholders, and so forth. Who is in charge of planning and directing the Task Force’s budget? Has the Task Force been affected by sequestration? If so, how much?

CDC-KINGSTON-37d RESPONSE:

CDC is Congressionally mandated to provide ongoing administrative, research, and technical assistance to the Community Preventive Services Task Force. Within CDC, the Epidemiology and Analysis Program Office is responsible for planning and executing the Community Guide budget. CDC has not released its FY 2013 operating plan levels. The budget associated with the Community Guide is allocated by the three functions that support the Task Force and that are outlined in the FY 2012 Congressional Justification. See the table below for a breakdown of the FY 2012 budget.

<i>FY2012 Budget</i>	
Systematic Review and Science	\$5,000,000
Dissemination	\$2,700,000

Task Force and Operations	\$2,800,000
Total Expenses	\$10,500,000

37e) Priorities listed in the 2012 Report to Congress include expanding the Task Force’s review capacity by using external contractors for policy updates. Would Task Force members select these external contractors or would that be decided by CDC staff? Is the Task Force contemplating such a vast expansion of its policy work that the 9,000 CDC full time staffers are inadequate for the job?

CDC-KINGSTON-37e RESPONSE:

Section 399U of the PHS Act calls upon CDC to “provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.” CDC’s use of contractors to support these functions is in congruent with the departmental guidelines of precluding contractors from final authorization of any action that affects the financial standing of the government.

37f) When the Task Force funds “cross-cutting” public health research as envisioned in the 2012 Report to Congress, what is the process for selecting research topics, who evaluates the proposals and who selects grantees?

CDC-KINGSTON-37f RESPONSE:

The Community Preventive Services Task Force does not fund research. It does identify gaps in the evidence, which are available to inform the research priorities of the field. The Community Preventive Services Task Force prioritizes its systematic review work through a multi-stage process that involves input from a wide range of stakeholders, including Task Force Liaison agencies and organizations, federal agencies, practice- and business-based partners and stakeholders, and the public.

37g) How do you define “cross-cutting” public health research? Is there any effort to coordinate with other federal agencies to ensure CDC is not duplicating the work of other government researchers or treading on their congressionally mandated jurisdictions?

CDC-KINGSTON-37g RESPONSE:

The Community Preventive Services Task Force does not fund research. The Community Preventive Services Task Force routinely connects with the U.S. Preventive Services Task Force (USPSTF) to ensure work is complementary and not duplicative. In addition, prior to beginning a review, the Community Preventive Services Task Force searches the literature to identify any prior systematic reviews already completed. Many federal agencies (e.g. Department of Justice,

Department of Transportation, and Department of Education) also participate on the coordination teams that conduct the systematic reviews of the evidence.

37h) Please give us a list of all universities, non-profit organizations, and other research institutions that received funding from the Task Force to do “cross-cutting” public health research, the amount of funding, the areas of concern, and major findings that can shape public health. How many peer-reviewed scientific articles were generated from that funding?

CDC-KINGSTON-37h RESPONSE:

The Community Preventive Services Task Force does not fund research, including cross –cutting public health research.

37i) At least some of the \$49 million the Task Force was to receive from the Prevention and Public Health Fund was to be used in disseminating evidence-based recommendations to “decision makers.” That sounds like the Task Force, or the community groups it finances, could be using taxpayer funds to advocate policy to members congress, governors and other state officials. As you know, members of the House and Senate raised serious questions last year about the use of PPHF funds for advocacy lobbying, and this Committee would like to have assurances that such practices will not be in question in the future.

CDC-KINGSTON-37i RESPONSE:

In FY 2011, The Community Preventive Services Task Force (Task Force) did not receive \$49 million from the Prevention and Public Health Fund. In FY 2011, Community Guide activities were supported with \$6.7 million dollars from the Prevention and Public Health Fund. The Task Force is an independent, nonfederal, and unpaid panel. Furthermore, CDC does not permit lobbying with CDC funds, and has provided guidance and extensive training to our grantees on compliance with restrictions. We carefully monitor grantees’ performance, and investigate all allegations of inappropriate activity.

In FY 2011, \$49 million from the Prevention and Public Health Fund was used to support a variety of prevention and public health research and evidence reviews across HHS – including CDC’s Prevention Research Centers and Public Health Research, Community Guide activities and AHRQ’s Clinical Preventive Services Research and the U.S. Preventive Services Task Force.

37j) Task Force Liaison Agencies and Organizations are described as “stakeholders” and listed on page 25 of the 2012 Report to Congress. State officials, public health nonprofits, community-based organizations and coalitions, and medical trade associations are listed, but nowhere is there any mention of private sector business groups which might offer valuable input to the Task Force policy making process. Do you think this is a fair balance of expertise that will lead to the best policy development? Or, is there something about organizations that represent commercial interests that disqualifies them from having a respected advisory role in public health policy decisions?

CDC-KINGSTON-37j RESPONSE:

The Community Preventive Services Task Force (Task Force) makes recommendations based on systematic reviews of all available evidence to provide evidence-based options from which decision makers in communities, companies, health departments, health plans and healthcare systems, non-governmental organizations, and at all levels of government can choose what best meets the needs, preferences, available resources, and constraints of their constituents. In all aspects of the Task Force's work—prioritizing reviews, forming review teams, conducting reviews, developing Task Force recommendations, disseminating Task Force recommendations, and helping decision makers use them—the Task Force works closely with and seeks feedback from official federal agency and organizational Liaisons, CDC Programs, and researchers, practitioners, and decision makers from throughout the United States. This includes a wide range of businesses and business groups.

To view examples go to

- Community in Action Story: Dow Investing in Worksite Wellness for Dow Employees <http://www.thecommunityguide.org/CG-in-Action/Worksite-Dow.pdf>
- Community in Action Story: Evidence-Based Recommendations Gets Minnesotans in the Groove <http://www.thecommunityguide.org/CG-in-Action/PhysicalActivity-MN.pdf>

**National Institutes of Health (NIH)
QFRs from Chairman Kingston**

NIH-Kingston-1. The Washington Post March 11, 2013 article title “Doubts about Johns Hopkins research have gone unanswered, scientists says”
(http://www.washingtonpost.com/business/economy/doubts-about-johns-hopkins-research-have-gone-unanswered-scientist-says/2013/03/11/52822c8a-7c84-11e2-82e8-61a46c2cde3d_story.html?wpisrc=emailtoafriend) raised a number of questions related to how NIH ensure the accountability of research supported with taxpayer funds.

NIH-Kingston-1a. Please explain how NIH ensures accountability of federal funds provided to grantees and institutions?

Answer. NIH takes the following steps to ensure accountability of federal funds provided to grantees and institutions:

- 1) Upon submission of every grant application, the Authorized Organizational Representative certifies that the applicant organization will be accountable for the appropriate use of funds awarded as imposed under the Terms and Conditions of award. The grantee institution further accepts the terms and conditions of the award by drawing funds from the HHS payment system.
- 2) The grantee must have accounting and internal control systems in place for appropriate monitoring of grant accounts to ensure that expenditures are made in accordance with cost principles. Grantees must have a financial system that can identify inappropriate obligations and expenditures of funds. NIH grants management officers also assess whether the applicant’s financial and business management systems will support the expenditure of and accountability for NIH funds.
- 3) NIH grants management officers may perform a cost analysis on grants involving a detailed budget. Cost analysis includes obtaining cost breakdowns, validating cost data, evaluating specific elements of cost, and examining the data to determine necessity, reasonableness, and allowability of the costs included in the application budget.
- 4) NIH awarding offices monitor grants for the duration of the grant project period to identify potential problems and areas where technical assistance might be necessary through financial and scientific progress reports, correspondence with the grantee, audit reports, and other information available to NIH. Monitoring continues for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements, which may continue after the grant is administratively closed out.
- 5) NIH grantees (other than Federal institutions) are also subject to the audit requirements of OMB Circular A-133, as implemented by 45 CFR 74.26 and 92.26, or the audit requirements stated in 45 CFR 74.26(d) and in the NIH Grants Policy Statement (for types of organizations to which OMB Circular A-133 does not directly apply).

NIH-Kingston-1b. Please explain how NIH works to ensure integrity of scientific data from grants it supports?

Answer. Institutions that receive NIH grants are required to establish and enforce standards of ethical conduct for their employees. Grantees must agree to adhere to specific requirements that foster safe and ethical conduct of research articulated in the terms and conditions of the awards. For example, NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research. Failure of grantees to comply with this or any of the terms and conditions of awards could result in NIH taking enforcement actions in accordance with applicable statutes, regulations and policies. These include actions to wholly or partially suspend the grant pending corrective action, or termination of the grant for cause. Detailed information on the extensive policies and procedures that NIH adopts to promote scientific integrity can be found in the document “NIH Policies and Procedures for Promoting Scientific Integrity” readily accessible by the public on the NIH website <http://www.nih.gov/about/director/sci-int-nov2012.pdf>.

NIH grants generally are issued for 3 – 5 year project periods, and scientific progress reports are submitted yearly. NIH Program staff review and monitor scientific progress submitted by the grantees with awards in their portfolios, and must approve each year’s progress report prior to the approval of the continuation award. Program staff communicate, in an ongoing way, with the investigators. Each NIH Institute and Center has a Research Integrity Officer with whom program staff may discuss questions or concerns about scientific misconduct. If the issues are not resolved or explained, NIH shares the concerns with the HHS Office of Research Integrity or the NIH Office of Management Assessment, who may make further inquiries.

NIH-Kingston-1c. The article asserts that according to the National Academy of Sciences that the percentage of articles retracted because of fraud increased tenfold since 1975. Please explain the potential ramifications to NIH supported institutes and investigators that NIH can impose?

Answer. Allegations of research misconduct involving NIH funding are handled according to policies and procedures established pursuant to the Public Health Service Policies on Research Misconduct, 42 C.F.R. Part 93. Allegations received at NIH are treated seriously, and NIH staff members who work with grantees receive regular training on how allegations of research misconduct are handled. Allegations that fall within the definition of research misconduct are promptly referred to the HHS Office of Research Integrity (ORI) for review and oversight, and other allegations are referred to appropriate authorities. After ORI has made findings of research misconduct, NIH takes appropriate administrative actions based on ORI’s recommendations. ORI may recommend retractions of publications by the respondent or the respondent’s institution when these records are deemed to have been significantly affected by the misconduct. In such instances, a retraction notice indicating research misconduct together with a link to the relevant notice of findings of research misconduct in the Federal Register will be included with the publication in NIH’s PubMed. Other ORI administrative actions include debarment, prohibition to serve on advisory committees to the federal government such as NIH peer review committees, requirement for institutional

certification that a respondent's work was conducted responsibly, and requirement for respondent to work under appropriate supervision.

NIH-Kingston-1d. Do NIH have authority to NIH require repayment of a grant and has it implanted guidance to that effect?

Answer. Yes, NIH has the authority to require repayment of costs for material violations of the cost principles and other terms and conditions of award as promulgated in regulation at 45 CFR 74.62 and implemented in guidance in section 8.5 of the NIH Grants Policy Statement, a term and condition of all NIH grant awards:
(http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch8.htm#_Toc271264977)

A grantee's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause NIH to take one or more actions, depending on the severity and duration of the non-compliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. NIH generally will afford the grantee an opportunity to correct the deficiencies before taking action unless public health or welfare concerns require immediate action. However, even if a grantee is taking corrective action, NIH may take proactive actions to protect the Federal government's interests, including placing special conditions on awards or precluding the grantee from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring.

NIH-Kingston-1e. How often over the past 10 years has NIH imposed the most severe ramification for grantees or institutions who engage in fraudulent or questionable behavior that undermines or has the potential to undermine the integrity of scientific data supported by tax payer funds?

Answer. Allegations and findings of research misconduct fall within the regulatory purview of ORI and, as such, ORI takes the lead for HHS in imposing appropriate administrative actions that may include debarment, arguably the most severe enforcement action. ORI's Findings of Misconduct in Science, including administrative actions imposed, are published on the Federal Register as well as the NIH Guide for Grants and Contracts. Case summaries of ORI's findings are also listed on the ORI website (http://ori.hhs.gov/case_summary). From 2011 until now, ORI has made 31 findings against individuals for research misconduct involving NIH funded research. Of these, 11 debarments were imposed. After ORI has made findings of research misconduct, NIH carefully considers the impact of the misconduct on its funded research and considers further actions including additional administrative actions, such as enforcement action.

NIH-Kingston-1f. What rules exist for the NIH intramural activity that violates rules of scientific integrity, what is the scope of ramifications, and when was the last time a violation occurred that resulted in the most sever ramification?

Answer. Allegations that an NIH intramural activity has violated rules of scientific integrity are handled in accordance with the *National Institutes of Health Intramural Research*

Program Policies & Procedures for Research Misconduct Proceedings

(<http://sourcebook.od.nih.gov/ethic-conduct/Research%20Misconduct%20Policy%20-%2008-03-2010.pdf>). These policies and procedures address allegations of misconduct involving research: carried out in NIH facilities by any person; funded by the NIH Intramural Research Program (IRP) in any location; or undertaken by an NIH employee or trainee as part of his or her official NIH duties or NIH training activities, regardless of location. They are based on the Public Health Service Policies on Research Misconduct, 42 C.F.R. Part 93, which are administered and overseen by the ORI.

What is the scope of ramifications?

If, at the conclusion of a research misconduct proceeding in the NIH IRP, NIH deciding official determines that research misconduct is substantiated by the findings, he or she will refer to other appropriate NIH officials (e.g., Director of Human Resources) to decide what, if any, NIH administrative actions should be taken. The administrative actions must be consistent with applicable personnel rules and regulations and may include, for example: withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found; removal of the respondent from the particular research project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment.

Where NIH has found research misconduct, the case is also submitted to the ORI for further review and response. ORI oversees and directs Public Health Service research integrity activities on behalf of the Secretary (with the exception of the regulatory research integrity activities of the FDA). Following its own review, ORI may recommend research misconduct findings and administrative action to the Assistant Secretary for Health, subject to appeal.

When was the last time a violation occurred that resulted in the most severe ramifications?

In March 2013, allegations of research misconduct involving fabrication of certain data were made against a trainee and submitted to the Agency Intramural Research Integrity Officer. The allegations were accompanied by an admission of guilt by the trainee, who was dismissed from the program. None of the data at issue directly affected the research or were contained in any published papers.

NIH-Kingston-1g. Finally, the article asserts that the threat to federal research, if there was one, ended with Mr. Lin's death. Is this accurate? If so, please explain why this would be the case as the data would still exist? If not, what NIH's position in situations is as described in the Washington Post story?

Answer. NIH defers to ORI with regard to questions concerning specific cases of research misconduct. ORI publishes the de-identified results of past investigations with no findings after they have closed. As a general matter, peer reviewers, journal reviewers, and journal editors play a vital role in identifying and correcting inaccuracies or inappropriate interpretations in scientific records. NIH supports good science by promoting transparency,

vibrant scientific debates free from undue influence, and responsible reviews by the scientific community.

NIH-Kingston-2 I understand NIH desires to change its logo or a number of logo.

NIH-Kingston-2a Please explain how the decision was made and when?

Answer: For many years, NIH leadership has heard from voluntary organizations, patient groups, professional societies, its own advisory committees, and even members of Congress, that NIH should do more to strengthen its communications efforts. Despite its \$30 billion budget and support of research in over 2,500 colleges, universities, medical centers, and research institutions in every state of the Union, public awareness of the role of NIH in advancing science and health has been low. Outside polling by Research!America (February 2010), for example, showed that only nine percent of the American public knew about NIH. As a government agency funded by tax dollars to advance biomedical research, it is incumbent upon NIH to communicate clearly to the public how the investment in NIH research is improving people's health—and that NIH is a primary source of trusted, reliable health and science information. Historically, NIH communications has been largely decentralized—at the agency's Institute, Center, or program level. As a result, NIH communications has been extremely fragmented. This made it very difficult, if not impossible, for the public to grasp the full scope of NIH's impact on health and medicine, or that information they may seek comes from the same, reliable source.

Over the last several years, there has been an internal effort to review NIH communications. In the spring of 2011, the Associate Director for Communications and Public Liaison, John Burklow, began putting together elements of a new NIH communications plan. He brought together a sub-group of IC (Institute and Center) communication directors to discuss how best to go about enhancing NIH communications. Several strategies were discussed, including ways to communicate more clearly to the public about NIH. Other strategies included bolstering communications with grantee institutions and patient, voluntary, and professional organizations, and investing additional resources into new media. For example, most of the public is unaware that NIH funding is behind many of the latest biomedical research results coming out of the nation's preeminent universities. Efforts to establish better communication and collaborations with grantee institutions, which are a priority, are under way.

At the outset, the proliferation of logos across NIH, estimated to be at least several hundred, was deemed problematic, counter-productive, and an inefficient use of resources. It was clear that the fragmented approach to communications across NIH needed to be addressed in order for NIH to be able to communicate with maximum impact. Tackling the multiplicity of logos was a natural place to start. In May 2012, Mr. Burklow presented a proposed plan to the IC Directors to strengthen NIH communications, including a plan for an updated logo that was easier to see and would work for mobile devices and social media. The group agreed that it was time to change NIH's fragmented, localized approach to communications. In November 2012, Mr. Burklow presented a new NIH logo that would supplant all current NIH/IC/Program logos. The Institutes/Centers/Programs would be identified with text. For

example, the new NIH “mark” would appear alongside “National Heart, Lung, and Blood Institute.” One set of guidelines would be developed and shared with all of the ICs. The precise dimensions, fonts, etc., would be supplied. The IC directors and NIH leadership agreed to this approach.

NIH-Kingston-2b What analysis and business case was prepared in advance to support the undertaking? Is there something you can refer to in the literature that says having a recognizable identify is important for an organization that provides important information (research results, etc) to the public?

Answer: Having a recognizable, consistent identity is important for an organization, such as NIH, that provides health and science information for the public. Several attempts have been made over many years to strengthen and streamline NIH communications, dating back to the late 1990s. For example, about seven years ago, all of the ICs began using the same letterhead for press releases, identifying NIH in their press releases, and to cite NIH on their home pages. There was a movement toward clearer, more transparent communication practices, however, there was still a great deal of fragmentation and duplication of effort across the ICs, and even within the Office of the Director. In the spring of 2011, Mr. Burklow put together a plan, based in part on available outside polling data, many years of observations made by NIH leadership and staff, members of Congress, patient, voluntary, and professional organizations, and NIH advisory committees regarding, with the goal of developing a more modern, streamlined, effective approach to NIH communications. Mr. Burklow consulted with NIH leadership and IC Communication Directors, who agreed it was time for NIH to modernize its approaches and follow sound communication principles. A new, single logo for NIH emerged as one of the principal components of such a new approach. This change also was influenced by a growing trend among other HHS agencies, such as the FDA and CDC, which had moved away from a fragmented communications approach many years ago and supported a single “mark” or logo. Mr. Burklow also consulted with other government agencies such as NASA and NSF, which face similar challenges as they attempt to communicate to the public. The trend is clearly toward a singular identity with links to and from the various parts of the agencies. The intention is to make it easier for the public to make connections among the thousands of components of NIH.

NIH-Kingston-2c Was this change directed by anyone from outside NIH?

Answer: No

NIH-Kingston-2d Was the change approved by the Secretary or OMB?

Answer: NIH informed HHS public affairs counterparts of the change in the logo and the plan to have a single logo, with accompanying text to identify the ICs and programs. NIH did not contact or involve OMB.

NIH-Kingston-2e Please provide cost analysis on how much this effort has and will cost once completed. Please include all staff development time, other staff/contractor time,

cost to change banners, signs, papers, websites, and other related activity cost across all NIH Institutes and Centers?

Answer: The costs have been relatively low for such an undertaking, and nobody has been hired specifically to work on the logo switches. Over the past two years, contractor costs for developing the logo design total are approximately \$150,000, which includes the development of the NIH logo, suite of IC logos, and logo use guidelines. With respect to estimated staff time to make the changes to the IC websites, we estimate it would take an IC approximately five hours, costing between \$3,000 and \$5,000 in FTE or contractor time, to make changes to the various components of an IC website.

Banners, signs, business cards, folders, print publications, etc. will be modified to incorporate the new logo when they are up for reprinting. Staff has been asked not to discard any existing print materials with the old logo. The goal is to make the transition as inexpensive as possible.

NIH-Kingston-2f In the hearing it was noted that this will save money – as it will replace all the other Institutes and Centers logos. Is that accurate?

Answer: Yes, the move toward a single logo, with clear implementation guidelines, was an effort to eliminate duplication of efforts and costs, and maximize NIH communications efforts. Currently, there are several hundred logos in operation at NIH with no link or visual connection to NIH. Each time a logo was developed—whether it is for a new research initiative or office—money was spent to hire contractors and designers and make all the necessary graphic changes, electronic and print. The ICs also regularly update or change their IC logos, incurring costs each time. Using a single logo is a less costly and more efficient means of doing business.

NIH-Kingston-2g Please provide the proposed timeline for the elimination of all other logos throughout NIH?

Answer: A primary focus of the switch to a single logo was to not create additional, unnecessary costs. For example, staff were explicitly asked not to discard any existing print publications or materials until they are ready to be reprinted. The focus has been on digital, electronic changes. For example, the ICs have switched out their old logos with the new one on their home pages. They have been given logo templates for PowerPoint slides. This process is being managed by the communications offices within each IC, with guidance from the NIH Office of Communications and Public Liaison. The plan is for all of the IC home pages to switch to their new logo by the end of FY 2013.

NIH-Kingston-2h Please summarize the outside stakeholder involvement in this endeavor and the involvement of the other NIH Institutes and Centers?

Answer: NIH leadership and IC leadership, including directors, deputy directors, executive officers, extramural research directors, in addition to communication directors, planning and evaluation officers across NIH have been consulted and briefed throughout the process. In

addition, NIH met with stakeholder groups and informed them of these changes in NIH communications. Without exception, outside groups have been very supportive of this modernization and streamlining effort and felt it was long overdue.

NIH-Kingston-2i What is the projected plan and cost to advertise the new brands and logo of NIH?

Answer: There is no plan to advertise the new logo, merely to encourage its use by NIH. It has been mentioned in internal newsletters to help staff become aware of the new mark.

NIH-Kingston-2j What is the meaning of the proposed logo?

Answer: NIH, based on consultation with the communication directors and the IC directors, chose to use the letters of the agency as the main element of the design, rather than a particular scientific image. The goal is to make the image easy to see—either from across the room or on a mobile device. The old logo, designed in 1975, was difficult to read, was confusing to many, and virtually disappeared on a mobile device (where more and more people are getting their information). The old logo also represented a rather dated image of science—the Erlenmeyer flask (which many people mistook for a clothes hanger). The new design is clean, modern, and unambiguous. The arrow on the right of the mark suggests progress and movement, and it points to the text of the IC or program name. The arrow also provides an opportunity for color variation.

NIH-Kingston-2k It seems NIH is pretty well recognized, why disturb the brand recognition and spend any money on this type of effort, especially during such a tight fiscal environment?

Answer: In fact, despite its significant role in advancing research to improve health, NIH is largely unrecognized by the public. Outside polling indicates that less than 10 percent of the public recognize NIH. NIH also is a primary source of unbiased, authoritative health and science information and is trusted by those who come to know it. The public should know if the information they are receiving is from such a trusted source. NIH's communications improvements are intended to help the public to make that distinction.

Moreover, the use of a single logo is cost-effective in the long-run because it will eliminate the cost of designing new logos for each new office, program, initiative, or clinical trial. Also, this effort is encouraging the ICs to collaborate in new, more efficient ways. For example, ICs are exhibiting at professional and voluntary organization conferences as a single entity, as opposed to many individual agencies. The focus for all of these efforts is on clarity, streamlining, increased efficiency, collaboration, and cost-savings whenever possible.

NIH-Kingston-3. Fetal alcohol syndrome research examines potential developmental issues in a baby when a mother drinks alcohol during pregnancy. It is funded in all of your organizations, except the Innovation Fund but maybe you do research there as well.

NIH spends about \$36 million a year on this syndrome. It also puts out guides or manuals for the public. CDC spends about \$10 million a year on fetal alcohol syndrome and also makes guidance available to the public. Further HRSA, AHRQ, and Substance Abuse and Mental Health Services Administration also fund this activity in their budgets.

NIH-Kingston-3a. How does NIH work with the other agencies to decide what activities to fund in the area of fetal alcohol syndrome?

Answer. NIH coordinates with other agencies on this topic primarily through the Interagency Coordinating Committee on Fetal Alcohol Spectrum Disorders (ICCFASD), established in 1996. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) chairs this committee with significant contributions from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) as well as agencies from the Department of Health and Human Services (HHS) (including the Administration for Children and Families (ACF), the Centers for Disease Control and Prevention (CDC), the Indian Health Service (IHS), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Health Resources and Services Administration (HRSA), the Agency for Healthcare Research and Quality (AHRQ), the Department of Education, and the Department of Justice (DOJ). The ICCFASD was established to improve communication, cooperation, and collaboration among federal agencies that address issues relevant to fetal alcohol spectrum disorders (FASD), including Fetal Alcohol Syndrome (FAS), caused by prenatal alcohol exposure. The ICCFASD meets regularly; the most recent meeting of the ICCFASD was on April 4, 2013. Through the ICCFASD, agencies share their current activities, program advances, and future plans. The ICCFASD includes special focus work groups on education issues, justice issues, diagnostic issues, and a special work group on women, pregnancy, and drinking. These special subgroups help ensure coordination across more specific areas. More information on the ICCFASD is available at <http://www.niaaa.nih.gov/ICCFASD>.

NIH-Kingston-3b. How do you coordinate the funding plan and goals?

Answer. The ICCFASD meetings help agencies exchange information and coordinate general funding strategies, plans, and goals. Each agency's funding plan is directed by their specific mission, although guided by the overall goals established through the ICCFASD. Within NIH, NICHD and NIAAA work closely together to coordinate FAS research activities. An important portion of the NIH research activity on FAS is conducted through the Prenatal Alcohol in Sudden Infant Death Syndrome (SIDS) and Stillbirth (PASS) research network, jointly funded by NIAAA, NICHD, and the National Institute on Deafness and Other Communication Disorders (NIDCD).

NIH-Kingston-3c. What actions do you take to reduce duplication, and ensure the scientific gaps across the various agencies are effectively addressed

Answer. Although several agencies fund activities related to FAS and related disorders, each agency's unique mission guides its activities and funding priorities. NIH focuses on basic and clinical research to prevent FAS and to treat affected children to minimize the

damage caused by FAS and related disorders. Within NIH, NICHD's major interests in this area are stillbirth, SIDS, and alcohol's role in these outcomes; NIAAA supported research is focused on identifying the biological mechanisms that underlie FASD, improving FASD diagnosis and prevention, and developing behavioral and/or pharmacological interventions to ameliorate the symptoms of FASD. Officials in ICCFASD agencies stay in close touch and exchange information on new, planned and ongoing activities to prevent duplication of effort. The ICCFASD's special focus groups allow agencies to work together to address research and program gaps. In addition, the ICCFASD conducts workshops and joint activities to address gaps across the various agencies and to allow agencies to work collaboratively to inform the public about FAS issues. For example, in 2012 the ICCFASD held a special workshop entitled "Alcohol-Related Birth Disorders and the Law: How Should Attorneys & Judges Respond to Fetal Alcohol Spectrum Disorders?". Held in collaboration with the American Bar Association, this meeting educated the legal community on FAS with presentations by NIH-funded researchers, program officials from ICCFASD agencies, public health officials, local district attorneys, and other experts.

NIH-Kingston-3d. How to you measure success and develop measures that build on each organization's strength?

Answer. The activities conducted by different federal agencies are diverse in their ultimate goals and objectives. Because the goals and activities of agency programs are so diverse, measures of success will also differ across programs and organizations. Within NIH, research success is assessed at the level of the individual project and also by assessing the impact of the overall research portfolio. NIH Institutes and Centers commonly assess FAS projects and portfolios through publication reviews, science advances, and the career development of early stage investigators.

NIH-Kingston-3e. How and how often do you conduct program evaluations?

Answer. NIAAA's FASD portfolio is evaluated annually by the Program Officer serving as NIAAA's representative to the ICCFASD. This evaluation is undertaken shortly after the close of each fiscal year to ascertain the number of FASD grants comprising this portfolio, overall dollars spent on this research, and the distribution of these projects addressing prevention, diagnosis, treatment, and mechanistic research. Information from this analysis is presented to the ICCFASD as well as to the FASD Study Group which is comprised of FASD researchers. FASD projects are also reviewed in the larger context of the NIAAA grant portfolio to ensure a balance of research projects across the entire spectrum of NIAAA-supported research.

NIH-Kingston-4. Please provide a table with the past 20 year history (up through FY 2014 est) of the percentage of NIH funds spend on basic science?

Answer.

Fiscal Year	Basic*
1995 Actual	56.8%
1996 Actual	56.8%

1997 Actual	57.1%
1998 Actual	57.1%
1999 Actual	58.5%
2000 Actual	59.5%
2001 Actual	60.3%
2002 Actual	58.8%
2003 Actual	56.1%
2004 Actual	54.9%
2005 Actual	57.4%
2006 Actual	56.5%
2007 Actual	55.5%
2008 Actual	55.4%
2009 Actual	54.3%
2010 Actual	53.5%
2011 Actual	53.8%
2012 Actual	53.2%
2013 Estimate	53.2%
2014 PB	53.0%

Note: %/ Percentages exclude amounts allocated for facilities and training.

NIH-Kingston-5. Please provide a table with the past 20 year history (up through FY 2014 est) of the percentage of NIH funds spend on intramural?

Answer. The table below displays the relative percentages of NIH funds for the Intramural budget mechanism obligated over 20 years.

**National Institutes of Health
Percentage of Funds Obligated Intramural Research**

Fiscal Year	Intramural % of Total*
1995	10.8%
1996	10.9%
1997	10.5%
1998	10.5%
1999	10.0%
2000	9.8%
2001	9.5%
2002	9.6%
2003	9.6%
2004	9.5%
2005	9.6%
2006	9.6%
2007	10.5%
2008	10.5%
2009	10.7%
2010	10.7%
2011	10.9%
2012	11.0%
2013	11.2%
2014	11.2%

Note: */ Percentages for FY 1995 - 2012 are based on actual obligations. Percentages for FY 2013-2014 reflect operating plans or budget request levels.

Before FY 2007, National Library of Medicine (NLM) funding was not part of the Intramural Research mechanism; the 0.9% increase that year is due to a change in the mechanism table. In prior years NLM had its own mechanism, but starting in FY 2007 over three-quarters of NLM funding has been in the Intramural mechanism. As a result, it is necessary to add 0.9% to the FY 1995-2006 percentages in order to make them comparable to the percentages in FY 2007 and later.

NIH-Kingston-7. In the creation of the National Center for Advancing Translational Sciences (NCATS) the committee specifically included language that NCATS activities shall not create duplication, redundancy, or competition with industry. It was assumed based on discussions with NIH that a rule making or formal guidance would be developed to ensure clear procedures are established in concert with industry to ensure NIH programs do not prevent or hinder the private sector from advancing the transformational medical research into clinical applications and economic growth. Please provide a timeline on the status of

the rule making or formal guidance that includes some form of mechanism for industry to comment on the proposed procedure.

Answer. NCATS has put in place many specific procedures to prevent duplication, redundancy, and competition with industry. NCATS is planning to post a Notice in the Federal Register that enumerates, and seeks comments on, those procedures and the methods it is using to ensure that industry is both aware of and able to provide input on its activities and planned initiatives. The Notice is expected in Spring 2013.

NIH-Kingston-8. Please provide a joint report from the National Cancer Institute (NCI) and the National Institute on Minority Health and Health Disparities on efforts to end the of disparity of cancer in minority communities and what activities are supported to focus on research, prevention, and treatment of cancer in minority communities.

Answer. The National Cancer Institute (NCI) and the National Institute on Minority Health and Health Disparities (NIMHD) have prepared a joint report describing NIH research and communications efforts addressing cancer health disparities in racially and ethnically diverse populations. The HHS Assistant Secretary for Financial Resources transmitted the report to Chairman Kingston and Ranking Member DeLauro on April 23, 2013.

NIH-Kingston-9. Please provide an update on NCI's plans and activities to ensure that the wealth of genomic data obtained through TCGA is fully utilized to maximize opportunities for advances to improve outcomes for U.S. gastrointestinal patients.

Answer. The Cancer Genome Atlas (TCGA) will yield a vast quantity of new data that promises to dramatically alter our knowledge of the genetic and epigenetic changes that drive cancer development, which will benefit all cancer types.

TCGA has collected genomic data on more than 1,000 cases of gastrointestinal (GI) tumors across gastric (325), esophageal (50), colon (424), rectal (165), pancreatic (57), and hepatocellular cancers (99). Together, these GI tumors represent almost 20 percent of the current TCGA dataset. TCGA data is now and will remain available to qualified researchers through public databases designed to protect patient privacy.

TCGA data is being used to refine the diagnosis of cancer and to elucidate molecular pathways that control the malignant behavior of cancer cells, with the long-term goal of improving treatment outcomes for cancer patients. Other National Cancer Institute (NCI) programs aim to capitalize on TCGA genomics data, such as the NCI Cancer Target Discovery and Development (CTD2) Network, which is defining new targets for therapeutic attack in cancer and developing means to block these targets. TCGA data is also being used to explore the relationship between germline genetic variation and the molecular features of tumors that arise. Recently, several clinical trials have been established using TCGA data as a foundation, and we expect additional trials to be initiated in coming years.

The TCGA team provides extensive support to researchers accessing TCGA data, including step-by-step protocols for how to apply and locate TCGA data, as well as preliminary data analysis to

those unable to manipulate the raw data to ensure efficient and effective use of the data. The availability and broad utilization of the TCGA data is demonstrated by the number of publications using TCGA data (to date, almost 400 since 2008) and the number of grant applications that include TCGA data (to date, more than 800).

NCI has recently consolidated a number of its genomics initiatives – including TCGA and several pediatric cancer initiatives, most notably TARGET (Therapeutically Applicable Research to Generate Effective Treatments) – into a single Center for Cancer Genomics. The new Center will work with other components of NCI to ensure that the findings are applied to developing new diagnostics and therapeutics and are integrated swiftly into medical practice. Pursuing the genetic foundations of many cancers is a vital component of NCI's current research, and such genetic and genomic studies comprise a substantial proportion of the institute's research portfolio. Our principal task in the years ahead – for NCI and for the entire cancer research enterprise – will be to capitalize on the information developed through TCGA by supporting additional studies that validate and extend critical pathogenetic roles for specific genomic changes in tumors, which can lead to more precise effective interventions that improve outcomes for patients.

NIH-Kingston-10. Please provide a status of the activity and plans NCI has for Pediatric Low Grade Astrocytoma (PLGA). Specially, describe any activity related NCI's continued focus on obtaining high-quality biospecimens for all cancer and sharing of tissues for research purposes.

Answer. The National Cancer Institute (NCI) continues to support promising research addressing Pediatric Low Grade Astrocytoma (PLGA), including preclinical research and clinical trials, as well as efforts to obtain high-quality biospecimens for research.

An important recent advance that is leading to new research opportunities in this area is the recognition that the vast majority of PLGA cases have genomic alterations involving a gene called BRAF, a known target for therapy of other cancers, particularly melanomas, using approved drugs. NCI is supporting the development of preclinical models that will allow identification of promising candidate treatments for PLGAs with this alteration. The NCI-supported Pediatric Preclinical Testing Program developed a model for a subtype of PLGA with the BRAF mutation and identified a targeted therapy, selumetinib (AZD6244), for additional research. Currently, the NCI-supported Pediatric Brain Tumor Consortium is conducting a Phase I trial of selumetinib in children with PLGA who have progressed after receiving radiation therapy, to study the side effects and the best dose of selumetinib. The trial is open at 13 sites across the country, including at the NIH Clinical Research Center in NCI's Pediatric Oncology Branch, and expects to enroll 40 children with PLGA. Data collection for the trial is anticipated to be complete in July 2014.

In addition to this study, NCI currently supports 14 other active clinical trials for which patients with PLGA are eligible and that address therapeutic, supportive care/quality of life, or biological questions relevant to PLGA. This includes a recently opened Children's Oncology Group (COG) Phase I trial for PLGA, investigating the use of lenalidomide, an immunomodulator that has been shown to enhance immune cell activity and inhibit inflammatory response. The trial is

active in 68 locations, with an NCI Pediatric Oncology Branch researcher serving as the principal investigator. The trial, which opened in March 2012, is studying low-dose or high-dose lenalidomide to see how well it works in treating younger patients with recurrent, refractory, or progressive juvenile pilocytic astrocytomas or optic nerve pathway gliomas. The trial expects to enroll 80 patients, and data collection is anticipated to be complete in May 2015.

NCI supports several projects that demonstrate our focus on obtaining high-quality biospecimens and sharing of tissues for research purposes. As a partner within the International Cancer Genome Consortium (ICGC), NCI continues to collaborate with German pediatric brain tumor research colleagues who are playing a leading role in genome sequencing of PLGAs. The ICGC collaborative effort allows member institutions to prioritize research efforts and avoid duplication. For example, while German researchers are taking the lead in collecting and analyzing PLGA tumor tissue samples, the NIH Cancer Genome Atlas (TCGA), which analyzes the complete genomes of various cancer types, is taking the lead on collection and analysis of other brain cancer types in adults. NCI additionally monitors results from other large scale genomics projects, so that results from these projects can be quickly incorporated into ongoing preclinical and clinical research programs. Along these lines, the St. Jude Children's Research Hospital-Washington University Pediatric Cancer Genome Project, a partnership of two NCI-designated cancer centers, published on-line on April 14, 2013 their findings from sequencing 151 PLGAs and low-grade glioneuronal tumors (Zhang, et al. Nature Genetics, 2013). The results confirmed the overwhelming importance of BRAF genomic alterations for pilocytic astrocytomas and identified novel genomic alterations in grade II diffuse PLGAs.

NCI also supports a number of efforts to collect high-quality biospecimens for all cancer types, including pediatric cancers. The Pediatric Cooperative Human Tissue Network (pCHTN) works with investigators to acquire specimens to meet specific research project requirements, with a focus on basic and applied research studies. In addition, NCI supports the COG Biopathology Center, the largest pediatric specimen bank in the country. An example specific to PLGAs and other brain tumors is a COG protocol focusing on collecting and storing blood and brain tumor tissue samples from children with brain tumors treated at COG institutions. The study provides for long-term storage of specimens from these patients and makes these specimens available to qualified researchers to understand the biology of pediatric brain tumors. Pediatric patients treated at COG sites are eligible at time of diagnosis, second-look surgery, recurrence, or the development of a second cancer. This study is open at 160 sites, including more than 100 sites across the U.S., 13 in Canada, and one each in New Zealand and Switzerland.

NIH-Kingston-11. Please describe the process the Institutes and Centers use to systematically coordinate through other HHS agencies to share new scientific information to ensure it reaches the community and providers through the various other HHS outreach programs funded for such activity.

Answer. NIH is dedicated to the pursuit of fundamental scientific knowledge about living systems and the application of that knowledge to improve people's health and reduce the burden of disease. Coordination between NIH and our sister HHS agencies also helps us contribute to the broader mission of HHS which is to protect the health of all Americans and provide essential human services, especially for those who are least able to help themselves.

NIH currently engages in more than 500 formal collaborations across the Department, involving all other HHS agencies. These collaborations can take many forms, including joint research and training initiatives, interagency committees or workgroups; information sharing through databases, registries, and clearinghouses; and joint public education campaigns. The following are examples of recent interagency collaborations.

- A number of NIH Institutes and Centers (IC) are collaborating with the Centers for Medicare & Medicaid Services (CMS) to advance efforts to address problems affecting the elderly. The National Cancer Institute (NCI) and CMS are working to facilitate important research related to the health of senior citizens through NCI's SEER (Surveillance, Epidemiology, and End Results) Program. The SEER-Medicare database allows cancer trends and outcomes among the elderly to be monitored. Collaborations with CMS are also in place with the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) on the U.S. Renal Data System, and with the National Heart, Lung, and Blood Institute (NHLBI) on important research cohorts including the Cardiovascular Health Study, the Atherosclerosis Risk in Communities Study, and the Women's Health Initiative.
- Diabetes is a significant public health concern that is often associated with other health problems. The "Action to Control Cardiovascular Risk in Diabetes Follow-On Study" is a longstanding collaboration between NIH and the Centers for Disease Control and Prevention (CDC). The study is designed to understand the association between type 2 diabetes and cardiovascular disease and to discover ways to prevent heart attack and stroke in patients with diabetes.
- Underage drinking is an issue of epidemic proportion in the United States. Over 70 percent of children say that parents are the leading influence in their decision to drink or not drink, and 40 percent say they have used alcohol by the time they reach eighth grade. NIH is working with the Substance Abuse and Mental Health Services Administration on a campaign for parents to emphasize the importance of talking early and often with children about underage drinking.
- Several NIH ICs have long supported tobacco-related research as part of their missions. Within the framework of the Tobacco Control Act, NIH and FDA have formed an interagency partnership to foster tobacco regulatory research that will inform FDA's authority to regulate the manufacture, marketing, and distribution of tobacco products in order to protect human health. Coordinated by NIH's Office of Disease Prevention within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in partnership with FDA's Center for Tobacco Products, NIH provides the infrastructure for the solicitation, review, and management of tobacco regulatory research.
- The Office of Research on Women's Health (ORWH) in DPCPSI and several NIH ICs disseminate research findings to qualified health clinics supported by the Health Resources and Services Administration (HRSA). For example, ORWH and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) are providing

educational materials to help women, their partners, and their health care providers better understand the problem of vulvodynia, a complex chronic pain disorder.

Additional information on NIH collaborations is available from the NIH HHS Collaborations RePORT website (<http://report.nih.gov/crs/>).

NIH-Kingston-12. NIH has 27 institutes and centers addressing various diseases, and there is invariably some overlap in research in these areas since diseases can have common pathophysiological mechanisms whether genetic, epigenetic or environmental. Is there an effort under way to eliminate redundancy between institutes – such as the functional merger between NIAAA and NIDA which you recently announced – so that budget adjustments will not have a drastic effect on critical research?

Answer. NIH has an established record of identifying scientific areas of shared interest across ICs and developing trans-NIH programs, activities, and policies to optimize the strengths and expertise within each of the Institutes and Centers (ICs) and ensure that their programs and activities are complementary. The Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the Office of the Director works closely with the ICs to plan and coordinate trans-NIH research activities that share commonality. Examples of the Division's coordinating activities are below.

The NIH Common Fund, administered by the DPCPSI Office of Strategic Coordination, supports research to address emerging scientific opportunities, new public health challenges, and knowledge gaps that deserve special emphasis or would otherwise benefit from strategic planning and coordination across the ICs. Strategic planning is used by NIH to identify research areas that are not currently well supported by the ICs and that would benefit from a synergistic effort at the agency level through a limited-term Common Fund investment (see details for the strategic planning process at <http://commonfund.nih.gov/planningactivities/overview-planning.aspx>). The strategic planning process gathers input from all ICs to ensure that Common Fund programs are responsive to trans-NIH needs. The process includes portfolio analysis, workshops, and expert panels meetings to assess the current state of the science and inform the design of Common Fund programs so that each program is designed to avoid redundancy with ongoing efforts and to make a unique and important contribution. For example, the NIH Common Fund, and many NIH ICs, co-fund the program called Knockout Mouse Phenotyping Program 2 (KOMP2). The KOMP2 project involves working with other members of the International Knockout Mouse Phenotyping Consortium to generate approximately 5,000 strains of knockout mice that will undergo a large battery of clinical phenotype tests. A phenotype includes biological information about appearance, behavior, and other measurable physical and biochemical characteristics. Such information will help reveal how all traits are affected by deleting a given gene in an individual mouse. By 2021, 2,500 human genes with unknown function will be characterized in a standardized, comprehensive, statistically valid way. The KOMP2 project has relevance to many NIH Institutes and Centers, and as a trans-NIH activity, is an example of how DPCPSI is working to minimize duplication of effort and increase technological efficiency.

DPCPSI's Office of Portfolio Analysis provides consultation and training to NIH program staff in the use of tools that will allow IC staff to better analyze their scientific portfolio. Better portfolio analysis tools will enhance NIH research administrators and decision-makers' ability to evaluate and prioritize current and emerging areas of research that will advance knowledge and improve human health. Many of these approaches are targeted to identify potential redundancies in research within and between the ICs.

DPCPSI's cross-cutting programmatic offices on women's health, HIV/AIDS, disease prevention, and behavioral and social sciences facilitate and foster the integration of research into the research portfolios of the ICs. The Office of Research on Women's Health (ORWH) works with the ICs to identify unique research opportunities, overlap, and gaps in research as well as to coordinate research activities across all of NIH, including intramural and extramural multidisciplinary activities. The trans-NIH Coordinating Committee on Research on Women's Health (<http://orwh.od.nih.gov/about/ccrwh/index.asp>), which ORWH chairs, is also a forum for coordination and collaboration. The Office of Disease Prevention (ODP) provides a forum for sharing relevant programmatic and scientific information and for planning and implementation of collaborative activities. The Office of AIDS Research (OAR) coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research portfolio and sets the trans-NIH scientific priorities for this large and diverse program. OAR processes identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that funds are invested effectively and efficiently.

In addition to trans-NIH strategic planning and coordination, functional integration, which is currently under way in the area of substance use, abuse and addiction research (SUAA), pool resources and expertise to capitalize on synergies in research, address scientific opportunities, and meet public health needs. The National Institute of Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the National Cancer Institute (NCI) formed a steering committee, the Functional Integration Coordination Committee, to guide efforts to integrate SUAA activities across ICs with SUAA-related research portfolios. Collaborative activities will involve the issuance of joint funding opportunity announcements between the ICs, development of an informational website for the extramural community, and solicitation of input from external stakeholders. In addition, NIAAA and NIDA Advisory Councils will meet jointly once a year. NIDA and NIAAA have taken steps to integrate the SUAA activities within their intramural research program, including by appointing a single clinical director to oversee both research programs.

Administrative processes are also in place to monitor for scientific overlaps in funding opportunity announcements (FOAs) and in grant applications. At the FOA stage, the new Guide Publishing System allows ICs to review funding opportunity announcements prior to publication. When grant applications are received, duplicative proposals can be identified at the receipt and referral stage and at the peer review stage. After review, meritorious applications are checked for other sources of support, including all existing and pending financial resources, whether Federal, non-Federal, commercial or organizational, to determine whether there may be budgetary, scientific, or commitment overlap. This step is key to identifying and eliminating duplicative proposals.

In considering whether to fund a new application, ICs consider many factors, including scientific opportunity, public health relevance, and, importantly, portfolio balance. Applications for projects in scientific areas that are already well studied by NIH are often considered a lower priority than those that are not.

NIH-Kingston-13. In some areas, epidemiological studies and behavioral research seem to have reached a plateau and are not adding new knowledge. Would it not be more effective if available funds were spent on alleviating pain and suffering from diseases than on generating statistical data that is at best marginally useful? And what process is used NIH wide to identify these issues and ensure the limited resources are allocated toward the best research opportunities.

Answer. It is critically important for NIH to maintain a balanced approach in order to carry out its mission. Human diseases have multifactorial causes, and it is essential to understand their dimensions using all of the scientific methods and disciplines available to us. Epidemiological and behavioral research has generated and continues to generate important new findings. For example, epidemiological research identified the most important factors associated with increased life expectancy of Americans during the 20th century – risk factors for heart disease – and set in motion active efforts to modify them. The decline in heart disease began just after the first publications from the NIH-funded Framingham Heart Study.

A variety of recent studies suggest that behavioral factors account for about 40 percent of premature deaths, and social and environmental factors account for an additional 15 percent. Epidemiological studies identify modifiable factors associated with health and disease, suggesting new targets for disease prevention programs which both improve health and reduce health care costs. Behavioral research targets many of these modifiable factors and provides a host of new intervention approaches, both treatment and prevention, that significantly improve health outcomes.

Just one example of the value and effectiveness of behavioral and epidemiological studies are exemplified by improvements in the treatment and prevention of HIV/AIDS. These strategies have shown that early access to medical care improves outcomes and reduces direct medical treatment expenditures. Initiatives to better understand the multiple factors related to adherence, using novel approaches to ensure that patients take their medications and prevention strategies appropriately, are adding to the body of evidence needed to improve outcomes and expenditures. Epidemiologic research on HIV/AIDS in domestic and international settings is critical to monitoring the evolving pandemic, evaluating prevention modalities, characterizing the changing clinical manifestations of HIV disease and related comorbidities, and measuring the effects of treatment regimens at the population level. These studies have delineated significant health disparities that are critical factors in the pandemic. Novel methodologies in the area of biostatistics, mathematical modeling, and laboratory technology provide the basis for new epidemiological approaches in addressing the HIV/AIDS pandemic. Multi-site epidemiologic studies in the U.S. are identifying new HIV-related co-morbidities and helping to differentiate effects related to antiretroviral treatment from those related the disease itself.

Priorities in epidemiological and behavioral research are determined at NIH in the same way as other research priorities, by balancing the research portfolio based on peer review, public health needs, scientific opportunities and the need to be as comprehensive as possible. NIH only funds research that has undergone peer review and is judged as highly meritorious by extramural scientific experts. Public health need, whether an emerging infectious disease or the growing burden of chronic disease management, is assessed through factors such as disease incidence, severity and associated pain and suffering, and cost. In addition, NIH continuously assesses and reassesses our research portfolio in light of emerging scientific opportunities. As the past has shown, significant research advances occur when new findings, often completely unexpected, open up new experimental possibilities and pathways. At the same time, and no matter how pressing the public health need, not all problems are equally ripe from a scientific standpoint for further investigation, nor are findings generated at the same rate across the portfolio. Thus, it is critical to maintain a balance in the research portfolio and support across the continuum of biomedical and behavioral research from the most fundamental sciences to the most applied. A diverse and balanced portfolio within the framework of our mission, including in the balance of basic research to applied, clinical and translational, helps to ensure important opportunities are not missed.

NIH-Kingston-14. Please describe how NIH and NHLBI work across Federal agencies, how it plans, and measures success to disseminate NIH science through appropriate Federal agencies to expand provider and patient knowledge related to new clinical guidelines, procedures, and prevention information.

Answer. The NIH Institutes and Centers (IC) collaborate closely with many federal agencies to facilitate the broad dissemination of research findings generated by NIH-funded investigators. These efforts occur both at the IC level of NIH and at the level of the NIH Office of the Director (OD).

Important examples of an Institute's collaborative efforts across federal agencies in order to disseminate NIH research information can be found in the National Heart, Lung, and Blood Institute (NHLBI). Through its National Asthma Education and Prevention Program (NAEPP), NHLBI is addressing the priority area of asthma identified by the President's Task Force on Environmental Health Risks and Safety Risks to Children. Charged with recommending strategies for protecting children's environmental health and safety, the Task Force was asked to specifically focus on issues that could best be addressed through interagency efforts in order to avoid duplication and to coordinate existing resources for maximum impact. The Task Force's *Coordinated Federal Action Plan to Reduce Racial and Ethnic Asthma Disparities* was launched in May 2012 at an event with HHS Secretary Kathleen Sebelius, EPA Administrator Lisa P. Jackson, HUD Secretary Shaun Donovan, and White House Council on Environmental Quality Chair Nancy Sutley. The goal of the *Action Plan* is to reduce disparities in asthma outcomes, as measured through community-level projects and national statistics. One of its key recommendations is to remove barriers to implementation of NAEPP guidelines, based largely on NIH-sponsored research, for diagnosis and management of asthma. Near-term progress toward that goal is being monitored through the intermediate objectives of implementing the *Action Plan*. The Task Force's Asthma Disparities Working Group (ADWG)—composed of representatives from more than 18 federal organizations and co-chaired by NHLBI, EPA, and

HUD—meets quarterly to identify, coordinate, and implement activities as well as identify specific metrics of success by which to evaluate and track the program’s success. Selected examples of progress toward implementing action items are the following:

- A web-based “Asthma Resource Starter Kit for Early Childhood Care,” directed at parents, providers, and children, was developed in collaboration with the Administration for Children and Families, EPA, and CDC.
- A toolkit for adopting smoke-free policies in multi-unit housing was developed by HUD in partnership with the American Academy of Pediatrics, the American Lung Association, and DHHS.
- The Centers for Medicare and Medicaid Services (CMS) established a technical advisory group composed of ADWG members to provide recipients of Health Care Innovation Awards with technical advice and links to resources to accelerate development of programs that align with *Action Plan* objectives.
- In collaboration with NAEPP and CDC, a draft “Key Clinical Practices” document has been developed to help health benefits managers, health care planners, and other payers make decisions regarding key elements of asthma care. Review of the drafts by representative stakeholders and ADWG members is under way.
- The Department of Energy Weatherization Plus Health program is collaborating with the ADWG to incorporate messages for “asthma-friendly” homes.
- A National Webinar was held on February 4 in conjunction with NAEPP to introduce the broader stakeholder community to the *Action Plan* and invite conversation about how stakeholders can join in its implementation.

Trans-agency coordination is core to the mission of several of program offices within the NIH’s Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), a division within the Office of the Director. The activities of DPCPSI’s Office of Disease Prevention serve as prime examples of how DPCPSI engages in trans-agency activities with the express purpose of disseminating new scientific findings throughout the government and to other pertinent individuals and groups.

In association with the HHS Office of Disease Prevention and Health Promotion and organizations such as the CDC, FDA, SAMHSA, U.S. Department of Education, and the Indian Health Service, NIH continues to contribute to collaborative programs such as the development and implementation of the Healthy People 2020 initiative. Healthy People 2020 is a comprehensive set of research-based disease prevention and health promotion objectives for the Nation. As the NIH liaison to Healthy People 2020, the Office of Disease Prevention works with NIH ICs to provide the scientific basis for the objectives in 17 topic areas used by Federal, state, and local agencies, as well as community-based organizations, community health clinics, individuals, and families to promote healthy development, and healthy behaviors and a high quality of life across all life stages. In addition to coordinating NIH scientific input, the Office of Disease Prevention has worked to ensure Healthy People 2020 information reaches the community level by funding specific components of the initiative. Activities include Data 2020 which allows users to access data related to measuring program objectives, and a new Evidence-Based Resources tool which provides the community with a searchable database of evidence-based resources that can be used to achieve Healthy People 2020 objectives.

DPCPSI's Office of Disease Prevention also works closely with colleagues at the HHS' Agency for Healthcare Research and Quality (AHRQ) to provide scientific input on draft evidence reviews and clinical practice guidelines to be included in the *Guide to Clinical Preventive Services*. The *Guide* is informed by the U.S. Preventive Services Task Force (USPSTF), an independent panel of non-Federal experts in prevention and evidence-based medicine supported by AHRQ and composed of primary care providers. The USPSTF conducts scientific evidence reviews of a broad range of clinical preventive health care services such as screening, counseling, and preventive medications and develops recommendations for primary care clinicians and health systems that are included in the *Guide*. The Office of Disease Prevention also disseminates information to NIH Institutes and Centers about high-priority evidence gaps for clinical preventive services that have been identified by the USPSTF that may benefit from additional investigation.

These examples above are in addition to other multi-pronged approaches used by the Office of Disease Prevention and more widely at NIH to ensure the efficient and effective dissemination and implementation of research findings to clinical and community practice. In addition, through funding opportunity announcements, NIH supports studies that evaluate the effectiveness of implementation strategies for biomedical and behavioral interventions (e.g., NIH Program Announcements on Dissemination and Implementation Research in Health, NHLBI Dissemination and Demonstration Grants, Common Fund's Health Care Systems Collaboratory). NIH also supports research and practice platforms (e.g., Cancer Research Network, Cardiovascular Research Network, Mental Health Research Network, and NIH/HRSA Collaboratives) to conduct pragmatic clinical trials to improve the application of effective guidelines, procedures, and preventive interventions. Scientific meetings with other agencies are also held to connect researchers, practitioners, and patients (e.g., NIH/VA Meetings on the Science of Dissemination and Implementation, Maternal Child Health Epidemiology annual conference, etc.).

NIH has employed many strategies for assessing its success in ensuring that the evidence-base resulting from research influences practice. Multiple Institutes and Centers have undertaken formal program evaluations to ascertain success of specific initiatives. In addition, progress toward the attainment of goals under the Government Performance and Results Act is tracked on a yearly basis. Many of these goals are relevant to the dissemination and implementation of evidence-based practices.

NIH-Kingston-15. Please explain how CDC and NHLBI are jointly developing and implementing the plan to address Chronic Obstructive Pulmonary Disease?

Answer. The key elements of the nation's public health program to control chronic obstructive pulmonary disease (COPD)—surveillance, biological/clinical research, and education/health promotion—span the missions of NHLBI and CDC, and the two organizations have been very successful in coordinating their relevant activities. Crucial surveillance data that identified COPD as a modern epidemic came from cooperation between the CDC, which carries out the National Health and Nutrition Examination Survey (NHANES), and NHLBI, which funded measurements of spirometry in that survey. Mortality data collected by the CDC have

documented a continued rise in COPD deaths, especially among women, such that COPD now ranks as the third most common cause of death in this country. Recently the CDC and NHLBI cooperated to obtain the first detailed surveillance data on COPD prevalence. With NHLBI funding, the CDC added five COPD-related questions to its Behavioral Risk Factor Surveillance System (BRFSS), which is administered in all 50 states, the District of Columbia, and U.S. territories. The data can be used to identify emerging health problems, establish and track health objectives, and develop public health priorities and education programs. Data from annual BRFSS interviews of nearly a half million individuals will also allow, for the first time, assessment of COPD prevalence in Native American and Asian American populations.

NHLBI is coordinating efforts with the CDC and more than 70 partners in 47 states to increase awareness of COPD among at-risk individuals and encourage them to seek appropriate health care. Ongoing analysis indicates that awareness is improving. The CDC is an active partner in the NHLBI *Learn More Breathe Better (LMBB)* COPD awareness campaign. Following a 2009 NHLBI-sponsored workshop of stakeholders active in COPD education, the CDC moved to promote *LMBB* via its existing communication channels, develop strategies to disseminate the results of the BRFSS among campaign partners, offer NHLBI the opportunity to co-brand CDC COPD-related educational materials with the NHLBI campaign logo, use *LMBB* campaign materials to educate CDC constituencies, and seek NHLBI experts to speak at conferences.

To expand collaboration among COPD programs of federal agencies, NHLBI plans to host a forum on COPD in May 2013 that will include the Surgeon General and representatives from AHRQ, FDA, CDC, CMS, VA, EPA, NOAA, HRSA, ASPE, ACL, NSF, OASH, OSD, and various NIH components. Attendees will discuss the current involvement of federal agencies in activities related to COPD, the scope and breadth of existing programs, the opportunities for increased cooperation and enhanced effectiveness of the federal response to COPD, and the possibility of developing a national action plan for COPD. NHLBI anticipates that improved communication among federal agencies may ultimately lead to broader interactions involving all COPD stakeholders and more effective approaches to address COPD nationwide.

NIH-Kingston-16. Please explain how NIH works with appropriate HHS agencies to ensure it the new knowledge reaches the community and providers through the various other HHS outreach on the Diabetes Prevention Program.

Answer. The statutory Diabetes Mellitus Interagency Coordinating Committee (DMICC, www.diabetescommittee.gov), chaired by the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), includes all agencies within the Department of Health and Human Services (HHS)—as well as other federal agencies—that support diabetes-related activities. Through its legislative mandate, the DMICC helps member agencies identify emerging issues and opportunities and develop ways in which government components can work together and build upon each other's expertise and resources. This approach helps ensure that federal diabetes activities are coordinated, and collaborative where appropriate.

As a result of such exchanges of information and expertise, the Centers for Disease Control and Prevention (CDC) built on NIH-led efforts—the Diabetes Prevention Program (DPP) and DPP translational research—to create the National DPP

(www.cdc.gov/diabetes/prevention/about.htm), based on work from an NIDDK-supported DPP translational research project. NDPP has four primary components: 1) training, to increase the workforce of people qualified to deliver a group-based lifestyle intervention based on the DPP; 2) a recognition program to ensure intervention quality, hopefully leading to reimbursement by more insurers; 3) increasing intervention sites, to make the program more widely available; and 4) health marketing, to support program uptake.

Other DMICC member agencies that have responded in key ways to DPP findings include:

- the Indian Health Service, which has utilized funds from the *Special Diabetes Program for Indians* to implement DPP-based lifestyle change programs in 38 communities (<http://www.ihs.gov/MedicalPrograms/Diabetes/?module=programsSDPI>);
- the Agency for Healthcare Research and Quality's (AHRQ) U.S. Preventive Services Task Force, which cited DPP results in issuing its recommendations on obesity screening and treatment (<http://www.uspreventiveservicestaskforce.org/uspstf/uspsobes.htm>);
- the Department of Veterans Affairs (VA), which issued guidelines on diabetes that incorporate findings from the DPP into guidelines on diabetes prevention (http://www.healthquality.va.gov/diabetes_mellitus.asp); and
- the Centers for Medicare & Medicaid Services (CMS), which awarded a Health Care Innovation Award to the YMCA to pilot diabetes-prevention services for 10,000 Medicare beneficiaries with prediabetes in 17 communities.

Another critical way in which HHS agencies partner to deliver the life-saving message of the DPP is through the National Diabetes Education Program (NDEP, <http://ndep.nih.gov/>). Co-led by NIH and CDC, and with more than 200 partners at the federal, state, and local levels, NDEP works to improve treatment and outcomes for people with diabetes, promote early diagnosis, and prevent or delay the onset of type 2 diabetes. One of the primary campaigns of NDEP is "*Small Steps. Big Rewards. Prevent type 2 Diabetes.*" (<http://ndep.nih.gov/partners-community-organization/campaigns/SmallStepsBigRewards.aspx>), which seeks to disseminate information from the DPP to people at risk for diabetes, with a special focus on groups at greatest risk, including African Americans, Hispanic and Latino Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, women with a history of gestational diabetes, and older adults. In addition, NDEP and its partners are promoting diabetes prevention to health care professionals, to give them the information and tools to help their patients take small steps to prevent or delay the disease.

NIH-Kingston-17. Please provide an update on the state of the science for Kennedy's Disease.

Answer. Basic research has driven encouraging progress in understanding Kennedy's disease (also known as spinal bulbar muscular atrophy, or SBMA) and in moving toward rational strategies for developing treatments. The discovery of the genetic error that causes SBMA implicated a defect in the androgen receptor, a protein that enables cells to respond to testosterone-related hormones. Since the discovery of the gene defect, there has been considerable progress in understanding step by step how the mutant protein is toxic to nerve cells and muscle, resulting in the progressively disabling, and even fatal, muscle weakness of the disease. Randomized, placebo-controlled clinical trials of candidate therapies have not yet found

a significant benefit in slowing SBMA. However, trials, including those at the NIH Clinical Center, provide information on the disease course and on outcome tests that will be useful in designing future clinical trials.

NIH continues to support basic, translational, and clinical research related to SBMA through both extramural and intramural research programs. At the most basic end of the research spectrum are studies to understand how testosterone-related hormones affect the development and function of the nervous system. More directly focused on SBMA, several extramural grants are developing better animal and cell models of SBMA, investigating specific molecular steps by which the gene defects in SBMA lead to the disease, and testing whether these steps present targets for intervention to halt the disease. Several strategies for intervention have shown promise in animal models. Complementing the extramural program, the National Institute of Neurological Disorders and Stroke (NINDS) Intramural Research Program continues to be a leader in SBMA research. In addition to continuing laboratory studies on the mechanisms of SBMA, intramural researchers are conducting a clinical trial to test whether an exercise program can improve strength, function, or quality of life in people with SBMA. Biotech and pharmaceutical companies are now building on progress from NIH-funded research to develop safe and effective treatments for SBMA. As therapies reach readiness for clinical testing from public or private research, NINDS is prepared to conduct clinical trials through NeuroNext, a new NINDS clinical network at 25 sites throughout the U.S. designed to expedite early phase clinical testing of novel therapies.

As research on neurological diseases advances, the relationships among diseases are becoming increasingly apparent, and research not focused on SBMA may also hold keys to progress against this disease. SBMA was the first disease found with a type of gene defect called a triplet repeat expansion, that is, an abnormal repetition of a three letter sequence of the gene code. At least nine diseases are now known to share the same repeat in different genes, and other triple repeat mutations cause at least 15 other diseases. More broadly, the gene defect in SBMA causes certain proteins to aggregate in an abnormal way, which contributes to the disease progress. Abnormal protein aggregation is similarly implicated in Alzheimer's, Parkinson's, Huntington's, ALS, and several other neurological disorders, both common and rare. These and other similarities among diseases illustrate how research on a single neurological disorder both informs and is informed by research on others. Similarly, research in cross-cutting areas, including gene therapy, stem cells, and natural nerve cell survival factors, may drive progress against SBMA and many other diseases.

NIH-Kingston-18. Please provide an update on NINDS new stroke planning efforts from 2012.

Answer. In 2012, the National Institute of Neurological Disorders and Stroke (NINDS) completed a new stroke research planning effort designed to identify a small set of high-priority research opportunities to guide the stroke research agenda over the next five to 10 years. Ideas for high-priority research topics were sought from the broad public and stroke research community through an online Request for Information (RFI) on Stroke Research Priorities. The NINDS Advisory Council oversaw the formation of three working groups consisting of scientific experts in stroke prevention, treatment, and recovery, and using a process similar to the Delphi

method, the workgroup members reviewed and prioritized the responses to the RFI. Through extensive deliberations and moderated discussions at the Stroke Research Priorities Meeting on August 29 and 30, 2012, the three working groups defined a total of nine high-priority research topics representing major opportunities for advancing stroke science over the next decade. The final priority research areas and recommendations can be found on NINDS website: www.ninds.nih.gov/strokepriorities.

One of the major challenges cited by the community, and identified as a priority by all three working groups, was the need for national infrastructure to conduct clinical trials in stroke. In response, NINDS has taken steps to establish a coordinated network that will conduct stroke trials in prevention, treatment, and recovery. The new network will improve the impact of NINDS investments in stroke clinical trials by fostering improved efficiency, prioritization of research questions, and greater scientific collaboration. NINDS will fund approximately 25 Regional Coordinating Centers and one National Coordinating Center in FY 2013, and one Data Management Center in fiscal year 2014. This initiative builds on the successes of the Specialized Programs of Translational Research in Acute Stroke (SPOTRIAS) consortium and will be coordinated with other NINDS networks, specifically the Neurological Emergencies Treatment Trials (NETT) network and the Network of Excellence in Neuroscience Clinical Trials (NeuroNEXT).

Another high-priority area, identified through the planning effort, was the prevention of vascular cognitive impairment. Recommendations highlighted in the final report have directly informed the development of the vascular cognitive impairment session at the upcoming meeting, Alzheimer's Disease-Related Dementias: Research Challenges and Opportunities, which will be held at NIH on May 1 and 2, 2013.

NINDS will continue to develop strategies and approaches for addressing the recommendations identified through the stroke planning effort, and is enthusiastic about the opportunity to improve the impact of its investments in stroke research.

NIH-Kingston-19. Please describe what NIAID and NIH is supporting in the field of Antibiotic Resistance Research to improve the efficiency and speed of its preclinical services and other resources, including genomic-related services, for both the investigator community and companies that are on a product development timetable. In addition, please provide a NIAID developed plan to recruit new investigators into antibacterial resistance research.

Answer. Preclinical research remains a critical part of the product development pipeline that bridges the gap between basic scientific discovery and clinical evaluation, and provides critical proof-of-concept data to help assess product viability. As part of its efforts to address the growing problem of antimicrobial resistance (AR), the National Institute of Allergy and Infectious Diseases (NIAID), provides free-of-charge, a broad array of preclinical resources to researchers in academia and industry. NIAID preclinical services are intended to help lower the financial risks to investigators and companies involved in early product development. These services include *in vitro* and animal model screening tools; therapeutic and vaccine development services; cutting edge technologies such as genome sequencing, proteomics, and bioinformatics;

and product development planning. Step-wise product development planning, which is complex and takes time to implement, ensures all necessary data are secured to meet the requirements for regulatory approval.

NIAID also has launched a variety of funding opportunities to advance AR research, and currently supports a robust portfolio focused on identifying how microbes develop resistance; designing faster and more accurate diagnostics to identify sensitive and resistant strains; developing new drugs that use novel approaches to circumvent resistance mechanisms; and repurposing certain older drugs that are regaining effectiveness. Selected ongoing research activities include:

- Discovering and exploiting novel targets for vaccines, diagnostics, and therapeutics.
- Diversifying the types of therapeutic candidate products in development, including novel members of existing classes of drugs with improved resistance profiles; novel classes of drugs; and novel therapeutic approaches such as monoclonal antibodies, host-targeted drugs, efflux pump inhibitors, biofilm inhibitors, and beta-lactamase inhibitors.
- Conducting clinical trials aimed at identifying ways to reduce the use of licensed antibacterials in the areas of greatest antimicrobial drug use. Strategies to reduce selective pressure include shorter treatment courses; combination therapies; the use of diagnostics to better target therapy; and the use of alternative, non-antibiotic treatment strategies.
- Conducting research on vaccines for resistant bacterial pathogens such as MRSA.
- Facilitating the development of novel diagnostic technologies, including multiplexed, point-of-care, and integrated sample-to-answer technologies, to rapidly provide information to healthcare providers on the best choice of drug to treat infections while minimizing the emergence of resistance.

This year, NIAID will launch a major new AR effort, the Leadership Group for a Clinical Research Network on Antibacterial Resistance (ARLG), modeled after the established NIAID AIDS Clinical Trials Group. The ARLG will develop a research agenda identifying the most important clinical questions in antibacterial resistance, with input from the global AR research community. Studies conducted by the ARLG may include clinical testing of new drugs to treat multi-drug resistant Gram-negative bacteria, evaluating diagnostic devices in clinical settings, evaluating the effectiveness of new antimicrobial stewardship programs, and optimizing treatment regimens to reduce the emergence of resistance. These priority clinical questions will be addressed using existing NIAID clinical trials infrastructure. In addition, this new program will provide training and mentoring for network staff, which could help recruit new investigators into the AR research arena.

The NIAID intramural research program (IRP) has extensive partnerships with researchers from both the public and private sectors that utilize the IRP's special resources to advance AR research and new antimicrobial drug development. The NIAID IRP actively seeks opportunities to partner with pharmaceutical companies, academia, and the non-profit sector to leverage NIAID's resources and encourage development of discoveries and inventions arising from collaborative IRP research. Through NIAID's programs at the NIH Clinical Center in Bethesda, MD, and international research collaborations, NIAID is training new investigators to conduct AR research and building research capacity to study and combat AR.

In addition, NIAID continues its efforts to fund new investigators interested in all areas of research that fall within the NIAID mission, including research on AR. To meet this goal, NIAID has created special programs and funding approaches for new extramural investigators described in the "NIAID New Investigator Guide to NIH Funding" on the NIAID website.

NIH-Kingston-20. On Institutional Development Awards (IDeA), please provide a list of the Institutes and Centers (ICs) with the amount each IC co-funded in FY 2012 to IDeA. Please explain how the ICs are working to expand co-funding opportunities with the IDeA program.

Answer. The National Institute of General Medical Sciences (NIGMS) works with the other Institutes and Centers (IC) to fund meritorious research grant applications across the ICs from institutions within IDeA-eligible states. The ICs nominate, for co-funding, applications that are just beyond their payroll.

The attached table provides a list of the 17 ICs that co-funded 22 Research Project Grants (RPG) with the IDeA program in FY 2012. The IDeA program will co-fund the second year of these awards in FY 2013.

In addition, new awards will be co-funded during FY 2013. NIGMS is in the process of receiving nominations for new awards from the other ICs. We expect to expand co-funding opportunities this year by awarding slightly more RPGs than in FY 2012, should funds allow. NIGMS anticipates that this will be an ongoing activity for the IDeA program in future years.

Research Project Grants Awarded by IDeA Co-funding in FY 2012				
(Dollars in thousands)				
NIH Institute or Center (IC)	Number of Awards	NIGMS IDeA Support	Other IC Support	Total Awarded
National Institute of Alcohol Abuse and Alcoholism (NIAAA)	1	\$ 260	\$ 191	\$ 451
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)	1	255	21	276
Fogarty International Center (FIC)	1	260	107	367
National Cancer Institute (NCI)	1	232	77	309
National Center for Complementary and Alternative Medicine (NCCAM)	1	260	324	584
National Institute of Allergy and Infectious Diseases (NIAID)	1	215	75	290
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	1	260	144	404
National Institute of Biomedical Imaging and Bioengineering (NIBIB)	1	260	0	260
National Institute of Dental and Craniofacial Research (NIDCR)	1	201	67	268
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	2	503	101	604
National Institute of Environmental Health Sciences (NIEHS)	1	260	191	451
National Institute of General Medical Sciences (NIGMS)	3	780	238	1,018
National Institute of Mental Health (NIMH)	2	520	742	1,262
National Institute of Neurological Disorders and Stroke (NINDS)	1	260	70	330
National Institute on Aging (NIA)	1	259	22	281
National Institute on Deafness and Other Communication Disorders (NIDCD)	1	260	109	369
National Library of Medicine (NLM)	2	520	0	520
	22	5,565	2,479	8,044

NIH-Kingston-21 Please provide an update on Osteogenesis Imperfecta activity supported by NIH in 2012.

Answer. NIH supports and manages a broad research portfolio that is relevant to osteogenesis imperfecta (OI). Many of the OI studies at universities and medical centers across the nation are

funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). NIAMS leads the Federal Working Group on Bone Diseases, which offers a forum for federal agencies and others who are interested in bone research—including emerging research opportunities related to rare bone diseases such as OI—to exchange information and coordinate their efforts.

New NIAMS fiscal year (FY) 2012 projects included preclinical studies of potential OI treatments. In one project, researchers will compare an experimental bone-building molecule and a bone preserving drug that has been approved for women who have osteoporosis; they will test the two compounds individually, and in different combinations, in a range of ages, and disease stages. Another project will assess whether transplanted bone cells or marrow from healthy donors can improve the bone quality of OI patients. These and other new grants complement NIAMS' existing basic and translational research portfolio, which includes an ongoing effort to correct the underlying, causative genetic defects.

As part of NIAMS' efforts to raise awareness about OI clinical research needs, NIAMS included OI in a FY 2012 initiative to encourage small businesses to conduct research that could lead to biomarkers or therapies for rare diseases.

In 2012, NIAMS partnered with the National Institute on Deafness and Other Communication Disorders (NIDCD) and the National Center for Advancing Translational Sciences (NCATS) to provide grant support for an Osteogenesis Imperfecta Foundation conference titled "Assessing the Impact of Osteogenesis Imperfecta on Non-Skeletal Systems" (<http://rarediseases.info.nih.gov/news-and-events/conferences/1144>). The meeting brought together leading OI researchers and clinicians, as well as adults living with the disease, to review current knowledge about the impact of OI as patients age, and to identify major information needs. The conference organizers will share insights gained through the OI Foundation website (<http://www.oif.org/>), the OI Foundation newsletter, and the submission of a workshop report to a peer-reviewed journal.

NIAMS is using additional strategies to work with stakeholders to encourage research that will improve the lives of people who have OI. For example, the Chief Executive Officer of the OI Foundation participated in a recent NIAMS roundtable (http://www.niams.nih.gov/News_and_Events/Meetings_and_Events/Roundtables/default.asp) to discuss strategies for building or regenerating bone, muscle, and connective tissue following disease or injury. Another member of the OI community joined the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council in 2012.

Like NIAMS, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) supports a range of basic, translational, and clinical research on OI. In response to a funding opportunity announcement soliciting research on the causes of birth defects, NICHD recently funded a grant studying how OI develops, testing the theory that mutations that produce OI may result from a convergence of cell defects. Scientists working in the NICHD intramural program are examining mouse models of OI to better understand the mechanisms of the disease, and to identify new genes that cause recessive forms of OI. This research focuses on clinical studies for pediatric patients, including an ongoing study on the

pulmonary, cardiac, auditory, and neurological complications of OI. Recently published data from this research demonstrated the decline of pulmonary function and early onset of cardiac valve problems in children with OI; the study will serve as the basis for the development of early interventions to prevent or delay these complications.

Other NIH activities related to OI include ongoing support of graduate and post-doctoral trainees researching the disease's underlying molecular causes. Two National Institute of Dental and Craniofacial Research (NIDCR) trainees, who developed mouse models reflecting different genetic mutations that give rise to recessive forms of OI, are investigating the resulting bone and cartilage defects. The work is expected to provide insights into the physiological role of these key signaling pathways required in skeletal development, an understanding of how these mutations lead to OI, and a foundation for these junior investigators to pursue independent careers in OI research or related fields.

NIH-Kingston-22. I concerned about prescription drug abuse, specifically the misuse of orally administered opioid drugs. And understand opioid narcotics are frequently abused through injection, inhalation, crushing, or oral overdose to create a highly addictive euphoria. According to some, more than 35 million Americans have abused prescription opioids at some point in their lifetimes. In addition, the June 2011 Institute of Medicine report on relieving pain indicates that such abuse and misuse resulted in an annual estimated cost to the nation of \$72.5 billion. I expect NIDA to support meritorious scientific activities that provide companies with the basic science to develop and implement innovative strategies to reduce opioid drug abuse. Such strategies may include new chemical molecule structures, coatings, agents, or other appropriate scientifically sound processes with a goal of providing insurmountable barriers for almost all abusers while still providing the required pain relief required for appropriate patient care. Please provide an update on the activities related to addressing the opioid drug abuse problem.

Answer. Commonly prescribed for treating severe pain, opioid pain medications are beneficial when used appropriately. But because they act on the same receptors as heroin, they are, as you note, also prone to abuse, with potentially dire consequences: CDC reports that, since 1999, unintentional overdose deaths involving prescription opioid pain relievers have more than quadrupled in the United States.⁴

The National Institute on Drug Abuse (NIDA) takes a multipronged approach to this public health crisis. It includes supporting research to identify new analgesic compounds, targets, and drug combinations with reduced abuse potential and educating prescribers about appropriate pain management. For example, NIDA is supporting several concepts for mitigating the likelihood of abuse or diversion of opioid medications, including the following:

- **Use of pro-drug technology for opioid medications.** This technology would allow the medication to become active only when cleaved by specific enzymes in the digestive system. Because the pro-drug is essentially inactive in blood and does not readily cross the blood-brain barrier, diversion and abuse via non-oral routes (e.g., injection or inhalation) would be prevented. At least one small biotechnology company has shown interest and made progress

⁴ Centers for Disease Control and Prevention, National Center for Health Statistics. *Multiple Cause of Death 1999-2010 on CDC WONDER Online Database, released 2012.*

in using this technology, thereby positioning NIDA/NIH to partner with industry in supporting the needed clinical studies.

- **Development of pain medications that act on non-opioid receptors.** Cannabinoid receptors represent one such alternative. Animal research suggests that these receptors, located both in the brain and throughout the body, affect nerve cells' responses to pain. By targeting peripheral cannabinoid receptors (i.e., those outside the brain), researchers may be able to develop non-addictive pain medications. Similarly, drugs that target the toll-like receptor 4 (TLR-4)—a type of immune detector located on non-neuronal cells called glia—have been shown to be involved in opioids' rewarding effects and to cause the loss of opioids' pain-relieving capacity with repeated use (i.e., tolerance). Medications that block TLR-4 could both reverse opioid tolerance (and the accompanying need for higher doses) and negate rewarding effects.

Clinicians are a key target for NIDA's outreach efforts. Educating prescribers about pain management is another primary focus—to help ensure that patients get the help they need while reducing their risk of addiction and other negative side effects—as the following initiatives illustrate:

- **Online courses to educate prescribers.** In October 2012, the Office of National Drug Control Policy (ONDCP) and NIDA launched two online continuing medical education courses, which include videos that model appropriate doctor-patient interactions around (1) safe prescribing for pain, and (2) managing patients who abuse prescription opioids. This initiative is in partnership with Medscape, a free web resource for physicians and other health professionals. Since the October 2012 launch, more than 40,000 physicians, registered nurses, and other clinicians have completed these courses.
- **Centers of Excellence in Pain Education (CoEPE).** NIDA is leading this effort, which involves nine NIH Institutes and Centers and the Office of the Director, to support the creation of pain management curriculum resources for medical, dental, nursing, and pharmacy schools. In May 2012, 12 CoEPEs were awarded to develop materials to help advance the assessment, diagnosis, and safe treatment of pain, and will include a focus on minimizing risks of addiction to and diversion of opioid pain medications.

Given the scope of prescription opioid abuse, it is important that the development of alternative analgesics quickly be translated into real-world use, while we continue to educate physicians on smart prescribing practices. Finally, NIDA participates in the HHS Behavioral Health Care Committee (BHCC), co-chairing the Pharmaceutical Abuse Subcommittee, which collaborates across agencies to devise holistic strategies for addressing prescription drug abuse.

NIH-Kingston-23. In FY 2012 we made clear that NCATS should not make any changes to the Clinical and Translational Science Awards (CTSAs) from how the program existed at the start of fiscal year 2012 until IOM completes its independent evaluation of the CTSA program. Please explain if any changes have been made in advance and explain how this complies with Congressional intent.

Answer. The language in the Conference Report for the Consolidated Appropriations Act, 2012, stated that “the conferees urge NIH to support a study by the IOM that would evaluate the CTSA program and recommend whether changes to the current mission are needed.” In response, the

National Center for Advancing Translational Sciences (NCATS) contracted with IOM to conduct such a study, and the final report is due from IOM on June 21, 2013.

NCATS released a Funding Opportunity Announcement (FOA) for Institutional Clinical and Translational Science Awards (CTSA) in July 2012, to ensure continued support for the full spectrum of translational research as required in the 2012 conference report. The FOA maintains the CTSA program by providing academic homes for clinical and translational research, training programs to ensure the robust workforce necessary for translational research, and access to resources and services for investigators. The FOA encouraged applicants to feature their areas of strength while still supporting the full spectrum of translational research. The determination of the requested budget was founded on the participating institutions' base of NIH supported research rather than a formula based on selected grants that applicant institutions held prior to the CTSA program's introduction. The FOA provided a mechanism for continuation of the CTSA program by allowing institutions with CTSA grants ending in FY 2013 and institutions without CTSA grants to apply for the program.

Funding decisions for these applications will be made after the IOM report is completed.

NIH-Kingston-24. NCATS expects to engage with the private sector partnerships to foster use of existing business models, tools, or processes aimed at accelerated drug or device development which have already demonstrated significant efficiencies in cost savings and the shortening of time from compound to commercialization in the development of therapeutics. Concerns have been identified that NCATS policies may overreach on its relationship in its agreements intellectual property rights in its agreements. We expect NIH to promulgate regulations or guidance related to the structure, process, and reach of the extent, reach, and impact its agreements, to include Cooperative Research Development Agreements and public private partnerships and collaborations, on intellectual property rights and licensing activity. Please provide an update on the timing to publish notice and comment rule making or guidance that in addition to the above items. Plus, includes an explanation on the other additional mechanisms and policies NCATS expects to establish to ensure private sector partners maintain the appropriate level of intellectual property rights.

Answer. The National Center for Advancing Translational Sciences (NCATS) applies all current Federal laws and NIH policies for intellectual property (IP), including IP ownership and licensing terms, in all of its public private partnership and collaboration agreements. Examples of types of NCATS agreements with industry and other non-profits are Cooperative Research and Development Agreements (CRADA), Material Transfer Agreements, and Research Collaboration Agreements. NCATS, like other NIH Institutes and Centers, does not have responsibility for any licensing activities. This responsibility is performed centrally by the NIH Office of Technology Transfer. To date, NCATS has not promulgated any new regulations or guidance related to the structure, process, or any IP terms for its CRADAs and public private partnerships and collaborations. However, NCATS published a Federal Register Notice on May 15, 2013, which enumerates, and seeks comments on, the methods that NCATS is using to ensure that the public, including private industry, is both aware of and able to provide input on its activities and planned initiatives.

NIH-Kingston-25. NCATS is more of engineering or process focused center as compared to other NIH entities. I expect NIH will include detailed goals and performance measures in the future budget request, starting in fiscal year 2014, for each program, project, or activity undertaken through NCATS.

Answer. The FY 2014 budget request will include a description of the goals for the programs undertaken by NCATS. Specific goals and performance measures for each program have been developed and are available.

The development of performance measures has also been part of the ongoing discussions with the NCATS Advisory Council and CAN Review Board. As requested in the FY 2012 Statement of Managers, the CAN Review Board has been tasked to “create general principles and measurable outcomes to track success” of CAN. A working group of the CAN Review Board has been formed and is expected to provide a set of recommendations in the near future.

NIH-Kingston-26. Please provide an update on the research efforts supported related to amyloidosis.

Answer. Amyloidosis is a group of disorders that have in common the presence of insoluble protein deposits in tissues and may affect the heart, kidneys, liver, spleen, nervous system, stomach and/or intestines. Treatments vary; they include anti-inflammatory treatment, dialysis, chemotherapy followed by stem cell replacement to reduce the levels of monoclonal immunoglobulin, and organ transplantation (particularly liver or kidneys). Several NIH Institutes and Centers are conducting research on amyloidosis or on diseases in which amyloidosis presents.

The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) is supporting research on hereditary transthyretin amyloidosis and has supported research which led to the development of the first animal model of Amyloid Light-chain (AL) amyloidosis, which has enabled researchers to identify doxycycline as a potentially effective new treatment for systemic amyloid disorders.

The National Cancer Institute’s (NCI) manufacturing unit, the Biopharmaceutical Development Program of the Frederick National Laboratory for Cancer Research, recently completed the manufacture, testing, and release of a clinical-grade monoclonal antibody, Ch11-IF4, for use by researchers in a therapeutic trial in AL Amyloidosis patients. NCI is proactively working with the researchers and the FDA to activate the Investigational New Drug (IND) application to allow the trial to begin, including the completion of certain animal safety studies and product stability testing. The researcher is applying to the FDA Orphan Drug grant program for funding for the clinical trial. This trial will be an extension of the previous FDA Orphan Drug grant-supported imaging study that also used antibody material manufactured by the NCI program.

National Institute of Environmental Health Sciences (NIEHS)-supported researchers are working to determine how Alzheimer’s disease (AD) may relate to brain amyloidosis. This research will

examine environmental exposures to arsenic and a high fat diet that may influence or coincide with pathological features of AD. The result from this study will help to understand the interplay between important genes and proteins involved in cholesterol transport in brain, and how the knowledge about disturbed function of those proteins can help in developing new therapeutic strategies for slowing AD progression.

National Institute of Deafness and Other Communication Disorders (NIDCD) researchers, in collaboration with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), are evaluating the hearing of individuals with Muckle-Wells syndrome, which is characterized by periodic episodes of skin rash, fever, and joint pain. Abnormal deposits of the amyloid protein cause progressive kidney damage in about one-third of people with Muckle-Wells syndrome; these deposits may also damage other organs.

NIH-Kingston-27. Please provide an update on the five year trans-NIH Basic Behavioral and Social Science Opportunity Network (OppNet) in fiscal year 2011 with support from 24 ICs. Please highlight the annual IC specific funding level and collective activity supported for each year and how the effort is being measured for success.

Answer. In FY 2011, OppNet expended \$11,887,317 for 48 extramural research grants on topics such as impulse control and managing health behaviors; factors affecting sleep; measurement of stress; maintaining healthy behaviors over time; and creating interdisciplinary teams to study basic behavioral and social science research. Additional grants provided mentoring opportunities in basic behavioral research for mid-career and senior investigators, and training opportunities for new investigators. The complete list of these grants with additional links to their descriptions can be found at <http://www.oppnet.nih.gov/resources-2011fundedapp.asp>.

Table 1 shows OppNet funding as displayed in the Congressional Justification for the President's Budget. Contributions to OppNet and the choice of NIH Institutes and Centers to manage OppNet grants are based on the closest match of scientific mission to each project grant.

**Table 1: NIH FY 2014 OppNet Funding
(Dollars in thousands)**

IC	FY 2012	FY 2013 CR	FY 2014 ¹
NCI	3,492	3,456	3,442
NHLBI	2,120	2,098	2,081
NIDCR	283	280	276
NIDDK	1,237	1,224	1,217
NINDS	1,120	1,108	1,103
NIAID	3,092	3,060	3,075
NIGMS	1,673	1,656	1,612
NICHD	910	900	899
NEI	484	479	470
NIEHS	472	467	464
NIA	760	752	801
NIAMS	369	365	363
NIDCD	287	284	284
NIMH	1,019	1,009	984
NIDA	725	718	720
NIAAA	316	313	312
NINR	100	99	98
NHGRI	353	349	347
NIBIB	233	231	228
NIMHD	190	188	190
NCCAM	88	87	87
NCATS	396	392	447
FIC	48	47	49
NLM	232	230	257
OD-ORIP/SEPA ²	0	207	193
OD-OTHER	0	0	0
B&F	0	0	0
TOTAL	20,000	20,000	20,000

¹T1D, SF, OD-Other, and B&F are excluded from OppNet funding Calculations.

²Includes only ORIP and not SEPA in FY 2014 due to proposed government-wide Science, Technology, Engineering, and Mathematics education reorganization plan.

NIH-Kingston-28. The FY 2013 NIH budget request made a number of policy assertions that if the FY 2013 budget was passed as proposed would have been implemented, such as an additional level of scrutiny on extramural investigators, who have previously undergone peer review and were found to have high quality meritorious scientific projects, is based on concerns that these researchers may not be effectively able to manage this high dollar level of program activity and that funds might be better redistributed to other activities. This proposed policy causes serious reservations with an additional scrutiny policy focused only on extramural researchers as it could undermine the value of NIH's

peer review process, impose an effective “cap” based on no apparent data, and limit the current open competitive process. The proposed policy would have had a significant lack of consistency as it appears to discriminate against extramural researchers as it creates a special class for NIH intramural researchers, who are not limited to the \$1.5 million level. I understand NIH had over 540 intramural researchers with over \$1.5 million projects in fiscal year 2011. In addition, in fiscal year 2011, several institute directors, scientific directors, and the NIH director who all have significant other responsibilities, had intramural programs funded at over \$4 million. It does not seem reasonable to the NIH intramural researchers as a class are any more unique at their ability to manage large science projects than extramural researchers. Fortunately, since we are under a continuing resolution and likely will be for the fiscal year 2013, the budget policies proposed were not approved by Congress and are not being implemented. Please address the following related to this issues:

NIH-Kingston-28a. Please validate that no such proposed budget policies are being implemented in fiscal year 2013, specifically the additional scrutiny policy?

Answer. During May 2012, NIH Institutes and Centers (IC) Advisory Council meetings piloted the Special Council Review (SCR) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-110.html>) procedures to provide additional review of grant and cooperative agreement applications from Program Directors (PD)/and Principal Investigators (PI) who receive \$1.5 million per year in total costs to determine if additional funds should be provided to investigators who are already well-supported. NIH piloted the SCR procedure and further refined the policy based on the feedback received from this pilot. After the pilot, NIH reduced the funding threshold for these investigators from \$1.5 million total costs to \$1.0 million direct costs from active NIH awards. The policy, announced in the NIH Guide for Grants and Contracts (NOT-OD-12-140 -- <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html>) on August 20, 2012, requires NIH IC Advisory Councils to perform additional review of grant and cooperative agreement applications from [PD(s)/PI(s)] who receive \$1.0 million per year in direct costs from active NIH research project grants. Advisory Councils are asked to recommend consideration of funding for applications that afford a unique opportunity to advance research which is both highly promising and distinct from the other funded projects from the PD/PI. This policy does not represent a cap on NIH funding.

NIH-Kingston-28b. Please identify the number of intramural researchers in fiscal year 2012 that had more than \$1 million and more than \$1.5 million in projects?

Answer. The NIH Research Portfolio Online Reporting Tools (RePORTER) system was used to obtain information on the number of intramural researchers and their research project costs. The NIH RePORTER does not distinguish direct costs of individual research projects (as for extramural grants) from total costs of all research under the supervision of an individual investigator (for intramural scientists). In FY 2012 there were 863 intramural investigators with a total of over \$1 million funds allocated to research projects, and 524 of those investigators had more than \$1.5 million. Many investigators had more than one project. It is important to note that funds shown in RePORTER for intramural projects

cannot be compared directly with funds awarded as extramural grants, since intramural allocations include the total cost of research, including the cost of maintaining the NIH campus, security, the cost of all personnel including trainees who are not paid separately by training and Kirschstein National Research Service Awards (NRSA) awards, IT infrastructure, all administrative expenses, etc. In addition, for NIH Laboratory and Branch Chiefs and other supervisory scientific leadership, budgets frequently include the cost of supporting scientific cores and shared facilities not directly related to the research of the scientist.

NIH-Kingston-28c. Please provide a list with the current NIH Director, IC Director, and Scientific Directors who have intramural labs, programs, and projects. For each person, identify the total level of annual funding for these efforts in each of the past fiscal years for the past 10 years, thorough fiscal year 2012.

Answer. The data that follow was captured from the NIH Intramural Database (NIDB), and then reviewed by the ICs to ensure accuracy. This database supplies information to NIH RePORTER and only contains data for the past six years. Intramural lab budgets reflect direct costs of the PI (e.g., salaries, travel, equipment, and supplies directly benefitting the activity).

Institute/Center/Office	Individual	FY	Amount
NIH Director:	Francis Collins	2007	2,541,114
		2008	2,043,225
		2009	2,224,353
		2010	2,774,435
		2011	2,771,563
		2012	2,775,439
NIH Deputy Director:	Lawrence Tabak	2007	602,885
		2008	426,867
		2009	385,009
		2010	449,755
		2011	931,991
		2012	636,065
NIH OIR Director:	Michael Gottesman	2007	1,284,955
		2008	1,242,434
		2009	1,555,919
		2010	1,414,175
		2011	1,006,579
		2012	1,211,258
NIH DPCSI Director:	James Anderson	2011	390,917
		2012	650,176
IC Directors:			

Institute/Center/Office	Individual	FY	Amount
NIDA	Nora Volkow	2007	811,468
		2008	1,055,794
		2009	1,162,889
		2010	1,351,670
		2011	1,618,176
		2012	1,587,062
NIAID	Anthony Fauci	2007	4,609,511
		2008	4,078,954
		2009	3,250,154
		2010	2,814,465
		2011	2,962,041
		2012	2,450,052
NIBIB	Roderic Pettigrew	2008	321,370
		2009	863,969
		2010	941,768
		2011	938,058
		2012	981,876
NIDCR	Martha Somerman	2011	241,188
		2012	962,611
NIEHS	Linda Birnbaum	2011	1,034,359
		2012	1,368,744
NCI	Harold Varmus	2011	1,689,162
		2012	1,321,500
NEI	Paul Sieving	2008	1,080,000
		2009	972,000
		2010	1,115,483
		2011	1,079,000
		2012	1,063,000
NIDDK	Griffin Rodgers	2007	881,048
		2008	912,224
		2009	1,055,671
		2010	1,076,031
		2011	1,215,933
		2012	1,221,838
NIA	Richard Hodes	2007	828,578
		2008	805,562
		2009	1,009,306

Institute/Center/Office	Individual	FY	Amount
		2010	988,519
		2011	1,021,215
		2012	939,147
Clinical Center	John Gallin	2007	150,000
		2008	269,047
		2009	390,000
		2010	198,148
		2011	337,467
		2012	242,217
NHLBI	Gary Gibbons		New Director
NIAMS	Stephen Katz	2007	394,395
		2008	380,082
		2009	417,748
		2010	451,306
		2011	451,010
		2012	515,556
Scientific Directors:			
NCI-CCR	Robert Wiltout	2007	913,261
		2008	887,021
		2009	936,180
		2010	951,171
		2011	1,009,605
		2012	978,850
NCI-CCR	Lee Helman	2007	800,585
		2008	913,470
		2009	862,615
		2010	924,758
		2011	720,442
		2012	923,290
NEI	Sheldon Miller	2007	1,268,502
		2008	1,361,972
		2009	1,164,638
		2010	1,075,457
		2011	1,289,756
		2012	1,243,276
NIA	Luigi Ferrucci	2007	1,620,756
		2008	1,761,234

Institute/Center/Office	Individual	FY	Amount
		2009	1,743,170
		2010	1,469,007
		2011	1,702,783
		2012	1,675,148
NIDA	Antonello Bonci	2011	935,410
		2012	1,984,707
NINDS	Alan Koretsky	2007	1,183,840
		2008	1,145,423
		2009	1,118,952
		2010	1,459,762
		2011	1,194,219
		2012	1,267,370
NHLBI	Robert Balaban	2007	1,352,109
		2008	1,738,749
		2009	1,178,062
		2010	1,338,651
		2011	1,618,711
		2012	1,081,187
NIAID	Kathryn Zoon	2007	2,287,483
		2008	4,857,063
		2009	1,436,273
		2010	1,316,664
		2011	1,389,692
		2012	982,314
NCCAM	Catherine Bushnell		New SD
NICHHD	Constantine Stratakis	2009	1,535,744
		2010	843,403
		2011	969,337
		2012	1,176,514
NIAMS	John O'Shea	2007	1,259,969
		2008	1,375,065
		2009	1,474,018
		2010	1,465,506
		2011	1,517,728
		2012	1,782,969
NIDCD	Andrew Griffith	2009	921,093
		2010	807,344

Institute/Center/Office	Individual	FY	Amount
		2011	778,376
		2012	755,374
NIDCR	Robert Angerer		No budget
NIEHS	Darryl Zeldin	2007	1,450,227
		2008	1,180,151
		2009	1,792,542
		2010	1,672,927
		2011	1,720,423
		2012	1,556,088
NIMHD	William Coleman	2011	403,470
		2012	463,233
NHGRI	Daniel Kastner	2011	2,700,891
		2012	2,680,829
NIDDK	Michael Krause	2007	1,388,741
		2008	1,091,968
		2009	784,297
		2010	576,790
		2011	887,228
		2012	1,115,817
NIBIB	Richard Leapman	2007	1,049,689
		2008	6,047,311
		2009	3,636,781
		2010	2,279,288
		2011	1,203,790
		2012	1,438,863
NLM	David Lipman	2007	30,264
		2008	36,949
		2009	55,285
		2010	83,944
		2011	59,961
		2012	83,944
NLM	Clement McDonald	2008	120,516
		2009	114,072
		2010	111,625
		2011	113,973
		2012	109,820
NIAAA	George Kunos	2007	918,236

Institute/Center/Office	Individual	FY	Amount
		2008	1,065,724
		2009	1,274,646
		2010	939,105
		2011	1,122,665
		2012	1,257,018
NIMH	Susan Amara		New SD

NIH-Kingston-28d. If NIH decides to re-propose the additional scrutiny policy the proposal should identify how shall be applied in an identical fashion and methodology to all it will be implemented to intramural and extramural researchers to ensure consistence and fairness.

Answer. In order to apply this policy to the intramural program, definitions for all cost elements related to the intramural research would be needed. For example, comparisons of intramural and extramural costs would need to address the inclusion or exclusion of indirect costs, and indirect cost rates. Additionally, Management Fund expenditures within the Intramural Research Program (IRP) would need to be considered for items such as the cost of supporting clinical research, direct costs for NIH trainees (analogous to Kirschstein NRSA awardees) that are not paid separately by training grants, NIH security, campus maintenance, etc. If the cost elements could be compared with accuracy, direct comparisons could be entertained and measures instituted to achieve a greater degree of comparability.

NIH-Kingston-28e. Please provide how NIH ensures all policies, such as reduction to projects from the prior year's level, are applied in an identical fashion and methodology to all intramural and extramural researchers to ensure consistence and fairness.

Answer. The IRP has a largely retrospective review process and the entire cost of the research is borne by the federal government, including support of the world's largest clinical research hospital. The review system assures that highly innovative research with significant impact on public health is being conducted. Oversight is continual and direct, and changes in budget and research priorities can be effected quickly as the need arises. Within the IRP, resources of each principal investigator are regularly reviewed and adjusted on an annual basis by IC leadership. At least once every four years, outside experts review the work of each PI and recommend resource adjustments to IC leadership, who respond by making appropriate changes. The extramural program is primarily based on prospective grant reviews with direct oversight provided by the institutions to which the funds are granted. Although both intramural and extramural systems require rigorous review and oversight, the review systems differ by design, and it would be difficult to apply identical mechanisms to both approaches.

NIH-Kingston-29. The NCATS' authorizing language requires its activity not create duplication, redundancy, and competition with industry. Recently I heard NCATS co-funded some research projects with the National Institute on Deafness and Other Communication Disorders and National Center for Advancing Translational sciences

(NIH/NIDCD R21DC012620, R01DC008408 and R01DC009404 grants and UL1TR000011 grant) on a project related to improving hearing implant products. Improving hearing is certainly a positive desire and the question does not make a judgment on the research. However, using this project as an example, please explain the process NCATS uses to ensure its supported activity does not create duplication, redundancy, and competition with industry.

Answer. NIDCD conducts and supports research in the normal and disordered processes of hearing, balance, taste, smell, voice, speech, and language. Three NIDCD grants provided support for the cochlear implant research studies. NCATS catalyzes the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. The NCATS Clinical and Translational Science Awards (CTSA) program provided support for the studies through the Vanderbilt initiative for Surgery and Engineering (ViCE), which provides administrative and research training support for researchers engaged in interdisciplinary research projects.

The structure of the project in question is typical of the collaborative model on which NCATS operates, in this case via its CTSA program. As is the case here, a disease-specific NIH IC (NIDCD) decides on the medical need, scientific priority of the work, and the fit with current technologies in the public and industry sectors, in accord with their IC goals and practices; NCATS provides the research training and administrative infrastructure and translational expertise needed to help make the project successful.

NIH-Kingston-30. In the fiscal year 2012 Statement of Managers, it requested NIH charter an IOM study on specific activities related to the Cures Acceleration Network (CAN). I am aware NIH had the IOM conduct a workshop on related CAN issues but not a study as intended by the Statement of Manager. What is the timeline and status for completion of the full study requested by Congress?

Answer. The FY 2012 Statement of Managers included the following language:

“The conferees encourage the CAN Board to create general principles and measurable outcomes to track success. The conferees request NCATS to charter an Institute of Medicine (IOM) work group to review, evaluate, and identify issues related to the CAN authority and provide a report for use by the CAN Board to help it identify ways to accelerate and expand the number of cures.”

As requested, NCATS contracted with the IOM in February 2012 to convene a work group to carry out the Statement of Managers request. The work group’s workshop, entitled “Maximizing the Goals of the Cures Acceleration Network to Accelerate the Development of New Drugs and Diagnostics,” was held on June 4-5, 2012. There were approximately 150 speakers and attendees at the workshop, which included representatives from NIH, FDA, OSTP, BARDA, and DARPA, as well as members from industry and biotech venture capital communities. As described by the objectives of the workshop, discussions focused around:

- Identifying and cataloging potential tools, methods and approaches that hold promise for accelerating translational science;
- Discussing the authorities conferred to CAN and identifying strategies for effectively using those authorities;
- Exploring promising models for public-private collaborations that could be strengthened or facilitated by activities under CAN; and,
- Identifying barriers and potential solutions to facilitate coordination of activities under CAN with the FDA regulatory review processes and timelines.

The workshop summary, which was released in August 2012 and is available from the IOM, is currently informing NCATS, patient groups, the public, and other stakeholders, as all of these parties work together to enhance the development and testing of therapeutics. The summary was also provided to the CAN Review Board as it works to create general principles and measurable outcomes to track success of CAN. A working group of the CAN Review Board has been formed and is expected to provide a set of recommendations in the near future.

NIH-Kingston-31. Previously NIH noted it planned to convert contractors to federal employees to reduce costs in fiscal years 2011 and 2012. Please provide an update on this process, the results of the fiscal years 2011 and 2012 conversions. Plus what is the expected savings for fiscal years 2013 and 2014 assumed activities. Further, please provide a table with how much NIH spends annually on personnel and services contracts from each fiscal year 2008 through fiscal year 2014 estimates.

Answer. At the time of this submission NIH used contract personnel to allow flexibilities in federal staffing levels and to obtain staff with specialized skill sets that were focused specifically on the project they were hired to work on. These flexibilities and levels of expertise came at a premium, and with uncertain budget climates, NIH realized it would be increasingly challenged to afford these premiums. It is estimated that the savings of replacing a contractor with a federal employee of equal experience and skill is approximately 19 percent. However, NIH and HHS personnel systems do not capture the data that would show where a newly hired employee previously worked and in what capacity so our systems would not show how many replacements of contractors have taken place. NIH is not able to provide overall expenditures for personnel and services contracts because this data is not available in a centralized system to aggregate capture. Updating current systems or creating new systems to capture and maintain contractor personnel records would be a large undertaking for which NIH does not have resources.

NIH-Kingston-32. I assume NIH is continuing the policy that ensures success rate parity between established and early stage investigators. Please provide an update by IC, the success rate percentages and numbers of early stage and established investigators for each fiscal years 2011, 2012, estimated 2013, and estimated 2014. The update should define each category and note any changes to these terms used an policy year over year.

Answer. NIH is continuing to implement the 2009 policies that are designed to achieve comparable success rates between new and established investigators for Type 1 R01 or equivalent grants. (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html>). Table 1, below provides the requested actual success rate percentages and numbers of new, R01 equivalent awards to new and established investigators by NIH Institute and Center (IC) for

fiscal year (FY) 2011 and FY 2012. The estimated percentages and award numbers for FY 2013 and FY 2014 assume that FY 2012 performance will be sustained.

The following definitions apply to the figures depicted in Table 1:

New Investigator: A Program Director/Principal Investigator (PD/PI) is considered a New Investigator if s/he has not previously competed successfully as the PD/PI for a substantial NIH independent research award, e.g., an investigator-initiated R01 Equivalent Grant (R01, DP2 or R37). Since almost all New Investigators apply for new awards, only new applications (and not continuation applications) are included in the success rates presented in Table 1 for established investigators.

More information on the NIH New Investigator Policy is available at:
http://grants.nih.gov/grants/new_investigators/index.htm

Success Rate: The success rate describes the percentage of reviewed grant applications that are funded. Success rates are computed on a fiscal year basis and include applications that undergo peer review by an Initial Review Group. Success rates are determined by dividing the number of competing applications funded by the total number of competing applications reviewed and the number of applications reviewed in a prior fiscal year funded in the current fiscal year. Applications having one or two submissions in the same fiscal year are counted once.

Not Applicable (NA): The National Center for Research Resources (NCRR) was eliminated as part of the Consolidated Appropriations Act, 2012, P.L. 112-74. Some of the NCRR programs were transferred to the newly formed Office of Research Infrastructure Programs (ORIP) within the Office of the Director (OD) while other programs were transferred to the National Center for Advancing Translational Sciences (NCATS), established in FY 2012. The New Investigator policy is not expected to be applicable to NCATS because, at present, the Center does not participate in the investigator-initiated R01 funding opportunity.

Table 1. Historical and estimated future success rates for new, competing R01-equivalent grants submitted by new versus established investigators.

Institute	New Investigators: FY2011		Established Investigators: FY2011		New Investigators: FY2012		Established Investigators: FY2012		New Investigators: FY2013	Established Investigators: FY2013	New Investigators: FY2014	Established Investigators: FY2014
	Awards	Success Rate	Awards	Success Rate	Awards	Success Rate	Awards	Success Rate	Success Rate (estimated)	Success Rate (estimated)	Success Rate (estimated)	Success Rate (estimated)
NCI	185	13%	329	13%	156	11%	355	13%	13%	13%	13%	13%
NHLBI	173	18%	251	15%	135	13%	272	13%	13%	13%	13%	13%
NIDCR	15	15%	38	17%	15	13%	46	21%	21%	21%	21%	21%
NIDDK	126	20%	154	16%	78	14%	163	16%	16%	16%	16%	16%
NINDS	112	18%	202	19%	104	18%	179	17%	17%	17%	17%	17%
NIAID	132	17%	174	14%	109	14%	241	17%	17%	17%	17%	17%
NIGMS	171	18%	222	16%	160	17%	281	19%	19%	19%	19%	19%
NICHD	66	12%	68	10%	54	9%	117	13%	13%	13%	13%	13%
NEI	48	24%	68	26%	54	29%	75	26%	26%	26%	26%	26%
NIEHS	22	11%	41	11%	27	19%	48	16%	16%	16%	16%	16%
NIA	57	13%	111	17%	44	13%	59	13%	13%	13%	13%	13%
NIAMS	46	14%	60	15%	39	13%	49	12%	12%	12%	12%	12%
NIDCD	19	18%	44	24%	25	21%	45	24%	24%	24%	24%	24%
NIMH	76	16%	135	17%	90	20%	180	21%	21%	21%	21%	21%
NIDA	41	14%	79	13%	53	18%	118	19%	19%	19%	19%	19%
NIAAA	22	18%	28	11%	15	13%	41	15%	15%	15%	15%	15%
NINR	12	8%	22	12%	13	10%	32	18%	18%	18%	18%	18%
NHGRI	11	20%	20	31%	14	21%	18	25%	25%	25%	25%	25%
NIBIB	24	11%	41	16%	21	10%	31	13%	13%	13%	13%	13%
NCRR*	3	14%	4	15%	NA	NA	NA	NA	NA	NA	NA	NA
NCATS**	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
NCCAM	11	8%	19	11%	11	9%	18	11%	11%	11%	11%	11%
NIMHD	6	13%	6	11%	7	11%	7	10%	10%	10%	10%	10%
FIC	2	100%	0	NA	3	5%	5	25%	25%	25%	25%	25%
NLM	9	19%	5	17%	10	18%	5	10%	10%	10%	10%	10%
OD	4	100%	5	100%	2	7%	11	26%	26%	26%	26%	26%
Common Fund	44	9%	18	7%	47	5%	30	4%	4%	4%	4%	4%
OD/ORIP-SEPA*	NA	NA	NA	NA	0	0%	3	38%	38%	38%	38%	38%
NIH	1,437	15%	2,144	15%	1,286	13%	2,429	15%	15%	15%	15%	15%

*The National Center for Research Resources (NCRR) was eliminated as part of the Consolidated Appropriations Act, 2012, P.L. 12- 74. Some of the NCRR programs were transferred to the newly formed Office of Research Infrastructure Programs (ORIP) within the Office of the Director (OD) while other programs were transferred to the National Center for Advancing Translational Sciences (NCATS), established in FY 2012.

**The New Investigator policy is not expected to be applicable to NCATS because, at present, the Center does not participate in the investigator-initiated R01 funding opportunity.

NIH-Kingston-33. Please provide an update and timeline on the on-going efforts to improve financial fund controls, to include ensuring real time linkage between the fiscal system and grants management system and hard funds controls that prevent obligation of funds above the apportionment, allocation, and reprogramming within the sub-mechanism level. Plus, provide an update on the all the fiscal controls identified by NIH and implemented status based on lessons learned from the most recent ADA contracts violations.

Answer. NIH implemented hard funds control at the Allowance level beginning in FY 2011 for obligations tied to appropriated funds, including contracts and grants from sources integrated with NIH's Oracle-based financial system. In order to achieve hard funds control for grants, NIH successfully implemented a real time web services interface between the NIH financial system (NIH Business System (NBS)) and the NIH Grants Management System (eRA), also at the beginning of FY 2011.

In addition, based on lessons learned, NIH and HHS have cooperated to establish a clearance process for significant research and development, studies, and data collection activities. All proposed actions valued at \$10 million or more for the types of project activities mentioned above, are subjected to an extensive review by the Division of Acquisition and Policy Evaluation, OAMP, OALM, followed by a review by the HHS Office of General Counsel. This two-step clearance process is designed to assess the extent of compliance with Federal appropriations laws under the more complex NIH acquisitions and to ensure that any changes required to fully comply with Federal appropriations laws are implemented prior to release of a solicitation or award of a contract modification.

This internal control process was fully implemented October 6, 2011.

NIH-Kingston-34. Please explain why NIH recently conducted a reorganization of certain health disparities and workforce diversity programs at the NIH. Please provide a detailed update each of these programs that include the home IC and each IC's annual funding level supported toward each of the NIH's stated goals of increasing biomedical workforce diversity and supporting health disparities research.

Answer. NIH invests substantially in population-based research to improve public health, including minority health and health disparities; it also devotes resources to identify, develop, support and maintain the quality of the Nation's scientific resources, including human capital. Although NIH has not engaged in a reorganization of health disparities research, the National Institute on Minority Health and Health Disparities (NIMHD) is in the process of developing the 2014-2018 trans-NIH health disparities strategic plan as well as an NIMHD-specific strategic plan. NIH is also in the process of changing its approach to scientific workforce diversity.

Scientific Workforce Diversity and the NIH Mission

NIH's ability to ensure that it remains a leader in scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds who will serve NIH and the Nation. Dr. Francis Collins tasked a Working Group of the Advisory Committee to the Director to provide recommendations on approaches to enhancing the diversity of the NIH-

funded workforce. The Advisory Committee to the Director Working Group on Diversity in the Biomedical Research Workforce (ACDWG; <http://acd.od.nih.gov/dbr.htm>) reported to the ACD, in June 2012, and its recommendations were considered by trans-NIH senior leadership. As a result, the following specific steps were recommended by the ACDWG and have been taken:

Chief Officer for Scientific Workforce Diversity

On January 13, 2013, the NIH Director announced the creation of a new position in the Office of the NIH Director, the Chief Officer for Scientific Workforce Diversity (COSWD). Dr. Roderick Pettigrew, the National Institute of Biomedical Imaging and Bioengineering (NIBIB) Director, was then appointed the Acting COSWD. The COSWD will work to enhance diversity in the NIH-funded biomedical research workforce, which includes the extramural and intramural components. The COSWD is charged with identifying new and effective, evidence-based strategies to enhance diversity, and to promote synergy among existing programs. This will be accomplished by working closely with the NIH Institute and Center Directors, Office of Extramural Research, Office of Intramural Research, Office of Human Resources, Office of Equal Opportunity and Diversity Management, and other stakeholders such as advocacy and advisory groups. The COSWD is currently partnering with NIMHD and the National Heart, Lung, and Blood Institute (NHLBI), in developing and executing new Common Fund initiatives to enhance diversity in biomedical research.

Common Fund Program: Enhancing the Diversity of the NIH-Funded Workforce

Three inter-related initiatives have recently been announced with the collective goal of significantly enhancing scientific workforce diversity. These are: (1) NIH Building Infrastructure Leading to Diversity (BUILD), (2) National Research Mentoring Network (NRMN), and (3) the Coordinating and Evaluation Center (CEC). The BUILD initiative intends to support training at multiple career stages and promote faculty development at comparatively under-resourced institutions with a track record of producing and supporting scientists from backgrounds underrepresented in biomedical and behavioral research. NRMN is intended to augment local mentoring efforts for undergraduate students through junior faculty members by creating a national group of scientific leaders who are willing to serve as external mentors. NIH intends to identify an entity that will engage and assemble multiple persons and/or professional organizations into a single, Nation-wide, consortium of mentors. The goal of the CEC is to help ensure optimal coordination of the BUILD and NRMN activities, minimize redundancy, and facilitate data tracking and analysis.

NIH-Kingston-35 The various NIH ICs and office of the NIH Director have different focuses and operational structures. Please provide the a table that lists the total funding provided to the Director's Office of each IC and the NIH Director that breaks out the cost of travel, personnel, performance bonuses, and all other, at a minimum by IC. The initial table should provide the last four actual years of obligations and projected for this fiscal year and fiscal year 2014. In addition, please provide this information in the supplemental material section of future annual budget requests.

Answer:

Provided below are the tables that list the total funding provided to the Office of the Director from each NIH Institute and Center (IC) -- (note: data for the National Center for Research

Resources (NCRR) is included in the NIH Consolidated totals for FY 2009 – 2011 before it was eliminated in FY 2012 and the National Center for Advancing Translational Sciences (NCATS) was established). Each IC maintains an organizational structure that is designed to meet its unique mission requirement. This can result in significant differences in these areas from one IC to the next. Also, variations between years can be the result of vacancies as well as reorganization of functions.

NIH Consolidated

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	1,782	1,776	1,991	1,547
Personnel	30,821	33,007	34,475	33,451
Performance Bonuses	1,348	1,391	1,441	876
All Other	11,601	11,983	11,055	9,266
Total	45,552	48,157	48,962	45,140

NCI

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	134	79	194	93
Personnel	1,790	1,851	2,403	2,353
Performance Bonuses	109	67	96	38
All Other	2,959	3,183	2,345	1,817
Total	4,992	5,180	5,038	4,301

NHLBI

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	78	55	33	50
Personnel	1,292	1,477	1,439	1,168
Performance Bonuses	43	78	55	21
All Other	69	42	37	49
Total	1,482	1,652	1,564	1,288

NIDCR

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	22	23	10	14
Personnel	1,043	878	312	840
Performance Bonuses	47	44	16	9
All Other	109	73	389	194
Total	1,221	1,018	727	1,057

NIDDK

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	102	147	130	114
Personnel	839	1,315	1,469	1,497
Performance Bonuses	38	64	54	43
All Other	1,015	1,128	1,128	855
Total	1,994	2,654	2,781	2,509

NINDS

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	73	82	100	72
Personnel	965	816	840	884
Performance Bonuses	37	51	44	31
All Other	92	133	203	264
Total	1,167	1,082	1,187	1,251

NIAID

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	157	173	118	56
Personnel	2,717	2,932	2,661	2,700
Performance Bonuses	101	93	105	61
All Other	459	426	455	402
Total	3,434	3,624	3,339	3,219

NIGMS

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	10	29	20	10
Personnel	818	859	958	860
Performance Bonuses	31	33	31	7
All Other	358	511	260	190
Total	1,217	1,432	1,269	1,067

NICHD

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	111	74	177	64
Personnel	1,771	2,139	2,193	1,966
Performance Bonuses	46	56	181	113
All Other	846	1,501	525	289
Total	2,774	3,770	3,076	2,432

NEI

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	87	100	95	101
Personnel	1,108	973	1,368	1,455
Performance Bonuses	67	38	56	31
All Other	867	761	910	769
Total	2,129	1,872	2,429	2,356

NIEHS

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	103	107	89	87
Personnel	760	874	1,264	1,157
Performance Bonuses	6	12	11	21
All Other	85	87	170	240
Total	954	1,080	1,534	1,505

NIA

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	8	11	47	8
Personnel	950	975	996	857
Performance Bonuses	41	42	36	24
All Other	20	7	12	36
Total	1,019	1,035	1,091	925

NIAMS

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	41	44	56	38
Personnel	1,512	1,389	1,525	1,594
Performance Bonuses	89	124	131	75
All Other	852	714	567	735
Total	2,494	2,271	2,279	2,442

NIDCD

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	2	17	10	4
Personnel	1,024	1,052	1,030	953
Performance Bonuses	87	63	64	33
All Other	319	184	435	41
Total	1,432	1,316	1,539	1,031

NINR

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	54	35	36	29
Personnel	681	752	796	929
Performance Bonuses	45	36	38	11
All Other	98	113	407	180
Total	878	936	1,277	1,149

NIAAA

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	64	53	80	117
Personnel	1,247	1,302	1,620	1,469
Performance Bonuses	62	38	53	28
All Other	220	167	72	93
Total	1,593	1,560	1,825	1,707

NIDA

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	96	81	60	61
Personnel	1,408	1,504	1,305	1,377
Performance Bonuses	67	74	52	36
All Other	153	156	56	233
Total	1,724	1,815	1,473	1,707

NIMH

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	69	68	119	63
Personnel	1,714	1,962	2,018	1,799
Performance Bonuses	66	71	53	43
All Other	535	309	211	371
Total	2,384	2,410	2,401	2,276

NHGRI

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	17	42	77	77
Personnel	916	988	1,070	1,005
Performance Bonuses	30	38	29	34
All Other	73	379	568	489
Total	1,036	1,447	1,744	1,605

NIBIB

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	162	130	124	105
Personnel	1,082	1,057	961	1,002
Performance Bonuses	42	49	38	24
All Other	631	396	377	586
Total	1,917	1,632	1,500	1,717

NCCAM

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	62	60	34	44
Personnel	967	925	953	956
Performance Bonuses	31	72	44	41
All Other	638	340	152	185
Total	1,698	1,397	1,183	1,226

NIMHD

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	6	19	11	15
Personnel	673	560	621	815
Performance Bonuses	29	17	23	17
All Other	11	9	106	112
Total	719	605	761	959

FIC

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	72	107	121	125
Personnel	1,046	1,132	1,145	1,343
Performance Bonuses	38	41	35	30
All Other	106	229	178	253
Total	1,262	1,509	1,479	1,751

NLM

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	171	122	113	114
Personnel	1,313	1,415	1,424	1,411
Performance Bonuses	34	62	66	21
All Other	255	247	213	220
Total	1,773	1,846	1,816	1,766

NCATS

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	0	0	0	22
Personnel	0	0	0	382
Performance Bonuses	0	0	0	7
All Other	0	0	0	104
Total	0	0	0	515

IMOD

(Dollars in thousands)

Expense Type	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual
Travel	22	45	100	64
Personnel	2,094	2,770	3,101	2,679
Performance Bonuses	111	82	96	77
All Other	748	690	1,033	559
Total	2,975	3,587	4,330	3,379

NIH-Kingston-36. NIH should support future adjustments to centralized programs like public access to research results and the National Center for Biotechnology Information (NCBI) with its Management Fund authority. Please provide a timeline on when the next review of the MF process is and ensure it includes examines the procedures to ensure centralized programs have long-term business plans in place prior to approval of any initiatives for MF support.

Answer. In lieu of utilizing the MF as a long-term solution for this purpose, NIH has proposed in recent Budgets to consolidate support for these activities in the National Library of Medicine appropriation (where NCBI resides and receives the majority of its funding). While these activities benefit all of NIH, converting annual Institute and Center contributions to direct funding would enhance administrative efficiency and accountability. For future consideration with respect to use of the budget/funding alternatives, NIH, as it currently does, would determine

the best alternative via the established governance through the Management and Budget Working Group and Steering Committee.

NIH-Kingston-37. I understand NIH has a significant backlog of maintenance and repairs. Please describe the NIH and HHS coordinated plan to address the backlog. Specifically, I would like to understand the projected backlog and five year plan to address the backlog.

Answer. NIH’s Backlog of Maintenance and Repair (BMAR) is currently estimated at approximately \$1.55B. In recognition of the significant budgetary constraints facing all federal agencies, NIH is applying its Buildings and Facilities (B&F) funds to address the highest risk areas, such as issues impacting patient safety, biosafety, animal welfare, central utilities, and other functions essential to NIH’s mission. In addition, NIH is working hard to increase our use of alternative financing mechanisms known as Energy Savings Performance Contracts and Utility Energy Savings Contracts in order to perform life cycle cost effective repairs and improvements to our facilities. These mechanisms allow NIH to use private sector financing to implement significant projects that improve the energy performance of our facilities without up-front capital, with future payments offset by the resulting savings from energy and water-use reductions. NIH is also systematically demolishing buildings that are beyond their services lives, such Buildings 127, 128, T18, and T21 in Poolesville, MD, and Buildings 7 and 9 in Bethesda. A breakdown of the current backlog of maintenance and repairs by location is shown below:

Location	Backlog of Maintenance and Repair (BMAR) (dollars in millions)
Bayview	\$37.36
Bethesda	\$1,344.66
Frederick	\$124.77
Montana	\$0.93
North Carolina	\$37.71
Poolesville	\$7.05

NIH-Kingston-38. NIH receives special authority to provide a limited level of support from the Office of the Director, institutes and centers for building and facility projects including the cost of design and construction attributes but excluding costs associated with existing authorities such as funding furniture or furnishings, pre-design, casework and IC scientific instrumentation. Please provide a report for fiscal years 2011, 2012, and estimated 2013 on the annual level of funds spend under this authority.

Answer. NIH uses this special authority for alteration, repair, or improvement of facilities as necessary for the proper and efficient conduct of its mission. The following table illustrates actual obligations for FY 2011, FY 2012, as well as the estimated obligations for FY 2013:

Fiscal Year	Expenditures
FY 2011	\$11.07M

FY 2012	\$11.28M
FY 2013 (Estimated)	\$7.38M

NIH-Kingston-39. On the Recalcitrant Cancer Research Act of 2012, enacted on January 2, 2013, it includes a provision on the Pancreatic Cancer Action Network. Please provide a report on the progress NIH and NCI are making in carrying out that Act. Please include a timeline and milestones for the implementation actions.

Answer. The recalcitrant cancer legislation, enacted as section 1083 of the National Defense Authorization Act for Fiscal Year 2013, requires that within six months of enactment, NCI identify two or more “recalcitrant cancers” with 5-year survival rates of less than 20 percent and that cause at least 30,000 deaths in the U.S. per year. Within 18 months, NCI is required to develop a “scientific framework” for each cancer so identified. The scientific framework will be sent to Congress and made publicly available on the HHS website within 30 days of completion. There is no provision in the Act specific to the Pancreatic Cancer Action Network.

NCI has identified pancreatic ductal adenocarcinoma (PDAC) and small cell lung cancer as “recalcitrant cancers” having 5-year survival of less than 20 percent and causing at least 30,000 deaths in the U.S. per year. NCI recently convened a group of experts and representatives of pancreatic cancer advocacy groups for a workshop focused on PDAC. Planning is under way for a similar workshop for small cell lung cancer in summer 2013.

The PDAC workshop was intended to identify new ideas and important, unsolved problems in PDAC research, and to identify approaches to solve those problems. The participants recommended several areas for further investigation, including studying connections between PDAC and recent onset diabetes mellitus, evaluating biomarkers for populations at high risk for PDAC, and utilizing new chemical biology data to develop treatments to target genetic mutations associated with PDAC. The workshop report was accepted by NCI’s Clinical Trials and Translational Research Advisory Committee in early March 2013. This report is the first step in the process of developing NCI’s scientific framework for PDAC research. Development of additional information to be included in the scientific framework is currently under way and will be completed over the next few months and submitted to Congress well in advance of the July 2014 deadline for completion of the scientific frameworks.

Since the initial workshop discussions on PDAC, NCI has begun discussions with a broad group of multidisciplinary experts to explore new approaches for examination of the *KRAS* oncogene, in which mutations are present in at least 90 percent of PDACs, as well as some lung, colon, and ovarian cancers, but for which researchers have been unable to develop a successful therapeutic approach. NCI is also partnering with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to host a Diabetes Pancreatic Cancer Workshop in June 2013 that will explore the known and suspected mechanism for the increased risk of PDAC associated with chronic pancreatitis and diabetes mellitus.

NIH-Kingston-40. The full year continuing resolution provides NIH Office of the Director with about a \$100 million increase to support research across all institutes and centers. Please describe the plan to co-fund or use these funds to support all institutes and centers as opposed to maintain the funds within the NIH Office of the Director programs.

Answer. After applying the rescission, sequestration, and transfer, the additional amount available to the Office of the Director for strategic initiatives is \$78.7 million above FY 2012. The Office of the Director plans to use these funds to support research across the institutes and centers (IC) through several initiatives. Approximately \$40 million will be used to fund Alzheimer’s disease research through two Requests For Applications issued as part of the National Plan. Approximately \$20 million will be used for NIH-wide IT infrastructure improvements under the Big Data to Knowledge – BD2K initiative designed to enable a quantum leap in the ability of the biomedical research enterprise to maximize the value of the growing volume and complexity of biomedical data. In addition, the Center for Scientific Review will conduct peer review studies associated with the NIH Scientific Workforce Diversity Initiative; and co-funding support will be provided for projects aimed at developing new therapeutic agents relevant to multiple ICs and a variety of diseases, as well as for IC commitments to existing Pioneer awards within the High Risk/High Reward program jointly supported by the Common Fund and the ICs.

NIH-Kingston-41. The NIH Director did not fully agree with the recommendations made by the Scientific Management and Review Board (SMRB) on substance use, abuse, and addiction-related research. We understand the NIH Director is required to submit a report outlined providing that the Director objects to the change and includes the reasons underlying the objection not later than 90 days after enactment. What is the status of this report? Plus, please describe the criteria and rationale related to NIH Director’s decision. We understand NIH expects these organizations to conduct a “functional integration” to advance this research rather than consolidation. Please provide specific details on how the two Institutes plan to achieve such integration and how will progress be measured.

Answer. The *Scientific Management Review Board Report on Substance Use, Abuse, and Addiction Research at NIH* found that the current organization of NIH substance use, abuse, and addiction (SUAA) research was not optimal and that changes were needed to integrate addiction-related research within NIH. After considering two organizational options aimed at optimizing SUAA research at NIH – a trans-NIH initiative on addiction and the creation of a new institute devoted to SUAA research – the Board concluded that creating a new institute would lead to the needed improvements in the conduct of SUAA-related research at NIH.

NIH leadership undertook an extensive process for considering how best to implement the recommendations of the Strategic Management Review Board (SMRB). An internal task force was established to provide advice to the NIH Director. The task force, with support from subject matter experts, analyzed the research portfolios of the Institutes and Centers (IC) that fund SUAA research in order to determine which programs could be included in a new addiction-focused institute and which non-SUAA research within the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA) portfolios could not fall within the new SUAA focused mission and subsequently could be transferred to other ICs.

With broad-based input from a range of experts and stakeholders from academic researchers, professional societies, patient advocates, and others, the task force also developed a strategic plan for SUAA prevention and treatment research. The plan identified a number of promising opportunities, including research on poly-substance use and abuse; the underlying neurobiology of addiction to different substances and behavioral addictions; and the development of effective behavioral, pharmacological, and biological interventions to treat individuals with multiple addictions.

While the work of the task force proceeded, the ICs with SUAA research portfolios began to strengthen their collaborative efforts. It eventually became evident to the task force that these efforts were bringing about the kind of improvements in the conduct of SUAA-related research that the SMRB recommendations were intended to achieve. NIH leadership also recognized that these improvements and further integration of SUAA research could be accomplished without expending the time, energy, and resources required for a major structural reorganization. Consequently, NIH decided to pursue the functional integration rather than implement the structural changes.

ICs with SUAA research portfolios have taken a number of steps to further the integration. Leaders at NIAAA, NIDA, and the National Cancer Institute (NCI) formed a Functional Integration Steering Committee that will guide integration efforts undertaken by the Functional Integration Coordinating Committee, which consists of representatives from all three ICs. Progress toward greater integration of SUAA-related research will be measured against the baseline of collaborative efforts that existed prior to NIH's decision to adopt a functional integration approach.

Greater integration of SUAA activities will include the issuance of joint funding opportunity announcements (FOAs); the Steering Committee has decided that co-morbidity will be a primary focus of FY 2014 FOA proposals. The three ICs will also develop an informational website for the extramural community and solicit input from external stakeholders. In addition, NIAAA and NIDA Advisory Councils will meet jointly once a year. NIAAA and NIDA have also taken steps to integrate the SUAA activities conducted within their intramural research program, including by appointing a single clinical director to oversee both research programs. Functional integration between ICs provides an opportunity to pool resources and expertise to more effectively capitalize on synergies in addiction research, address scientific opportunities, and meet public health needs.

Although NIH did not implement the approach recommended by the SMRB, we accepted the Board's finding that greater integration of SUAA-related research is needed, and we are actively pursuing that goal.

NIH-Kingston-42. What steps are NIH taking in regard to research and other programs related to Amyloidosis?

Answer. NIH, and several of its Institutes and Centers, will continue to support research on Amyloidosis when sufficiently meritorious grant applications are received via the

unsolicited/investigator initiated grant application process. See earlier response to similar question for examples of current research efforts.

NIH-Kingston-43. Pediatric low grade astrocytoma (PLGA) is a slow growing children's brain cancer. Existing treatments for slow growing children's brain tumors are invasive, highly toxic, and relatively ineffective. In the FY 2013 budget submission, NIH notes that, "Major advances in understanding the biology of PLGA have been achieved over the past five years, and because of these advances, clinical research teams are now poised to translate these findings into new therapeutic options." Could you please provide an update on research related to PLGA and your views on its ability to contribute to new therapeutic options available to children battling slow growing brain tumors?

Answer. The National Cancer Institute (NCI) continues to support promising research addressing Pediatric Low Grade Astrocytoma (PLGA), including preclinical research and clinical trials, to evaluate targeted therapies and other treatment approaches. NCI currently supports 15 active clinical trials for which patients with PLGA are eligible and that address therapeutic, supportive care/quality of life, or biological questions relevant to PLGA.

An important recent advance that is leading to new research opportunities in this area is the recognition that the vast majority of PLGA cases have genomic alterations involving a gene called BRAF, a known target for therapy of other cancers, particularly melanomas, using approved drugs. NCI is supporting the development of preclinical models that will allow identification of promising candidate treatments for PLGAs with this alteration. The NCI-supported Pediatric Preclinical Testing Program developed a model for a subtype of PLGA with the BRAF mutation and identified a targeted therapy, selumetinib (AZD6244), for additional research. Currently, the NCI-supported Pediatric Brain Tumor Consortium is conducting a Phase I trial of selumetinib in children with PLGA who have progressed after receiving radiation therapy, to study the side effects and the best dose of selumetinib. The trial is open at 13 sites across the country, including at the NIH Clinical Research Center in NCI's Pediatric Oncology Branch, and expects to enroll 40 children with PLGA. Data collection for the trial is anticipated to be complete in July 2014.

The NCI-supported Children's Oncology Group (COG) recently opened a Phase I trial for PLGA, investigating the use of lenalidomide, an immunomodulator that has been shown to enhance immune cell activity and inhibit inflammatory response. The trial is active in 68 locations, with an NCI Pediatric Oncology Branch researcher serving as the principal investigator. The trial, which opened in March 2012, is studying low-dose or high-dose lenalidomide to see how well it works in treating younger patients with recurrent, refractory, or progressive juvenile pilocytic astrocytomas or optic nerve pathway gliomas. The trial expects to enroll 80 patients, and data collection is anticipated to be complete in May 2015.

Additionally, COG has completed a Phase III study comparing two combination chemotherapy regimens for PLGA, and also has completed enrollment for a Phase II study evaluating the efficacy and toxicity of specialized radiation therapy that delivers radiation directly to the tumor and reduces radiation to normal tissue. The Phase III study enrolled previously untreated children younger than age 10 with progressive or residual PLGA, and they were randomly

assigned to receive either the therapies carboplatin and vincristine (CV) or a combination of thioguanine, procarbazine, lomustine, and vincristine (TPCV). The five-year event-free survival rates were 39% (+/- 4%) for CV and 52% (+/- 5%) for TPCV, and the overall survival rates at five years were similar for both arms (approximately 87%). Treating physicians can use these outcome results, combined with the acute and long-term toxicities of the two regimens, to guide treatment for individual patients. Results from the Phase II study of radiation therapy require longer follow-up before reporting.

In other efforts focused on neurofibromatosis-associated PLGAs, NCI researchers screened thousands of existing drugs and new compounds isolated from plants and marine life for potential therapeutic activity for PLGAs. Also, certain PLGAs, called optic pathway gliomas, which occur in children with neurofibromatosis Type 1, are frequently not biopsied, given their diagnostic appearance on initial imaging. In an effort to learn more about these tumors, the NCI intramural research program has initiated an imaging study that combines imaging techniques – newer MRI sequences in addition to a type of positron emission tomography scan known as FDG PET – for an enhanced approach to noninvasively evaluate the biology of pediatric brain tumors as well as their response to therapy.

Additionally, the National Institute of Neurological Disorders and Stroke (NINDS) continues to support several therapeutic development initiatives, including a translational research program and the trans-NIH Neurotherapeutics Grand Challenge, which encourage proposals for the development of novel drugs for all neurological disorders, including PLGA. The National Institute for Biomedical Imaging and Bioengineering (NIBIB) continues to support the development of multifunctional drug and gene delivery systems. Such systems can target therapies to particular cells and intracellular compartments in the affected tissue, including the brain, and can monitor drug delivery and therapeutic efficacy using advanced imaging and/or sensing technologies. This approach has the potential to reduce treatment toxicity while increasing efficacy.

Centers for Medicare & Medicaid Services (CMS)

QFRs from Chairman Kingston

- 1) **Please provide funding plan by fiscal year for the Innovation Fund that show by Innovation Fund program with the annual funding already provided or projected from inception to exhaustion of these funds.**

CMS-KINGSTON-1 Answer: See attached chart.

- 2) **Please provide a breakout to identify the annual level of spending for all ACA activity from the inception of the ACA through the fiscal year 2014 estimate. The table should include all mandatory, discretionary, and any other funding sources, by fiscal year, and identify at the program, project, activity the funds spend from each source by fiscal year.**

CMS-KINGSTON-2 Answer: CMS has implemented many parts of the Affordable Care Act from initial setup of the Federally-facilitated Marketplace (FFM) to establishing model programs under the Centers for Medicare and Medicaid Innovation. ACA responsibilities are now a part of CMS' core mission and many of the activities are supported through our base operations; therefore, it is difficult to breakout all of our expenditures related to ACA. We are able to breakout the costs associated with CMS' Marketplace responsibilities. In FY 2011 and FY 2012, CMS spent \$118 million and \$304 million on Marketplace activities, respectively, from the Health Insurance Reform Implementation Fund (HIRIF), CMS Program Management, and the Secretary's Transfer. In FY 2013, CMS is planning to spend \$1.5 billion from Program Management, the Secretary's Transfer Authority, Non-Recurring Expenses Fund, HIRIF, and the Prevention Fund. In the FY 2014 President's Budget, CMS requested a total of \$2 billion for the Marketplace implementation. That includes \$1.5 billion in appropriated funds and \$450 million in user fees.

- 3) **The fiscal year 2012 appropriations act provided funds to allow the establishment of the CMS Test Environment for testing industry solutions to ensure full implementation of this test environment. Please provide an update on the activity supported in fiscal years 2012 and 2013 that includes a description on the status of the initiative and a plan to advertise it to users.**

CMS-KINGSTON-3 Answer: In 2012, CMS funded a Data Enclave Pilot to examine, compare, and test different methods for allowing access into CMS' existing Chronic Conditions Data Warehouse (CCW). While CMS is committed to increasing access to Medicare program data to support innovative analytics, the pilot sought to identify how CMS could balance these priorities with the need to protect beneficiary privacy and to assure that protected health information is made available with appropriate safeguards. Based on lessons learned from the Data Enclave Pilot, CMS allocated \$2M of the conferees "sandbox" funding to purchase initial IT infrastructure and begin the development of required access control tools to fully operationalize a CMS Data Enclave.

Currently, CMS has completed installation of the initial infrastructure equipment to support approximately 200 Data Enclave “seats” (users) and is finalizing the development of tools for managing the environment and supporting the users. In addition, development of output review procedures and enclave access pricing models, as well as a systematic review of CMS’s data access policies and procedures, is underway. CMS expects initial enclave functionality to be operational within the CCW by late Spring 2013.

The development of a CMS Data Enclave supporting virtual access to enrollment and medical billing information for over 100 million of the country’s most vulnerable patients is an important first step to achieving the agency’s goal of providing transparency for its program operations. The Data Enclave also offers an environment where data entrepreneurs can test and develop creative solutions to both improve the care that beneficiaries receive and inform CMS operations.

While CMS is taking steps to make its program data more accessible to outside users/researchers, it is concerned about the stress these increased demands will place on our infrastructure. As a result, CMS continues to make investments in its IT infrastructure, especially in the areas of data capacity and identity management. In FY 2012, CMS invested an additional \$3M in two ongoing projects: the Integrated Data Repository (IDR) and Enterprise Identity and Access Management (EIAM). Both of these projects support the success of the sandbox. EIAM strengthens remote identity proofing for potential users of our data. The IDR consolidates CMS’ data in one place, ensures its integrity, quality, and consistency, and enables shared access with external business partners. Together the IDR and the CCW are CMS’ enterprise data warehouse.

In FY 13, CMS expects to spend \$5M on the sandbox, building out the enclave infrastructure, enhancing data assets in the enclave, and developing a governing structure for users to access the sandbox.

Once the data sandbox pilot is complete and allows vendors to work independently and with CMS to seek solutions and execute proof of concept tests to Medicare issues in a secure environment using Medicare data CMS will alert the Committee of a plan to announce the data enclave to potential users.

- 4) CMS uses Medicare Administrative Contractors (MACs) as its agent in lieu of federal employees to process reimbursement activity. It appears a significant lack of CMS guidance consistency occurs across a majority of the MACs. Further, the Committee understands the MACs develop and implement independent policies, which may be inconsistent with CMS guidance. For example, a majority of MACs, through either stated or informal policies, routinely deny coverage of healthcare services utilizing medical technologies assigned category III Current Procedural Terminology (CPT) codes that are designed to describe procedures utilizing emerging and innovative technologies. CMS has provided guidance stating procedures described by Category III codes should be covered and reimbursed when they are medically necessary but MACs have independent MAC policies contradicting this guidance, which results in broad non-coverage, significant payment delays, and undue administrative cost for the use emerging and innovative**

technologies, discouraging adoption of new procedures and devices with the potential to offer Medicare beneficiaries treatment options that may be safer, more efficient and/or less costly. Specifically, we have heard a new minimally invasive treatment for lumbar spinal stenosis (LSS) is routinely denied based on implementation of MAC guidance that is contradictory to the CMS policy related to Category III coding. Please provide a detailed description in the fiscal year addressing what steps CMS has taken and its plan to take to ensure its contracting agents, like the MACs, adhere to CMS guidance. The description should explain how CMS will monitor future compliance by the MACs. CMS should strive to promote policies that ensure it employees and agents alike do not negatively impact Medicare beneficiary access to new and emerging technologies, which may also reduce cost and improve health outcomes.

CMS-KINGSTON-4 Answer: The Social Security Act authorizes Medicare coverage decisions at both the national level, through the national coverage determination (NCD) process, and the local level, through decisions made by the Medicare contractors. If CMS has issued an NCD for a particular item or service, that NCD applies nationally and must be followed by all the Medicare contractors. However, most coverage decisions are made at the local contractor level, in the absence of an NCD – either pursuant to a local coverage determination (LCD) or based on a case-by-case determination by the contractor medical director.

Pursuant to guidance provided by CMS in the Program Integrity Manual, LCDs must be based “on the strongest evidence available”. CMS further outlines criteria to be considered by the contractors in developing an LCD, and requires them to provide opportunities for public comment. However, the contractors have broad discretion to establish local policies or make case-by-case determinations, absent an NCD. This broad discretion, based in statute, is meant to provide the contractors with flexibility to consider local practices and new technology that may not yet be widely or nationally available.

CMS uses Current Procedural Terminology (CPT) codes developed by the AMA to establish billing and payment codes for Medicare services. The AMA developed CPT Category III codes as a set of temporary codes to represent emerging technologies. These codes are used to report services with relevance to research, or to track and evaluate the frequency of use of such services. The Medicare contractors may cover items and services billed with Category III codes when such coverage is supported by available evidence, according to the criteria for LCDs. CMS works with the contractors to ensure that these criteria are followed in the development of LCDs.

In regard to Medicare coverage of treatment for lumbar spinal stenosis, on April 5, 2013, CMS opened a national coverage analysis (the first step in the NCD process) to review the available evidence on Percutaneous Image-guided Lumbar Decompression for Lumbar Stenosis. The status of this review can be followed through a tracking sheet available on the CMS website at <http://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=269&>. This review was open for an initial 30 day public comment period that ended on May 5, 2013, during which CMS requested public comment on clinical evidence of health outcomes of this procedure in the Medicare population. A proposed national coverage

decision will be issued by October 5, 2013, on which further public comments will be accepted for a 30 day period. A final decision is expected by early January 2014. In the interim, coverage or non-coverage of this procedure continues to be at the discretion of the Medicare contractors.

- 5) We understand CMS utilizes scores on the Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey for Inpatient Prospective Payment System payments and other determinations affecting hospitals. There is concern that Patient Mix Adjustments to the HCAHPS survey may disadvantage safety net hospitals by lowering the scores based on the characteristics of the populations served. Please describe how the adjustments used for the HCAHPS, including whether these adjustments properly reflect the quality of care provided by hospitals, do not disproportionately impact uninsured, and low-income, individuals.**

CMS-KINGSTON-5 Answer: In order to achieve the goal of fair comparisons across all hospitals that participate in HCAHPS, it is necessary to adjust for factors that are not directly related to hospital performance but do affect how patients answer HCAHPS survey items. These adjustments are intended to eliminate any advantage or disadvantage in scores that might result from the mode of survey administration or patient characteristics beyond a hospital's control. (See <http://www.hcahpsonline.org/modeadjustment.aspx>).

The HCAHPS Project Team has investigated safety-net hospitals' performance on HCAHPS scores and on the Patient Experience of Care Domain score in Hospital VBP and has found that these hospitals perform as well as non-safety-net hospitals in the official scores that use the current patient-mix adjustment methodology.

It should be noted that research on safety-net hospitals is fundamentally affected by how such hospitals are identified (See Zwanziger and Khan. "Safety-Net Hospitals." *Medical Care Research and Review*, 65: 478-495. 2008). We have employed the definition of safety-net hospital developed by the Agency for Healthcare Research and Quality: a hospital with share of Medicaid days greater than one standard deviation above the state Medicaid mean, in a county with a poverty rate greater than one standard deviation above state's mean county poverty rate, or in the top decile nationally for reported 'IPPS bad debt' as a percentage of total revenue (a measure of uncompensated care). Among hospitals that participate in HCAHPS, those that met one, two or all three of these criteria perform as well on HCAHPS as non-safety-net hospitals (those that met none of the criteria) using these currently adjusted scores.

- 6) In January the President issued a memorandum regarding firearms, one of the instructions in the memorandum requests CDC spend \$10 million to research causes and preventions of gun violence. Current law prevents any HHS funds provided through the appropriation process from being used such activity. Please explain where the funds for the requested gun advocacy activity will come from within CDC's current budget?**

CMS-KINGSTON-6 Answer: CMS is unable to comment on CDC's budget.

- 7) **On the critical access hospital review process, requests the Secretary establish a review process for those hospitals less than 35 miles by primary road from the nearest hospital as stipulated in section 1820(c)(2) of the Social Security Act for the purposes of improving access to essential health services, including acute medical inpatient care.**

CMS-KINGSTON-7 Answer: This question appears to relate to granting critical access hospital (CAH) status to hospitals that are less than 35 miles by primary road from the nearest hospital if doing so would improve access to essential health services. Please note that since 2006, all CAHs are required by statute to be no less than 35 road miles away from the nearest hospital or no less than 15 miles away in mountainous terrain. CMS has no discretion to waive or modify this requirement, so it is unclear what CMS would review under a review process.

- 8) **On educational material, I encourage CMS to ensure providers understand in advance the information that is required from patients in order to process requests for devices like power mobility. CMS should ensure clear standards to in provider educational guides and continue to develop ways to improve the process to reduce error rates and administrative burdens. Please provide an update on steps CMS is or will undertake to further these desires.**

CMS-KINGSTON-8 Answer: CMS conducted outreach and education including webinars, in-state meetings and other education sessions for suppliers, physician/practitioners and beneficiaries on Power Mobility Device (PMD) requirements. CMS published numerous educational materials to assist suppliers and physicians/practitioners on the policies and documentation requirements for PMDs. CMS recognizes the importance of consistency within this benefit and is in the process of developing an electronic clinical template as part of a provider's electronic health records.

CMS is currently testing prior authorization of PMDs in seven states. The Medicare Prior Authorization of PMDs Demonstration was implemented on September 1, 2012 in CA, IL, MI, NY, NC, FL and TX. CMS conducted extensive education and outreach before implementation to clarify all demonstration requirements to ordering physicians, practitioners, suppliers and beneficiaries. CMS has just entered the initial stages of collecting data to analyze and evaluate the effectiveness of the demonstration.

- 9) **On transcutaneous electrical nerve stimulation for chronic low back pain, I understand there is concern about changes in the May 2012 policy on Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain policy. Please conduct a review of these the policies to ensure the policy is consistent with the most current scientific evidence and is publically vetted prior to denying coverage. Please provide an update for the record on the timeline and findings of this review.**

CMS-KINGSTON-9 Answer: On June 8, 2012, CMS issued a final National Coverage Determination (NCD) on the use of Transcutaneous Electrical Nerve Stimulation (TENS) for chronic low back pain. The final NCD included consideration of public comments received on a

proposed decision that was issued in March 2012. Under the final NCD, Medicare will cover the use of TENS for chronic low back pain under “coverage with evidence development” (CED) – that is, this use of TENS is covered only for beneficiaries enrolled in an approved clinical trial. Chronic low back pain is defined as pain lasting 3 months or longer, and which is not caused by another primary illness like cancer or multiple sclerosis. Coverage of all other uses of TENS – including use for acute back pain or other types of pain – remained unchanged.

CMS initiated this coverage review after the American Academy of Neurology published a report finding TENS ineffective for chronic low back pain. Other professional groups such as the American College of Physicians and the American Pain Society came to the same conclusion, which was also confirmed by our own independent review of the best available clinical evidence. Based on this information, we concluded that the use of TENS for chronic low back pain does not produce a meaningful reduction in pain or improvement in function for Medicare beneficiaries.

However, rather than choosing to non-cover TENS for chronic low back pain, we are allowing the continued use of TENS for this purpose under CED to provide opportunities to develop further clinical evidence. The CED coverage will last for 3 years, providing TENS proponents time to develop studies, enroll participants and complete their analysis, and for CMS to reconsider its coverage if warranted by any new evidence. To date, we have received a few inquiries regarding CED as well as a draft research proposal, but we have not received any finalized requests for approval of a clinical trial studying the use of TENS for chronic low back pain.

10) On rural patient access, I understand there are concerns on the impact of CMS’s Durable Medical Equipment Competitive Bidding on rural patients’ access to providers. Please provide an analysis on how the changes in price and availability of providers in counties included in Competitive Bidding Areas, analyzing differences in counties which meet one, two and three of the criteria for exclusion are impacted.

CMS-KINGSTON-10 Answer: By statute, rural areas are exempt from competitive bidding competitions that occur prior to 2015 and are therefore not included in Rounds 1 or 2. CMS has closely monitored the results of the competitive bidding program since implementation to ensure that savings goals of the program have been achieved and – more importantly – to ensure that beneficiary access to appropriate supplies and equipment has not been compromised. To ensure effective monitoring, CMS implemented a real-time claims monitoring system which analyzes the utilization of the nine product categories. CMS’ claims monitoring system was designed to pay particular attention to potential changes in key secondary indicators such as hospital admissions, emergency room visits, physician visits, and admissions to skilled nursing facilities before and after the implementation of the new payment model. For the first year of the program, CMS’ real-time claims monitoring and subsequent follow-up has indicated that beneficiary access to all necessary and appropriate items and supplies has been preserved in the nine Round 1 competitive bid areas.

11) I am concerned CMS has not instituted a systematic processes within program and administrative operations to ensure information related to fraud, waste, and abuse activities focuses on pay it right the first time, in lieu of the focus on paying and chasing activities. Please describe what systems, tools, and mechanisms have been put in place to or are planned within the next year to ensure systematic process exist. Plus, provide the performance measures that will be used across CMS contractors and employees to improve prevention and increase the sharing of information between all the functions of CMS.

CMS-KINGSTON-11 Answer: Thanks to new authorities and resources provided by the Affordable Care Act and the Small Business Jobs Act of 2010, CMS has new powerful anti-fraud tools to shift the agency beyond a “pay and chase” approach to preventing fraud before it happens. These include provider risk-based screening and predictive analytic technology to identify fraudulent claims. We are also better leveraging our fraud and improper payment recovery contractors. Finally, CMS is collaborating in an unprecedented way with the private sector, law enforcement, and our State partners to share information and develop best practices in our fight against health care fraud.

Enhanced Provider Screening

As part of our enhanced program integrity efforts, CMS has implemented a risk-based screening process for newly enrolling and revalidating Medicare providers and suppliers. This screening process requires certain categories of providers and suppliers that have historically posed a higher risk of fraud to undergo greater scrutiny prior to their enrollment or revalidation in Medicare. In 2012, CMS began the implementation of the Automated Provider Screening System (APS). The APS is designed to move CMS away from manual provider screening and allow us to verify the data submitted on enrollment applications against independent commercial and health care data to establish eligibility for enrollment or revalidation in the Medicare program. Automating screening will also allow CMS to monitor on an ongoing basis any changes to the provider’s status (e.g. licensure, adverse actions against provider, etc).

Under the new Affordable Care Act screening requirements CMS has embarked on an ambitious project to revalidate the enrollments of all existing 1.5 million Medicare suppliers and providers. Doing so will ensure that only legitimate providers and suppliers serve our beneficiaries. Since March 2011, CMS validated or revalidated enrollment information for 458,435 Medicare providers and suppliers under the enhanced screening requirements of the Affordable Care Act. Because of revalidation and other proactive initiatives, CMS has deactivated 159,449 enrollments and revoked 14,009 enrollments.⁵ These efforts will ensure that only qualified and legitimate providers and suppliers can provide health care items and services to Medicare beneficiaries. These initiatives complement the traditional program integrity work and additional provider enrollment enhancements that CMS performs.

Fraud Prevention System

⁵ “Deactivate” means that the provider or supplier’s billing privileges were stopped, but can be restored upon the submission of updated information. Revoke means that the provider or supplier’s billing privileges are terminated and cannot be reinstated.

A key component of CMS's fraud fighting effort is the Fraud Prevention System (FPS), which was launched on June 30, 2011 pursuant to the Small Business Jobs Act of 2010. The FPS uses predictive analytics to analyze all Medicare fee-for-service claims using risk-based algorithms developed by CMS and the private sector prior to payment. CMS uses the FPS to target investigative resources to suspect claims and providers, and swiftly impose administrative action when warranted. The system generates alerts in priority order, allowing program integrity analysts to quickly investigate the most egregious, suspect, or aberrant activity. CMS and our program integrity contractors use the FPS information to stop, prevent, and identify improper payments using a variety of administrative tools and actions, including pre-payment review, claim denials, payment suspensions, revocation of Medicare billing privileges, and referrals to law enforcement.

Early results from the Fraud Prevention System show significant promise and CMS expects results to improve as the system matures over time. As reported in our first year Report to Congress⁶, in its first year of implementation, the Fraud Prevention System has already provided several measures of its effectiveness:

- Stopped, prevented or identified an estimated \$115.4 million in improper payments;
- Achieved a positive return on investment, saving an estimated \$3 for every \$1 spent in the first year;
- Generated leads for 536 new fraud investigations;
- Provided new information for 511 existing investigations; and
- Triggered 617 provider interviews and 1,642 beneficiary interviews regarding suspect claims or provider activity.

Importantly, the FPS is a resource management tool; the system automatically sets priorities for the ZPICs workload to target investigative resources to suspect claims and providers, and swiftly impose administrative action when warranted. The system generates alerts in priority order, allowing program integrity analysts to quickly investigate the most egregious, suspect, or aberrant activity.

MACs

CMS contracts with private firms to process and pay approximately 4.8 million Medicare claims per business day. These Medicare administrative contractors (MACs), are required to pay claims properly and administer the Medicare program effectively using "prepayment edits"—as internal controls in our claims processing systems that approve, deny or flag claims for additional review, by comparing claim information to Medicare requirements. Most of the prepayment edits implemented by CMS and its contractors are automated, meaning that if a claim does not meet the criteria of the edit, it is automatically denied. In a 2012 GAO Report <http://www.gao.gov/assets/650/649968.pdf> CMS reported that the use of prepayment edits saved Medicare \$1.76 billion in fiscal year 2010, but the reported total is likely to be an underestimate because CMS does not collect information on savings from all of its current edits.

⁶ Report to Congress: Fraud Prevention System First Implementation Year 2012
<http://www.stopmedicarefraud.gov/fraud-rtc12142012.pdf>

Recovery Audit Contractors (RACs)

The Recovery Audit Contractors are tasked with identifying a wide range of improper payments – including, but not limited to fraud – and making recommendations to CMS about how to reduce improper payments in the Medicare program. In the fee-for-service Medicare program, RACs have identified several vulnerabilities where CMS has implemented corrective actions to prevent future improper payments. For example, CMS' contractors have implemented edits to stop the payment of claims provided after a beneficiary's date of death, stop the payment of durable medical equipment claims while the beneficiary is receiving care in an inpatient setting, and stop the payment for individual services that should have been bundled into another payment. If RACs identify or uncover potential fraud, they are required to report it directly to CMS, and to refrain from reviewing claims that are subject to an ongoing fraud investigation. In FY 2012, Medicare fee-for-service RACs collected its largest amount yet --nearly \$2.3 billion in overpayments.

Partnership with Private Sector and with Law Enforcement

CMS is also collaborating in an unprecedented way with the private sector, law enforcement, and our State partners to develop best practices in our fight against health care fraud.

In addition to collaborating with other agencies, CMS is partnering with the private sector in anti-fraud efforts. Last year, HHS and DOJ launched a voluntary, collaborative partnership between the Federal government, State officials, several leading private health insurance organizations, and other health care anti-fraud groups.⁷ The goal of the partnership is to improve fraud detection and prevent payment of fraudulent health care billings by finding and stopping schemes that cut across public and private payers. The partnership will enable those on the front lines of industry anti-fraud efforts to share information more easily with investigators, prosecutors, policymakers and other stakeholders. It will help law enforcement officials to more effectively identify and prevent suspicious activities and use the full range of tools and authorities provided by the Affordable Care Act and other essential statutes to combat and prosecute illegal actions.

Established in July 2012, the agency's new Command Center is using advanced technologies and a collaborative environment to help multi-disciplinary teams of experts and decision makers more efficiently coordinate policies and case actions, reduce duplication of efforts, and streamline fraud investigations for more immediate administrative action. Since opening on

⁷The following organizations and government agencies are among the first to join this partnership: America's Health Insurance Plans, Amerigroup Corporation, Blue Cross and Blue Shield Association, Blue Cross and Blue Shield of Louisiana, Centers for Medicare & Medicaid Services, Coalition Against Insurance Fraud, Federal Bureau of Investigation, Health and Human Services Office of Inspector General, Humana Inc., Independence Blue Cross, National Association of Insurance Commissioners, National Association of Medicaid Fraud Control Units, National Health Care Anti-Fraud Association, National Insurance Crime Bureau, New York Office of Medicaid Inspector General, Travelers, Tufts Health Plan, UnitedHealth Group, U.S. Department of Health and Human Services, U.S. Department of Justice, and WellPoint, Inc.

July 31, 2012, CMS has led 61 missions that included over 450 unique participants from CMS and our partners, including the OIG and the Federal Bureau of Investigations (FBI) in the new Command Center. These collaborative activities enable CMS to take administrative actions, such as revocations of Medicare billing privileges and payment suspensions, more quickly and efficiently. The missions also help identify fraud vulnerabilities for new FPS models. CMS is also working with other Federal agencies combating fraud in the government in the Command Center to tackle cross-cutting issues surrounding fraud prevention.

12) Please provide describe how CMS links its overall strategic plan and vision for operations, program integrity, information technology and other areas in to a comprehensive approach to measurable objectives and resource allocation decisions. The response should include the annual performance measures for key CMS funding request items for fiscal year 2013 and 2014.

CMS-KINGSTON-12 Answer: Every four years, the Department of Health and Human Services (HHS) updates its strategic plan as required by the Government Performance and Results Act (GPRA) of 1993 (Public Law 103–62) and the GPRA Modernization Act (GPRA-MA) of 2010 (PL 111-352). HHS’ plan defines its mission, goals, and the means by which it will measure its progress in addressing mission-related challenges. CMS Strategic Plan directly aligns with the HHS plan. As we refine our Strategic Plan over time, we align and draw upon the various planning efforts at work throughout the federal government. This alignment helps ensure that the CMS Strategic Plan reflects the most current priorities and best available thinking, while also providing a coordinated implementation approach that ensures the Strategic Plan is put into action.

CMS will continue to leverage our internal resources and external partnerships to fulfill our mission – as an effective steward of public funds, CMS is committed to strengthening and modernizing the nation’s health care system to provide access to high quality care and improved health at lower cost. Performance measures for all CMS budget requests can be found in the FY 2013 and FY 2014 Congressional Justifications.

In our effort to fulfill this charge, our vision of future success is a high quality health care system that ensures better care, access to coverage and improved health. We are focused on measurably improving care and population health by transforming the U.S. health care system into an integrated and accountable delivery system that continuously improves care, reduces unnecessary costs, prevents illness and disease progression, and promotes health. We will find better ways to ensure the right care is accessible and delivered to the right person at the right time, every time.

To fulfill our mission and achieve our vision of a high quality health care system, CMS has chosen four Strategic Goals that we must achieve. These strategic goals cut across programs and support functions throughout CMS. In addition, each Strategic Goal is described in “end state” language that describes the goal’s intent.

Goal 1: Better Care and Lower Costs – Beneficiaries receive high quality, coordinated, effective care. As a result, health care costs are reduced.

Goal 2: Prevention and Population Health – All Americans are healthier and their care is less costly because of improved health status resulting from use of preventive benefits and necessary services.

Goal 3: Expanded Health Care Coverage – All Americans have access to affordable health insurance options which protect them from financial hardship and ensure quality health care coverage.

Goal 4: Enterprise Excellence – We will have achieved “Enterprise Excellence” when CMS’ high quality, diverse workforce develops, supports, and utilizes innovative strategies, tools, and processes, and collaborates effectively with its partners and agents to reach its goals.

13) In the FY 2013 budget request the CMS did not provide the details for all resources available to perform its CMS functions, not just plans for the discretionary funding portion of the request. If the FY 2014 budget request does not provide this level of detail – please provided tables include the prior year actual, current year request level, current year actual (based on the operating plan) and budget request year level that include a breakout of all resources available for each program to support CMS operations. In addition, the CMS operating plan should provide the detail level of the programs, projects, and activities and should include the prior year actual level, request level, and operating plan level that serves as the starting point for potential future reprogramming actions.

CMS-KINGSTON-13 Answer: Following the enactment of a budget or continuing resolution, CMS anticipates delivering an updated FY 13 operating plan to Congress that details the distribution of its resources.

14) The Senior Medicare Patrol program is supported in part by Health Care Fraud and Abuse Control (HCFAC) funds. Please explain why this program which is designed to assist the HCFAC program through the identification of fraudulent claims to Medicare beneficiaries is not fully funded in total from these HCFAC funds?

CMS-KINGSTON-14 Answer: The Senior Medicare Patrol program has, from its creation in the mid 1990s, been funded through direct appropriations under the authority of title IV of the Older Americans Act. SMP provides competitive grants to States and Territories to support a national volunteer-based network of retired seniors whose purpose is to educate older adults on preventing and identifying healthcare fraud and abuse. Subsequent to the creation of the SMP program, the HHS Office of the Inspector General (OIG) initiated Operation Restore Trust, which was charged with combating “waste, fraud and abuse” in Medicare and funded with HCFAC money. Once Operation Restore Trust was underway, the Administration on Aging proposed integrating their SMP grants with this larger initiative, and requested HCFAC funding to help AoA support, coordinate and track its SMP activities. HCFAC funding was provided and AoA has worked collaboratively with the OIG, CMS, DoJ and other partners on these activities since that time, continuing to receive discretionary appropriations for the State grants and

mandatory HCFAC funding for the supporting infrastructure. In FY 2012, the HCFAC wedge funding provided directly to ACL was increased by the Secretary of HHS and used to provide supplemental funding for expansion grants to SMP grantees to enhance their ability to fight Medicare fraud in high-fraud areas. These expansion grants are in addition to the base grants, which are paid out with funds appropriated in the Older Americans Act.

HCFAC funds are provided annually under per the Section 1817(k)(3)(a) of the Social Security Act, which appropriates monies from the Medicare Trust Funds to an expenditure account that is jointly allocated between the Department of Justice and HHS by the Attorney General and the Secretary of HHS. Some of these funds are specifically directed to OIG; remaining unallocated amounts, referred to as “wedge” funding, are then allocated to related anti-fraud and abuse activities by the Secretary and Attorney General. ACL receives a portion of the HHS “wedge” to administer and provide expanded grants for the SMPs.

15) It has come to my attention that there are potential unintended consequences of the Medicare Recovery Audit Program (RAC). Specifically, Georgia hospitals have reported that 80% of the cases heard by the Administrative Law Judges are being overturned in favor of the provider. Specifically, I understand from the Office of Hearings and Appeals that in total about 50% of all appeals we fully or partially overturned. Plus, of the remaining 50% another almost 37% were fully or partially overturned at the Departmental Appeal Review process.

CMS-KINGSTON-15a Answer: The CMS reports appeal statistics in the annual Report to Congress and on its website at www.cms.gov/rac. The most recent published appeal statistics are for FY 2011 and the total overturn rate of Recovery Auditor decisions was actually 2.9%. I would note that providers do not appeal Recovery Auditor decisions nearly 90 percent of the time. The 2.9% statistic is the overturn rate based on the total number of improper payment determinations. In addition, for a claim to reach the ALJ level of appeal, a Recovery Auditor determination would have to have been upheld at the first and second level of appeal by two independent appeal entities and at the second level of appeal an independent physician review was required for which claims involved medical necessity. Many of the claims that were overturned by the ALJ related to claims denied for an inpatient service, where the ALJ agreed with the Recovery Auditor denial for the inpatient service but allowed the provider to rebill for the outpatient service.

I fully support efforts to reduce improper payments and often advocate for more focus to be placed on combating fraudulent activity. However, I am concerned that extremely high overturn rates may indicate a flaw in the current RAC process and types of cases being reviewed. This process has become overly burdensome to hospital operations without resulting in an increase of successful RAC cases. It also increases the cost to taxpayers as the appeals process becomes overburdened and results in requests for increased resources to optimize and ineffective front-end process. I hope there is a way to achieve the goals intended by CMS in a manner that would be more appropriate to the hospital community while also addressing improper payments.

Please explain how CMS and the RAC systematically review the claims overturned through the appeal process to improve the front-end identification process to reduce the appeal workload and burden on the medical providers and hospital systems. Further, explain how CMS plans to put in place controls and tools to track this issue and improved the value of the RAC and appeal process.

CMS-KINGSTON-15b Answer: CMS does review appeal decisions at every level to determine if there are systematic issues with contractor review decisions. The review contractors also follow these decisions very closely to inform their reviews in the future.

One example where CMS made a policy change based on ALJ decisions is related to hospital rebilling of claims denied for place of service. In these situations the ALJ agreed with the review contractors that the beneficiary should have been an outpatient rather than an inpatient. However, the ALJ ordered CMS to pay full benefits under Medicare Part B, contrary to CMS policy. It should be noted that these situations show up in the appeal statistics as “in favor” of the appellant even though the ALJ upheld the review contractor’s decision to deny the inpatient service. CMS policy allowed providers to bill for limited ancillary services under Part B when inpatient stays are denied as not reasonable and necessary, however, in these cases the ALJs ordered CMS to pay for all Part B services that would have been reasonable and necessary if the beneficiaries had been treated as outpatients. In response to these kinds of decisions, CMS released CMS Ruling 1455-R on March 13th 2013. This ruling permits providers to submit Part B inpatient claims for those services that would have been payable if the beneficiary had been treated as an outpatient, rather than admitted as an inpatient, thereby decreasing the provider burden resulting from total payment denials. The release of CMS Ruling 1455-R will ensure consistent application of CMS policy throughout all levels of Medicare appeal and remains in effect until the effective date of final regulations for the proposed rule entitled, “Medicare Program; Part B Inpatient Billing in Hospitals,” which was also released on March 13, 2013, and which contains proposals that differ slightly from the policies included in CMS Ruling 1455-R. CMS is diligent in its oversight of Recovery Auditors and their decisions. Each month CMS conducts accuracy reviews of the decisions of Recovery Auditors. The CMS reports the accuracy rates in the annual Report to Congress (RTC). The FY 2011 RTC can be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Recovery-Audit-Program/Downloads/FY2011-Report-To-Congress.pdf>. In addition, to the accuracy reviews conducted by CMS, it should be noted that for a claim to make it to the ALJ level of appeal, the original decision of the claims reviewer would have to have been upheld (at least in part) at two levels of appeal. At the second level of appeal (reconsideration), if the matter under appeal involves a medical necessity decision, a panel of physicians or other appropriate health care professionals is also involved in the review of the appeal.

16) I urge you to reassess the current RAC system and investigate the reasons behind an 80% overturn rate in order to maintain a system aimed at addressing improper payments without unnecessarily burdening good actors. Thank you for your time and consideration of this matter.

CMS-KINGSTON-16 Answer: CMS is diligent in its oversight of Recovery Auditors and their decisions. Each month CMS conducts accuracy reviews of the decisions of Recovery Auditors.

The CMS reports appeal statistics in the annual Report to Congress and on its website at www.cms.gov/rac. The most recent published appeal statistics are for FY 2011 and the total overturn rate of Recovery Auditor decisions was 2.9%.

17) The CMS Innovation fund is conducting comparative effectiveness research on prenatal care models to reduce elective deliveries. PCORI is also looking at this same research area. What is the specific process that was used to coordinate w PCORI to ensure efforts complement rather than duplicate each other?

CMS-KINGSTON-17 Answer: The Strong Start for Mothers and Newborns initiative, a joint effort between the CMS Innovation Center, the Health Resources and Services Administration (HRSA), and the Administration on Children and Families (ACF), aims to reduce preterm births and improve outcomes for newborns and pregnant women. On February 8, 2012, CMS announced the two strategies of this initiative to achieve these goals. The first is a public-private partnership and awareness campaign to reduce the rate of early elective deliveries prior to 39 weeks for all populations. The other component is a funding opportunity to test the effectiveness of specific enhanced prenatal care approaches to reduce the frequency of premature births among pregnant Medicaid or Children's Health Insurance Program (CHIP) beneficiaries at high risk for preterm births.

The Strong Start effort to test new approaches to prenatal care is a four-year initiative to test and evaluate enhanced prenatal care interventions for women enrolled in Medicaid or CHIP who are at risk for having a preterm birth. The goal of the initiative is to determine if these approaches to care can reduce the rate of preterm births, improve the health outcomes of pregnant women and newborns, and decrease the anticipated total cost of medical care during pregnancy, delivery, and over the first year of life for children born to mothers in Medicaid or CHIP.

The Innovation Center seeks to ensure that our efforts build, strengthen and complement, not duplicate, other federal grant programs and initiatives. Reducing adverse outcomes for maternal and prenatal populations is a priority across several of our agency programs to ensure that we can provide quality care while lowering costs and improving overall health and outcomes for the populations we serve.

18) Prior to the enactment of the American Taxpayer Relief Act of 2012, did Centers for Medicare and Medicaid Services conduct a cost comparison of the various types of radiosurgery considering cost of individual treatments as well as number of treatments needed to correct brain indications?

CMS-KINGSTON-18 Answer: While we consider various configurations of ambulatory payment classifications (APCs) as part of our rulemaking process, and as a result consider the cost of different services that are clinically similar, we have performed no formal cost comparisons of the various types of radiosurgery considering both the cost of individual treatments and the number of treatments needed.

Health Resources and Services Administration (HRSA)**QFRs from Chairman Kingston****HRSA-KINGSTON-1**

1: I know that we recently had over 8,000 people on waiting lists to access medications for the AIDS Drug Assistance Program (ADAP), but that has been reduced due to some increased funding. What will happen if funding for ADAP was decreased, either through sequestration or appropriations?

A: HRSA closely monitors ADAP and provides technical assistance to help states forecast demand, identify additional cost saving opportunities. In the event of decreased funding, HRSA will work with states to assist individuals on ADAP waiting lists with accessing alternative resources for HIV/AIDS prescription drugs such as manufacturer's pharmaceutical patient assistance programs.

HRSA-KINGSTON-2

2: The Ryan White HIV/AIDS Program currently provides care, treatment and support services to nearly 550,000 people with HIV/AIDS in our country. With implementation of the Affordable Care Act (ACA) and many people gaining coverage through private insurance and expanded Medicaid, how will this impact the Ryan White Program in the future?

A: ACA will provide primary medical care coverage for many people living with HIV (PLWH) in States that expand Medicaid and through access to private health insurance. However, the actual scope of coverage for Ryan White HIV/AIDS services in the context of expanded Medicaid program will be determined by states. It is likely that in many states, coverage for the Ryan White service categories will be included in the essential health benefits package and reflected in each state's individualized Medicaid, Basic Health Plans, and qualified health plans offered through the Marketplaces (aka Exchanges). We understand that the challenges of improving health outcomes for PLWH are best addressed by a comprehensive care management approach reflected in the Ryan White HIV/AIDS Program (RWP). The RWP will remain vital to ensuring that PLWH remain in care and on medications, which is essential to decreasing HIV/AIDS morbidity and mortality and preventing transmission of the disease. . Many Ryan White Program services are not typically covered by Medicare, Medicaid or private health insurance, and are not explicitly included in the essential health benefits (EHB) as defined by the Affordable Care Act. For example, Ryan White Early Intervention Services such as referral services and linkage to care will not be covered under EHB. Other services that are critical to engaging and retaining people living with HIV (PLWH) in care such as medical case management, treatment adherence counseling, and other core medical services such as adult dental and vision services are not required to be covered as essential health benefits. There will be continued need for these and other services provided through the Ryan White HIV/AIDS Program.

HRSA-KINGSTON-3

3: Currently, about 70 percent of people in the Ryan White Program have some sort of health coverage, predominately from Medicaid or Medicare. Will health care reform impact their needs and their reliance on Ryan White services and programs?

A: An issue brief released by HHS/Assistant Secretary for Planning and Evaluation in February 2012 entitled *Medicare Beneficiary Savings and the Affordable Care Act* provides estimates of Medicare Parts A, B, and D savings from the Affordable Care Act to seniors and people living with disabilities enrolled in traditional Medicare. According to this issue brief, the ACA will favorably affect beneficiary expenditures in four ways: lowering part B premiums growth, lowering beneficiary copayments and coinsurance growth under Part A and B, closing the Medicare prescription drug coverage gap, and providing many preventive services to seniors at no additional cost. The Affordable Care Act also provides States the option to enhance Medicaid coverage by expanding full Medicaid eligibility to non-elderly adults under 138 percent of the Federal Poverty Level (FPL).

However, as noted in Question #2, many Ryan White Program services are not typically covered by Medicare, Medicaid, or private health insurance, and are not explicitly included in the essential health benefits (EHB) as defined by the Affordable Care Act. Services that are critical to engaging and retaining people living with HIV (PLWH) in care such as medical case management, treatment adherence counseling, and other core medical services such as adult dental and vision services are not required to be covered as essential health benefits. There will be continued need for these and other services provided through the Ryan White HIV/AIDS Program. By keeping people living with HIV in care and on medications, the Ryan White program plays a critical role in preventing the spread of HIV epidemic, as people living with HIV who are on antiretrovirals and virally suppressed are much less likely to transmit the infection. Ryan White Program service utilization data show that one-third of the clients receiving medical case management services that include treatment adherence counseling in 2010 were Medicare beneficiaries or Medicaid recipients. Over 40 percent of the clients receiving RWP-funded medical nutrition therapy in 2010 were Medicare beneficiaries or Medicaid recipients. Clients with traditional Medicaid were more likely to receive RWP-funded home health care and home and community-based services.

HRSA-KINGSTON-4

4: Massachusetts has already expanded health care coverage in their state. Can you explain how they utilize Ryan White Program funds for people with HIV in their state and the results that they have experienced?

A: The Massachusetts experience with the transition to health care reform has been very informative for how we think about the Ryan White Program (RWP) and ACA going forward. Specifically, we have two examples of how the RWP and the Massachusetts (MA) Health Care Reform (HCR) experience intersect:

- As HCR has been implemented, MA has continued to demonstrate a commitment to supporting health care for its residents. This means that they strategically utilized Ryan White funding to support insurance premiums assistance and coverage completion for core medical and support services that maintain PLWH in care – the end result being improved morbidity and mortality. Overall morbidity (newly diagnosed and reported cases) has decreased by 45 percent from 2006 to 2010 and mortality (deaths) has decreased by 44 percent between 2002 and 2008.
- The Boston Public Health Commission (the Part A grantee) applied for and has received a waiver of the Ryan White HIV/AIDS Program core medical services requirement that at least 75 percent of funds by a grantee must be spent on core medical services although the majority continues to be spent on medical case management and treatment adherence services. This flexibility in the context of ACA may, like in the case of MA, provide us with the tools and case studies on how the RWP may need to be applied in the future in other jurisdictions. By allowing Boston more flexibility to determine how to spend their grant dollars under their health reform program, they have managed to decrease their epidemic in the state.

HRSA-KINGSTON-5

5: How are you preparing Ryan White Program grantees for implementation of the Affordable Care Act?

A: HRSA has been preparing Ryan White Program grantees for ACA implementation by bolstering our outreach and enrollment activities. Our recent activities include:

Communication Efforts

- Launched RWP-ACA Mailbox for grantees to submit ACA questions at: RWP-ACAQuestions@hrsa.gov.
- Launched ACA Webpage on HAB website “Ryan White and the Affordable Care Act: What You Need to Know” at: <http://hab.hrsa.gov/affordablecareact>.
- Launched ACA Section on TARGET Center site at: <https://careacttarget.org/library/affordable-care-act-and-ryan-white-program-learning-modules>.

Outreach and Enrollment

- Letter and chart posted on HAB ACA webpage to inform grantees about how they can use existing program resources to prepare for ACA implementation.
- Posted Key Provisions of ACA document for Ryan White Program Grantees on HAB ACA webpage.
- Posted non-exhaustive list of essential community providers (ECPs) from CMS on HAB ACA webpage.

New Policies

Newly posted Program policies 13-01 and 13-02 on the HAB ACA webpage:

- 13-01 – This policy clarification reiterates HRSA policy regarding Ryan White HIV/AIDS Program (RWHAP) clients who are currently eligible for Medicaid or will become eligible for Medicaid beginning on or after January 1, 2014.
- 13-02 – This policy clarification outlines the Ryan White HIV/AIDS Program (RWHAP) expectations for client eligibility assessment and clarifies the recertification requirements.

Grantee and Stakeholder Training

- Held first in a series of ACA-related webinars co-hosted with CMS on April 5th. The first webinar was titled “The Affordable Care Act and the Ryan White HIV/AIDS Program: Eligibility 101.” Over 570 participants connected by webinar and over 680 participants connected by phone (some participants joined via both webinar and phone).

Development of Technical Assistance and Tools

- Working with HRSA Outreach and Enrollment Workgroup to ensure HRSA grantees are assisting clients to enroll in new health insurance options.
- Drafting FAQs for common ACA questions.
- Working with AIDS Education and Training Centers National Resource Center to develop toolkit to help grantees and providers enter into new Managed Care contracts.
- Initiated task under HAB TA Contract to develop other tools needed by grantees and RWP clients.

QFRs from Congressman Simpson**HRSA-SIMPSON-1****1. How will the sequestration affect dental residencies?**

A: HRSA is working to determine the impact on grant funding amounts. Our goal is to minimize the negative impact of sequestration on our grantees while working within the budgetary parameters established by the Congress and the President.

HRSA-SIMPSON-2**2. Can you give me an idea of how much money will HRSA attempt to budget for general practice, pediatric and public health dental residencies for FY14? How does that compare to current funding? Will you be able to seek grants in FY14 for general practice, pediatric or public health residencies? Will that be a goal?**

A: HRSA will follow whatever decision Congress and the President ultimately make regarding budget allocations in FY 2014. Based on the projected funding levels and commitments to current grantees, we do not anticipate any new funding opportunities in FY 2014. The anticipated FY 2014 continuation commitments to current grantees in our Postdoctoral Training in General, Pediatric, and Public Health Dentistry program is \$9.222 million. The funding breakdown may vary slightly from the current 25% for general dentistry, 72% for pediatric dentistry, and 3% for dental public health residencies with differences due to variations in individual grantee budgets from year-to-year. Residency programs may also apply for our Faculty Development and Dental Faculty Loan Repayment programs.

HRSA-SIMPSON-3**3. Several years ago this Committee requested that HRSA name a chief dental officer. Who is serving in that position now? What are the duties of that person? Does that person answer directly to you?**

A: Currently CAPT Renee Joskow serves as HRSA's Senior Dental Advisor and is responsible for coordinating oral health activities across all HRSA programs, advises program officials throughout HRSA on the recruitment, assignment, deployment, retention, and career development of dentists and other oral health professionals within the agency. The Senior Advisor position encompasses the same reporting level and duties of the Chief Dental Officer.

HRSA-SIMPSON-4**4. I understand that HRSA has put out a consensus statement on oral health and pregnancy. My understanding is that such a statement was needed because there was confusion about whether a pregnant woman should undergo dental treatment.**

(a) Can you tell me what the statement recommends to dentists and other primary care providers? (b) What action do you plan to take as a next step to issuing the statement? (c) Are you working in partnership with dental groups like the ADA?

A: (a) *Oral Health Care During Pregnancy: A National Consensus Statement—Summary of an Expert Workgroup Meeting* presents a summary of an expert workgroup meeting held on October 18, 2011, in Washington, DC, convened by HRSA in collaboration with the American College of Obstetricians and Gynecologists (ACOG) and the American Dental Association (ADA). This document was released to the public in July, 2012. A supplemental document, *Oral Health Care During Pregnancy: A National Consensus Statement*, was also recently released.. This document is posted at http://www.mchoralhealth.org/materials/consensus_statement.html .

It is essential for health professionals (*e.g.*, dentists, dental hygienists, physicians, nurses, midwives, nurse practitioners, physician assistants) to provide pregnant women with appropriate and timely oral health care, which includes oral health education. Yet, in many cases, neither the pregnant woman nor the health professional understand that oral health care is an important component of a healthy pregnancy.

This document provides guidance on oral health care for pregnant women for both prenatal health and oral health professionals. It includes pharmacological considerations for pregnant women and guidance to share with pregnant women that all professionals can use when caring for pregnant women.

(b) Dissemination and implementation of the guidance in the consensus statement will foster change by improving health professionals' awareness of the importance of oral health during pregnancy and their understanding that it is safe to provide oral health care to pregnant women; in turn, the oral health of pregnant women and, ultimately, of their children, will improve. In June, 2012, members the original Perinatal Planning Committee reconvened to develop a strategic path for dissemination and implementation of the guidance. A summary of this meeting is posted at http://www.mchoralhealth.org/materials/consensus_statement.html . The National Maternal and Child Oral Health Resource Center (OHRC) at Georgetown University is supporting HRSA's efforts to inform the necessary stakeholders, highlighting this resource and others that will support professionals working in states and communities to plan, develop, and implement programs that ensure pregnant women receive optimal oral health services. A brief sample of dissemination efforts include:

- This OHRC web page has received 5,116 hits and was the third most popular page on OHRC's website for this 9-month period.
- In response to requests, 9,646 copies of the consensus statement have been distributed. Examples of requests include:

- ADA's annual session, perinatal continuing education course (San Francisco, CA)
- Private practice dentist to provide outreach and education to physicians' offices (Forest Park, IL)

- MassHealth, Office of Clinical Affairs in collaboration with a statewide coalition of community health centers for distribution to community health center-based Medicaid providers and allied health staff throughout state (Boston, MA)
- Oral Health Network of Missouri and Missouri Primary Care Association hosted Perinatal Oral Health Workshop for oral health and medical professionals from Missouri's community health centers (Jefferson City, MO)
- Newark Beth Israel Medical Center for general practice residents and for lecture room library (Newark, NJ)
- Neighborhood Health Center to distribute to medical professionals and oral health professionals to integrate and coordinate oral health care for clients in both their primary care and their oral health care sites (Oregon City, OR)

(c) Representatives from the ADA and ACOG participated in the Perinatal Planning Committee (now called the Perinatal Advisory Committee), which convened for the first time to develop an agenda for the *Improving Perinatal Oral Health: Moving Forward – An Expert Meeting*, held September, 2008. The first of five priority strategies identified during this meeting, determined necessary for the improvement of oral health care during pregnancy, was the impetus behind the development of the national consensus statement.

A conference call with the Perinatal Advisory Committee was held on January 25, 2013, to discuss progress in achieving the dissemination and implementation efforts planned, in particular relating to activities on behalf of the ADA and ACOG. Another call is planned for April 26, 2013, to discuss recent promotion and implementation efforts and to refine the action plan to address one or more priority strategies (from a set of five priority strategies developed out of the *Improving Perinatal Oral Health: Moving Forward – An Expert Meeting*).

HRSA-SIMPSON-5

- 5. More and more patients are seeking oral health care in hospital emergency rooms. Usually all the ER can do is provide antibiotics and pain relief. They generally don't provide dental care. We are aware of at least two ER dental diversion programs aimed at getting the patients out of the ER and into a dental program. One program has saved the local hospital \$6 million in 4 ½ years. What can HRSA do to promote more programs like this?**

A: HRSA is working in a number of capacities to improve access to oral health services so that patients do not have to rely on emergency rooms where they may not receive all the care they need. Specifically, HRSA is supporting activities to improve access through increasing the number, distribution and training of providers.

National Health Service Corps:

Increase the number and distribution of dental providers practicing in safety net settings by providing scholarships and loan repayment.

Interprofessional Oral Health Core Clinical Competencies:

By increasing the number of providers trained in oral health screening, prevention and referral, patients get the care they need before it becomes an emergency. HRSA is leading an

effort to define, disseminate, and implement oral health clinical competencies that prepare safety net primary care providers with the knowledge, attitudes and skills to work proactively and cooperatively regarding patients' oral health needs.

HRSA also funds a cooperative agreement with the National Network for Oral Health Access (NNOHA) that has a pilot project in Federally Qualified Health Centers on implementation strategies regarding, and the evaluation of, interprofessional oral health core clinical competencies in practice. If the implementation strategies of oral health competencies by primary care providers are demonstrated to be effective, they would increase access to oral health care. In addition, NNOHA provides oral health leadership training and technical assistance to support oral health programs in the safety net settings, and has a promising practice database and various communication vehicles (newsletter, issue brief, webinars), that could disseminate innovative models to reduce dental ER visits to its members and stakeholders.

National Opinion Research Center:

HRSA's Office of Rural Health Policy (ORHP) has funded the National Opinion Research Center (NORC) to develop an evidence-based toolkit around oral health. This toolkit was comprised of extensive literature reviews regarding oral health models around the country including examples of ER diversion projects. The findings were compiled and used towards the development of the toolkit, which is organized by modules. The modules include Barriers, Models, Implementation of Models, Planning for Sustainability, Evaluation and Dissemination. The toolkit will be hosted by the Rural Assistance Center (RAC), at www.raconline.org (available in Summer, 2013).

Oral Health Workforce Grant Program:

HRSA's State Oral Health Workforce grant program currently funds 34 states to improve dental and oral health access through workforce development and prevention strategies. This program provides States flexibility in developing and implementing innovative programs to address their individual dental workforce needs in Dental Health Professional Shortage Areas. Alaska is working to collect surveillance data on general anesthesia cases in Alaska for treatment of early childhood caries and dental-related emergency room visits that will be used to inform workforce programs. In addition, 22 states conduct community-based prevention services such as community water fluoridation and dental sealant programs that increase access to preventive services in underserved areas. (Only Alaska currently has an activity related to ER visits.)

Dr. Frieden (CDC) -

1) Thank you again for maintaining the Division of Oral Health. I know it is one of your smallest divisions but they play an important role in dentistry. They have formed great partnerships with the various dental organizations and interact with them to promote research, patient care and state level oral health care programs. The Division of Oral Health grants to states have been instrumental in helping states maintain their oral health programs. With the funding they have been able to maintain a state dental office and maintain oral health prevention programs like placing sealants on children's teeth. What is

the status of this program? Is it facing cutbacks? Does your FY14 budget allow you to increase the number of states who will receive funding?

CDC-SIMPSON-1 RESPONSE:

Centers for Disease Control and Prevention (CDC) announced the availability of FY 2013 funds to implement the State Oral Disease Prevention Program in April. The overall purpose of this Funding Opportunity Announcement is to assist state health departments to build and/or maintain effective public health capacity for implementation, evaluation, and dissemination of best practices associated with oral disease prevention and improvement of oral health. We expect to fund up to 20 states.

- 2) **According to government contract and grant tracking data – USA Spending.gov – Health & Human Services has provided the National Academies of Sciences about \$258 million dollars through over 1,120 contracts and over 150 grants since 2005. Please provide to the committee a list of contracts and grants, the amounts provided, and a description of each, that have been provided by the CDC to the National Academies of Sciences Institute of Medicine since 2005.**

CDC-SIMPSON-RESPONSE 2:

Contract Type	2005-2012 CDC Contracts with National Academy of Sciences* (dollars in thousands)							
	2005	2006	2007	2008	2009	2010	2011	2012
MARKETING CONSULTING SERVICES	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$136
ENVIRONMENTAL CONSULTING SERVICES	\$0	\$0	\$25	\$0	\$125	\$50	\$2,137	\$1,229
OTHER SCIENTIFIC AND TECHNICAL CONSULTING SERVICES	\$2,474	\$3,242	\$2,141	\$905	\$1,060	\$225	\$217	\$219
RESEARCH AND DEVELOPMENT IN THE PHYSICAL, ENGINEERING, AND LIFE SCIENCES	\$1,100	\$0	\$0	\$0	\$0	\$0	\$0	\$0
RESEARCH AND DEVELOPMENT IN THE PHYSICAL, ENGINEERING, AND LIFE SCIENCES (EXCEPT BIOTECHNOLOGY)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$50
ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES	\$25	\$0	\$0	\$0	\$0	\$0	\$0	\$0
OFFICE ADMINISTRATIVE SERVICES	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$20
MEDICAL LABORATORIES	\$700	\$345	\$744	\$4,761	\$1,328	\$3,098	\$0	\$0
OTHER	\$835	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total	\$5,134	\$3,587	\$2,910	\$5,611	\$2,512	\$3,373	\$2,354	\$1,653

**2005-2012 CDC Contracts with National Academy of Sciences*
(dollars in thousands)**

Grant Type	2005	2006
Assistance Programs for Chronic Disease Prevention and Control	\$992	\$0
CENTERS FOR AGRICULTURAL RESEARCH AND MUSCULOSKELETAL	\$0	\$69
Occupational Safety and Health Program	\$0	\$972
Public Health and Social Services Emergency Fund	\$0	\$81
Total	\$992	\$1,122

*All data from USASpending.gov

AHRQ QFR from Congressman Simpson

1. Do you do any oral health research? Why not?

Dr. Clancy: AHRQ conducts and sponsors health services research focused on how social factors, financing systems, organizational structures and processes, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately, our health and well-being. Within this framework, AHRQ also supports dental research efforts. The primary emphasis of these oral health research studies is concentrated on the production of evidence reports for the United States Preventive Services Task Force (USPSTF) and research findings based upon data obtained from AHRQ's Medical Expenditure Panel Survey (MEPS), Healthcare Cost and Utilization Project (HCUP) and the Consumer Assessment of Healthcare Providers and Systems (CAHPS) program. For more complete information, please see the agency's dental research summary provided at : <http://www.ahrq.gov/research/findings/final-reports/oral-health/index.html>.

NIH-Simpson-1. I know that NIH does a lot of research to better detect and diagnose diseases at the earliest possible stage before they become difficult and expensive to treat. Some of that research involves using saliva as a way to pick up early signals for various diseases including prostate, breast and oral cancer. Can you give us an update on how that research is going? If this research proves to be successful couldn't it save a lot of money in not using x-rays or performing invasive procedures?

Answer. Many indicators or "biomarkers" of disease, disorders, or clinical risk factors can be obtained from saliva, making it an easy to obtain, non-invasive source of information. The National Institute of Dental and Craniofacial Research (NIDCR) funds research to develop new saliva-based assays, improve related technology and to identify and validate new potential biomarkers. For example, there are currently, three NIDCR clinical studies ongoing which test the utility of potential diagnostics:

- 1) A team of investigators has developed a "lab-on-chip" sensor system suitable for analysis of small volumes of saliva for several biomarkers at the same time. During the project's first phase, the research team identified promising biomarkers for cardiac events and developed

the miniaturized, portable platform technology. The clinical research study is evaluating these biomarkers for diagnostic purposes. Recruitment of subjects for this study is well under way while laboratory efforts are focused on the development and subsequent validation of a panel of biomarkers indicative of a heart attack.

- 2) The same lab-on-chip technology is also being used in another project to monitor for changes that could signal oral cancer. By using a minimally-invasive brush biopsy to obtain oral tissue from lesions in the mouth, physical cell measurements and chemical expression of molecular biomarkers will be examined in an automated manner using pattern recognition techniques and advanced statistical methods. By providing results in a matter of minutes as compared with days for traditional pathology, this novel approach has already demonstrated its ability to distinguish between normal mucosa and oral cancer lesions. Recruitment of subjects is complete and the biomarker panel is being analyzed and validated.
- 3) A new clinical research study is under way to analyze saliva for potential biomarkers indicative of Sjögren's Syndrome, an autoimmune disease affecting approximately 4,000,000 Americans, predominantly women. The dominant symptoms of Sjögren's Syndrome are dry eyes and dry mouth. Because Sjögren's Syndrome often mimics other conditions, patients may suffer for years before receiving a diagnosis and appropriate treatment. Recruitment for this study will begin soon after all clinical sites have been trained and inspected on the study procedures.

Biomarkers obtained from saliva can be excellent sources of biomarker indicators of a disease or disease risk. Although, they are not currently ready to replace more precise diagnostic tests, they have the potential to speed diagnoses, promote earlier initiation of therapy, and offer the potential for financial and physical relief from repeated invasive procedures or radiation exposure. The value of salivary diagnostic research is in its potential to develop cost-effective, minimally invasive testing protocols for circumstances such as the monitoring of suspicious mouth lesions for change over time or increasing the speed of diagnosis of acute heart attack.

NIH-Simpson-2. I understand that one of the most significant challenges of clinical research is successful translation of research findings to "real-world" clinical practice and into the community. I think the concept of practice-based research - where the research is actually done in "real world" conditions – like a dentist's office - is especially valuable. Can you tell us about what NIH is doing to support this kind of research – especially with dental research?

Answer. Today, the length of time for an evidence-based intervention to travel from “bench to bedside” averages nine years. One approach the National Institute of Dental and Craniofacial Research (NIDCR) is using to reduce this lag time is to support clinical research within a practice-based research network (PBRN). In 2005, NIDCR established three regional dental PBRNs to provide scientific evidence to guide dentists in their everyday treatment choices. Through these regional networks, nearly 1,500 practitioner-investigators have participated in network projects, and over 30,000 patients from their practices have been enrolled in more than 35 different dental PBRN studies.

In 2012, NIDCR awarded a seven-year grant to a consolidated national network with the goal of extending practitioner participation across the country, expanding the profession's evidence base, and further refining care. The new network, named the National Dental Practice-Based Research Network (NDPBRN), is headquartered at the University of Alabama at Birmingham, and has six regional research nodes in Rochester, NY; Gainesville, FL; Birmingham, AL; Minneapolis, MN; San Antonio, TX; and Portland, OR. These nodes support practices within their geographic area so that dentists in many U.S. states can participate in network studies. The main goals of the NDPBRN are to conduct national oral health research studies in dental practices on topics of importance to practitioners, to provide evidence useful in daily patient care, and to facilitate the translation of research findings into clinical practice. These efforts should generate clinical research findings that reflect the diverse U.S. population. NDPBRN aims to expand the number of participating practitioners to 5,000 for greater national representation, to increase the number and range of studies beyond those done during 2005-2012, and to enroll a diverse cohort of dentists and patients in studies. To date, NDPBRN has already successfully recruited practitioners in every U.S. state. Practitioners involved in the network contribute to the overall science by participating in studies and enrolling patients from their dental practices, and by identifying knowledge gaps and suggesting research questions for future studies. Because the research is developed in conjunction with those in the "real-world" of dental practice, results are more likely to be accepted by participating dentists, and certain types of clinical research can be conducted rapidly.

Individual studies from the first three regional networks (2005-2012) addressed a wide range of topics. One study assessed pain medication effectiveness following invasive dental treatments. This study can help dentists decide how the dosage of pain relievers a typical patient needs after a procedure like a dental extraction. Another dental PBRN study is examining the change in pain intensity from one week to six months after a root canal, to investigate how frequently patients continue to have pain despite evidence that the root canal appears successful. In other studies, practitioners are assessing teeth with suspected caries (cavities) to determine best practices to manage these teeth. The three regional networks also worked together to conduct an important case-control study to determine risk factors for osteonecrosis of the jaw (ONJ), quickly involving over 100 dental practices, and confirming that bisphosphonates, a class of drugs used for treating osteoporosis and certain forms of bone cancer, were strongly associated with ONJ. The results of this study have helped dental clinicians advise their patients who take bisphosphonates about possible complications following procedures such as dental implant placement and tooth extractions.

Examples of how dental practice-based research impacts daily practice comes from the practitioners themselves who were interviewed by NIDCR. When asked, a participating practitioner commented, "I participated in a PBRN study that showed elderly patients who take three or more medications daily tend to have decreased salivary flow. I've always been cognizant of dry mouth and root caries [cavities] in my older patients [because] I find root caries in the elderly to be one of the most difficult problems to treat in dentistry. Now that I am aware of the results, I...more actively try to prevent these caries situations before they become a problem."

(<http://www.nidcr.nih.gov/Research/DER/ClinicalResearch/DentalPracticeBasedResearchNetwork/Interviews/Dr.Lingam.htm>)

Another practitioner commented about her PBRN experiences: "Instead of reading about the future of dentistry, I was a part of doing the research and building that future. I've met colleagues through the PBRN network who have been some of the best and brightest, and they've given me ideas and helped to re-energize me in my practice."
<http://www.nidcr.nih.gov/Research/DER/ClinicalResearch/DentalPracticeBasedResearchNetwork/Interviews/Dr.Barna.htm>)

NIH-Simpson-3. According to government contract and grant tracking data – USA Spending.gov – Health & Human Services has provided the National Academies of Sciences about \$258 million dollars through over 1,120 contracts and over 150 grants since 2005. Please provide to the committee a list of contracts and grants, the amounts provided, and a description of each, that have been provided by the NIH to the National Academies of Sciences Institute of Medicine since 2005.

Answer.

Project Title	Fiscal Year	Funding Amount
SPECIAL STUDIES AND ANALYSIS UMBRELLA CONTRACT – NIH USED THIS CONTRACT TO FUND REPORTS, FORUMS, WORKSHOPS, ETC., TO FULFILL U.S. SCIENTIFIC, HEALTH, AND POLICY NEEDS	2005	53,523,692
ESTABLISHMENT AND CONDUCT OF A RESEARCH ASSOCIATESHIP PROGRAM IN BIOTECHNOLOGY	2005	1,108,500
SUPPORT FOR THE NATIONAL ACADEMY OF SCIENCES FEDERAL FACILITIES COUNCIL (CY 2005)	2005	10,000
TRANSFER OF FUNDING TO THE NATIONAL ACADEMY OF SCIENCES FOR THE REPRINT OF MANUSCRIPTS AND JOURNALS	2005	2,925
TRANSFER OF FUNDING TO THE NATIONAL ACADEMY OF SCIENCES FOR THE PURCHASE OF BOOKS, PAMPHLETS, AND OTHER READING MATERIAL	2005	51,820
OTHER PROFESSIONAL SERVICES	2005	50,000
PARTIAL SUPPORT FOR CONTINUED ACTIVITIES OF THE CODATA COMMITTEE	2005	25,000
DISEASE AND DECISIONS: THE CURRENT SCIENCE ON EMERGING THREATS EXHIBITION	2005	270,000*
SUPPORT FOR INSTITUTE FOR LABORATORY ANIMAL RESEARCH	2005	300,780*
INSTITUTE FOR LABORATORY ANIMAL RESEARCH JOURNAL	2005	60,792*
SERVICES (MANAGEMENT/SUPPORT)	2006	6,613,688
SCIENCE WRITER CONTRACTED TO PREPARE DOCUMENT FROM MATERIALS PROVIDED AT THE NUTRIGENOMICS AND BEYOND: INFORMING THE FUTURE CONFERENCE	2006	10,000

SUPPORT FOR THE NATIONAL ACADEMIES' FORUM ON NEUROSCIENCE & NERVOUS SYSTEMS	2006	50,000
SUPPORT FOR THE PRINTING OF THE TEACHERS GUIDE "SCIENCE, MEDICINE, AND ANIMALS" REPORT	2006	10,000
SUPPORT FOR THE INSTITUTE OF MEDICINE CONFERENCE "NUTRIGENOMICS AND BEYOND: INFORMING THE FUTURE"	2006	20,000
PLAN AND IMPLEMENT: A DNA DAY PROGRAM AIMED AT HIGH SCHOOL STUDENTS & SCIENCE TEACHERS IN THE WASH., D.C AREA. VENDOR WILL DEVELOP PROGRAMS & MATERIALS ON GENETICS FOR HIGH SCHOOL STUDENTS FROM 2/1/06-5/20/06	2006	24,642
TRANSFER OF FUNDING TO THE NATIONAL ACADEMY OF SCIENCES FOR THE REPRINT OF MANUSCRIPTS AND JOURNALS	2006	3,400
STUDY/DATA - OTHER THAN SCIENTIFIC	2006	58,000
INSTITUTE FOR LABORATORY ANIMAL RESEARCH JOURNAL	2006	61,020*
SUPPORT FOR INSTITUTE FOR LABORATORY ANIMAL RESEARCH	2006	300,907*
DISEASE AND DECISIONS: THE CURRENT SCIENCE ON EMERGING THREATS EXHIBITION	2006	263,620*
NATIONAL ACADEMY OF SCIENCE FEES	2007	40,000
INSTITUTE FOR LABORATORY ANIMAL RESEARCH JOURNAL	2007	70,640*
SUPPORT FOR INSTITUTE FOR LABORATORY ANIMAL RESEARCH	2007	315,821*
DISEASE AND DECISIONS: THE CURRENT SCIENCE ON EMERGING THREATS EXHIBITION	2007	255,798*
INSTITUTE FOR LABORATORY ANIMAL RESEARCH JOURNAL	2008	70,867*
SUPPORT FOR INSTITUTE FOR LABORATORY ANIMAL RESEARCH	2008	323,724*
DISEASE AND DECISIONS: THE CURRENT SCIENCE ON EMERGING THREATS EXHIBITION	2008	250,522*
INSTITUTE FOR LABORATORY ANIMAL RESEARCH JOURNAL	2009	72,553*
DISEASE AND DECISIONS: THE CURRENT SCIENCE ON EMERGING THREATS EXHIBITION	2009	250,259*
TRANSFER OF FUNDING TO THE NATIONAL ACADEMY OF SCIENCES FOR THE REPRINT OF MANUSCRIPTS AND JOURNALS	2010	4,220
REPRINT ORDER FOR A STRUNNIKOV (CADMUS). ESSENTIAL GLOBAL ROLE OF CDC14 IN DNA SYNTHESIS REVEALED	2010	3,315
AGES AND STAGES: BRAIN, LEARNING, AND AGING	2010	931,200*
INSTITUTE FOR LABORATORY ANIMAL RESEARCH JOURNAL	2010	74,292*
CORE SUPPORT FOR THE COMPUTER SCIENCE AND TELECOMMUNICATIONS BOARD OF THE NATIONAL ACADEMY OF SCIENCES	2011	0

THE NATIONAL ACADEMIES' DIVISION ON ENGINEERING & PHYSICAL SCIENCES (DEPS) REQUESTING PARTIAL SUPPORT OF THE ACTIVITIES OF THE FEDERAL FACILITIES COUNCIL (FFC) FOR 12 MONTH PERIOD JAN 1, 2011 THRU DEC 31, 2011 - HQC61272 - F. A. CLIFFORD	2011	10,000
IN RESPONSE TO A CONGRESSIONAL REQUEST, THE NIH HAS COMMISSIONED THE INSTITUTE OF MEDICINE TO CONDUCT A STUDY OF THE CLINICAL AND TRANSLATIONAL SCIENCE AWARDS PROGRAM	2012	799,174
FOOD FORUM PROPOSAL (RENEWAL TO TASK ORDER 196 UNDER THE NATIONAL ACADEMY OF SCIENCES).	2012	100,000
A WORKSHOP ON THE SEXUAL ORIENTATION AND GENDER IDENTITY DATA COLLECTION IN ELECTRONIC HEALTH RECORDS	2012	40,000
SHARING CLINICAL RESEARCH DATA	2012	25,000
CORE SUPPORT FOR THE NATIONAL ACADEMIES' ROUNDTABLE ON TRANSLATING GENOMIC-BASED RESEARCH FOR HEALTH REVIEW	2012	25,000
INSTITUTE OF MEDICINE STUDY OF YOUTH CONCUSSIONS IN SPORTS	2012	87,500
CORE SUPPORT FOR THE NATIONAL ACADEMIES' FORUM ON MEDICAL AND PUBLIC HEALTH PREPAREDNESS FOR CATASTROPHIC EVENTS	2012	100,000
CORE SUPPORT FOR THE NATIONAL ACADEMIES' GOVERNMENT-UNIVERSITY-INDUSTRY RESEARCH ROUNDTABLE	2012	400,000
CORE SUPPORT FOR THE NATIONAL ACADEMIES' BOARD ON RESEARCH DATA AND INFORMATION.	2012	50,000
CORE SUPPORT FOR THE NATIONAL ACADEMIES' INNOVATION POLICY FORUM	2012	350,000
UNDERTAKING A COMPREHENSIVE DISSEMINATION AND COMMUNICATION STRATEGY FOR THE UPCOMING NATIONAL ACADEMIES REPORT: "UNDERSTANDING INTERNATIONAL HEALTH DIFFERENCES IN HIGH-INCOME COUNTRIES"	2012	131,600
COMMON RULE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH IN THE BEHAVIORAL AND SOCIAL SCIENCES (CANCELLED)	2012	196,181
CORE SUPPORT FOR THE NATIONAL ACADEMIES' ROUNDTABLE ON ENVIRONMENTAL HEALTH SCIENCES	2012	200,000
CORE SUPPORT FOR THE NATIONAL ACADEMIES' BOARD ON BEHAVIORAL, COGNITIVE AND SENSORY SCIENCES	2012	80,000

ADVANCES IN BIODEMOGRAPHY: CROSS-SPECIES COMPARISONS OF SOCIAL ENVIRONMENTS AND SOCIAL BEHAVIORS, AND THEIR EFFECTS ON HEALTH AND LONGEVITY	2012	212,000
CORE SUPPORT FOR THE NATIONAL ACADEMIES' COMMITTEE ON NATIONAL STATISTICS	2012	105,000
CORE SUPPORT FOR THE NATIONAL ACADEMIES' COMMITTEE ON POPULATION	2012	170,000
EXPERT MEETING ON NEXT STEPS FOR DEVELOPING NATIONAL TRANSFER ACCOUNTS	2012	49,351
NATIONAL CHILDREN'S STUDY – A WORKSHOP ON THE DESIGN OF THE NATIONAL CHILDRENS STUDY	2012	240,000
CORE ACTIVITIES OF THE NATIONAL ACADEMIES' INSTITUTE FOR LABORATORY ANIMAL RESEARCH	2012	125,000
CORE SUPPORT FOR THE NATIONAL ACADEMIES' BOARD ON LIFE SCIENCES	2012	120,000
FUNDING FOR NATIONAL RESEARCH COUNCIL FELLOW	2012	1,109,557
THE NATIONAL ACADEMIES' DIVISION ON ENGINEERING & PHYSICAL SCIENCES (DEPS) REQUESTING PARTIAL SUPPORT OF THE ACTIVITIES OF THE FEDERAL FACILITIES COUNCIL (FFC) FOR 12 MONTH PERIOD (JAN 1, 2012 THRU DEC 31, 2012)	2012	10,000
SUPPORT FOR THE NATIONAL CANCER POLICY FORUM: MEETINGS, INVESTIGATIONS, AND REVIEWS ON ISSUES IDENTIFIED BY THE NATIONAL CANCER POLICY FORUM (NCPF)	2013	1,791,667
INDEPENDENT REVIEW AND ASSESSMENT OF THE ROLE OF THE RECOMBINANT DNA ADVISORY COMMITTEE IN THE REVIEW OF HUMAN GENE TRANSFER TRIALS	2013	599,811
THE NATIONAL ACADEMIES' DIVISION ON ENGINEERING & PHYSICAL SCIENCES (DEPS) REQUESTING PARTIAL SUPPORT OF THE ACTIVITIES OF THE FEDERAL FACILITIES COUNCIL (FFC) FOR 12 MONTH PERIOD (JAN 1, 2013 THRU DEC 31, 2013)	2013	10,000
NIH Total		\$72,618,837

Note: Funding amounts marked with * are grants, all others are contracts.

QFRs from Congressman Joyce

NIH-Joyce-1. As the former prosecutor in Geauga County, Ohio, I was heavily involved in the Chardon High School shooting that took place last February. We must ensure that students and young adults receive adequate treatment for their mental health issues. What specifically is the National Institute of Mental Health (NIMH) doing to evaluate and improve mental health for young people?

Answer. The National Institute of Mental Health (NIMH) is the lead federal agency for research on mental disorders, with a mission to transform the understanding and treatment of mental illnesses through basic and clinical research. One of the primary objectives of the NIMH Strategic Plan⁸ is to chart the course of mental disorders over the lifespan to determine when, where, and how to intervene, with the ultimate goal of preempting or treating mental disorders and hastening recovery. The symptoms of mental disorders often begin to appear in childhood and adolescence and ebb and flow over the course of an individual's life. Behavioral manifestations, such as psychosis and depression, are in fact late events in the timeline of these brain disorders that began years earlier.⁹ Thus, providing youth with the treatment they need as early in life as possible is essential to ensuring positive long-term outcomes. NIMH is committed to supporting research on earlier diagnosis and quicker delivery of appropriate treatment, be it behavioral or pharmacological.

For example, most young people who develop mental disorders such as schizophrenia have pre-psychotic symptoms, known as the prodrome, for 2-3 years before the onset of psychosis. In order to enhance early detection and preempt psychosis, NIMH is funding a consortium of eight clinical research centers, called the North American Prodrome Longitudinal Study, which is using biological assessments, including neuroimaging, electrophysiology, neurocognitive testing, hormonal assays, and genomics, to improve our ability to predict who will convert to psychosis, and to develop new approaches to pre-emptive intervention. Moreover, NIH recently approved \$2 million from the NIH Director's Discretionary Fund to add to the \$14.2 million budgeted by NIMH for fiscal year 2013 to support an NIMH initiative entitled, *Early Psychosis Prediction, Pathophysiology, and Prevention*. This initiative aims to support accelerated research regarding the detection of risk states for psychotic disorders, to prevent onset of psychosis in high-risk individuals, and to reduce the duration of untreated psychosis in people who have experienced a first psychotic episode.

A number of NIMH-funded projects are developing and/or testing strategies to prevent depression among children and adolescents who are at risk for the disorder. These clinical trials vary with regard to the types of intervention (e.g., cognitive, behavioral, interpersonal), setting (e.g., school, employment center), and age of enrolled participants. All of the studies are focused on developing strategies that could be implemented and disseminated widely in order to reduce the public health burden of depression. In addition, NIMH-funded studies are developing school-based programs to prevent early-onset behavior problems, aggression, and violence, and promote positive adjustment among school children.¹⁰ The results of these and similar studies will advance evidenced-based prevention interventions designed to reduce mental health problems in youth that might otherwise result in antisocial behavior that often leads to problems of high public health significance.^{11,12}

⁸ <http://www.nimh.nih.gov/about/strategic-planning-reports/index.shtml>

⁹ Cannon TD, Cadenhead K, Cornblatt B, Woods SW, Addington J, Walker E, Seidman LJ, Perkins D, Tsuang M, McGlashan T, Heinssen R. Prediction of Psychosis in High Risk Youth: A Multi-Site Longitudinal Study in North America. *Arch Gen Psychiatry*. 2008 Jan;65(1):28-37.

¹⁰ Grant number: P30-MH086043; Clinical trial: NCT01583127; Grant number: P20-MH085987

¹¹ <http://www.ncbi.nlm.nih.gov/pubmed/23071207>

¹² http://www.air.org/reports-products/index.cfm?fa=viewContent&content_id=2077

When violence is associated with mental illness, it is much more often directed toward the self rather than others. In fact, approximately five percent of individuals with schizophrenia will die by suicide during their lifetime.¹³ In line with the Department of Health and Human Services' priority on suicide prevention, NIMH has increased its focus on suicide prevention, particularly among youth. NIMH-supported researchers recently reported that four questions that take emergency department nurses or physicians less than 2 minutes to administer can successfully identify youth at risk for attempting suicide.¹⁴

NIMH is committed to increasing mental health literacy and understanding of mental health research among the public. In honor of Children's Mental Health Awareness Week (May 5-11, 2013), NIMH hosted a series of Twitter chats for youth and their families, featuring the NIMH Director, Thomas Insel, M.D. and scientists from NIMH's Division of Intramural Research Programs. Topics included attention deficit-hyperactivity disorder (ADHD) and pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS).

Research has taught us to detect diseases early and intervene quickly to preempt later stages of illness. This year, we will avert 1.1 million deaths from heart disease because we have not waited for a heart attack to diagnose and treat coronary artery disease.¹⁵ The 100,000 young Americans who will have a first episode of psychosis this year will join more than two million individuals with schizophrenia. NIH is working to evaluate and improve mental health for young Americans by gaining a better understanding of brain and behavior. As with other medical disorders, our best hope is research to diagnose and intervene before the symptoms become manifest.

NIH-Joyce-2. One field where there is a need for strong and sustained commitment to biomedical research is pediatric research. The House of Representatives recently passed the National Pediatric Research Network Act of 2013 by an overwhelming margin, underscoring the bipartisan support for this objective. What more can NIH do within existing resources to assure that children participate in the full potential of NIH research?

Answer. NIH is committed to ensuring that children participate in the full potential of relevant NIH research. In FY 2012, NIH pediatric research funding totaled approximately \$3.6 billion across the country, including studies in pediatric patients with rare diseases conducted in NIH's intramural research program at the Clinical Center in Bethesda, MD. NIH supports nearly 100 multidisciplinary center and network programs focused on children's health needs. These include the Autism Centers of Excellence, the Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers, and the Children's Oncology Group. NIH's Office of Rare Diseases Research and several NIH Institutes and Centers fund the Rare Diseases Clinical Research Network to facilitate collaboration among experts in many different types of rare

¹³ Hor K. & Taylor M. Suicide and schizophrenia: a systematic review of rates and risk factors. *J Psychopharmacol.* 2010;24(4S): 81-90.

¹⁴ Horowitz LM, Bridge JA, Teach SJ, Ballard E, Klima J, Rosenstein DL, Wharff EA, Ginnis K, Cannon E, Joshi P, Pao M. Ask Suicide-Screening Questions (ASQ). A Brief Instrument for the Pediatric Emergency Department. *Arch Pediatr Adolesc Med.* December 2012. 166(12):1170-1176.

¹⁵ Vital Statistics of the United States, CDC/National Center for Health Statistics. (2011, August). Age-adjusted Death Rates for Coronary Heart Disease (CHD). National Heart Lung and Blood Institute. Retrieved January 23, 2013, from <http://www.nhbi.nih.gov/news/spotlight/success/conquering-cardiovascular-disease.html>

diseases. NIH works with the FDA to administer the Best Pharmaceuticals for Children Act to support and coordinate pediatric pharmacology research, with the goal of increasing the dosage and efficacy information available about therapeutics used by children. The 60 centers that comprise NIH's Clinical and Translational Sciences Awards (CTSA) include pediatric expertise.

NIH reviews and awards these and other network and center programs on a regular basis, usually at about five-year intervals, ensuring that they are productive and continue to produce the best science. For example, during the coming year, NIH will post a funding opportunity announcement seeking applications for sites to participate in the ongoing Collaborative Pediatric Critical Care Research Network, which provides the infrastructure to pursue rigorous clinical trials and other studies in pediatric critical care medicine. The eight currently funded sites include pediatric expertise in pulmonology, cardiology, nursing, and other disciplines essential to children's health.

Current NIH policy requires clinical research studies, even those without a pediatric focus, to include children in their study population unless there is an appropriate scientific, regulatory, ethical, and/or safety reason to exclude children from research. The NIH Director has appointed a committee to look specifically at inclusion of subpopulations, including children, in clinical research -- and to propose ideas for a trans-NIH approach to better understand how NIH's pediatric and lifespan research portfolios are meeting the goal of including these subpopulations.

QFRs from Congresswoman Lee

NIH-Lee-1. Many leaders in HIV/AIDS research, including NIH's Dr. Anthony Fauci, have expressed that a vaccine will be the ultimate end to the AIDS epidemic. How can we move forward to develop the best biomedical solutions for HIV/AIDS while resources are scarce and budget sequestration is in effect?

Answer. Due to thirty years of congressional and taxpayer support for NIH research on HIV/AIDS, groundbreaking treatment and prevention strategies resulting from biomedical research now make an AIDS-free generation an achievable goal. In order to move toward the ultimate end of the AIDS pandemic, NIH is advancing research on and evaluating optimal combinations of new prevention strategies. Additionally, NIH research on improved therapies to achieve a functional cure of HIV infection is facilitating the end of AIDS. Under tighter budgets and the sequestration, HIV/AIDS research, including HIV vaccine development, will proceed, but at a slower pace.

There is a new sense of optimism in HIV vaccine research in the wake of the modestly successful HIV vaccine clinical trial called RV 144. This trial provided the first demonstration that an effective HIV vaccine is feasible. Follow-up studies are being conducted to determine potential correlates of protection and risk. Emerging results from these studies are guiding the scientific community in new research directions aimed at discovering how to build more effective immunogens to elicit lasting protective immunity. Additionally, the recent isolation of broadly neutralizing antibodies that can inactivate over 90 percent of all circulating HIV strains provides a promising approach for HIV vaccine development. The path to proof-of-concept for both of these vaccine approaches is emerging through NIH support for extramural research and

research conducted at the NIAID Vaccine Research Center, whose promising broadly neutralizing VRC01 antibody is scheduled to enter Phase I clinical testing in 2013.

As an HIV prevention strategy, antiretroviral drugs have a profound impact on HIV transmission. Two major strategies -- treatment as prevention and use of antivirals for pre-exposure prophylaxis -- have demonstrated impressive efficacy in proof-of-concept studies. NIAID and its partners are conducting research to determine how best to combine these new prevention modalities with existing, strategies to provide optimized, cost effective, combination prevention strategies for target populations. This work is critical to tackling the domestic and global HIV pandemic.

Globally, approximately 7,000 people are infected with HIV each day. NIH remains committed to maintaining its life-saving research on HIV/AIDS, especially in HIV prevention. Key to this effort will be partnerships with other federal agencies; private research sponsors, such as the Bill and Melinda Gates Foundation; academia; and industry.

ADAP:

You mentioned ADAP in your remarks, just to expand on that further: I know that we recently had over 8,000 people on waiting lists to access medications for the AIDS Drug Assistance Program (ADAP), but that has been reduced due to some increased funding.

The sequester requires an automatic 5% across-the-board funding cut. The AIDS Drug Assistance Program (ADAP) faces a cut that will result in 7,400 people living with HIV losing access to life-saving medications, as you mentioned. The science tells us that treatment is prevention, in other words, putting individuals on treatment translates to a greater public health benefit.

HRSA-LEE-1

- 1. With more than 7,000 individuals potentially dropped from the ADAP waiting list because of sequestration, what do we anticipate the impact could be on our HIV/AIDS effort in this country as a whole?**

A: HRSA closely monitors ADAP and provides technical assistance to help states forecast demand, identify additional cost saving opportunities, and in the event of decreased funding, ensure that individuals on ADAP waiting lists have access to alternative resources for HIV/AIDS prescription drugs such as manufacturer's pharmaceutical patient assistance programs.

HRSA-LEE-2

- 2. What would this mean for the long term outlook on Ryan White and HIV funding in the future?**

A: With the implementation of ACA, the outlook for access to care and treatment is expected to improve for people living with HIV. Many uninsured Ryan White (RW) clients will likely transition to Medicaid, as States expand coverage. Additionally, many RW-

program clients may become eligible for plans in the health insurance marketplaces with premium tax credits available to those who qualify.

HIV and viral hepatitis screening:

HRSA plays an important role in disease prevention including screening for infectious diseases like HIV/AIDS and viral hepatitis.

HRSA-LEE-3

3. What is HRSA doing to prevent, screen and treat viral hepatitis and HIV/AIDS?

A: HRSA is dedicated to prevention, screening and treatment of viral hepatitis. Per legislation, Ryan White-funded clinical providers are supposed to follow the HHS Antiretroviral Treatment guidelines. These guidelines state that all patients diagnosed with HIV should be screened for hepatitis B and C. In addition, Ryan White legislation mandates screening and prevention counseling for hepatitis B and C by grantees. HRSA's HIV-AIDS Bureau (HAB) collects data on screening for hepatitis B and C in the Ryan White Services Report. In 2010, it was estimated that 71% of patients were screened for hepatitis B since their HIV diagnosis, and 75% of patients were screened for hepatitis C.

With regard to treatment, HRSA/HAB supports 11 telehealth training centers through the AIDS Education Training Centers as they expand coverage to include viral hepatitis treatment. HRSA/HAB also continues to implement the Hepatitis C Treatment Expansion Initiative through Special Projects of National Significance (SPNS). This initiative is supporting 29 organizations across the United States to serve as demonstration sites to increase hepatitis C treatment for HIV/HCV co-infected individuals using different models of care. Working collaboratively with HRSA and the demonstration sites, the initiative's evaluation center at the University of South Florida is assessing the project's effectiveness, feasibility, and the costs of the service delivery models implemented by each site. From these assessments, the project will determine which model of patient care best serves HIV/HCV co-infected patients within a diverse set of communities. The findings from this project will be published, with the goal of sharing a replicable and sustainable model for integrating HCV treatment into HIV care programs. As the project progresses, HAB will be looking at cross-cutting findings that can be widely disseminated.

HRSA's Bureau of Primary Health Care (BPHC) reported that in 2010, grantees performed 162,320 screening tests for hepatitis C and 256,133 screening tests for hepatitis B. HRSA/BPHC reported that, in 2011, grantees performed 197,987 screening tests for hepatitis C and 228,050 screening tests for hepatitis B.

HRSA's Bureau of Health Professions (BHPR) also supports the Public Health Training Centers and Area Health Education Centers, which regularly offer provider training on prevention, screening, and treatment for viral hepatitis and HIV.

In addition, through its Office of Special Health Affairs (OSHA), HRSA partners with the Substance Abuse and Mental Health Services Administration (SAMHSA) on the Center for Integrated Health Solutions. This center is developing a webpage regarding primary care, HIV, Hepatitis C and the relationship of behavioral health to this constellation of issues.

HRSA-LEE-4

4. Do these prevention activities lead to lower costs for the health care system?

A: There is general evidence (not specific to HRSA activities) that indicates the HIV/AIDS and viral hepatitis prevention activities lead to lower health care costs:

- For HIV prevention:
 - In 2010, CDC authors measured the value of HIV prevention efforts in the United States by comparing the difference between the number of infections that have occurred with the number that might have occurred in the absence of prevention programs. The study estimated the medical savings from infections averted by US HIV prevention programs from 1991-2006 to be \$129.9 billion with 361,878 HIV infections averted. (Farnham PG, Holtgrave DR, Sansom SL, Hall HI. Medical costs averted by HIV prevention efforts in the United States, 1991-2006. *JAIDS* 2010; 54(5): 565-567.)
 - The lifetime treatment cost of an HIV infection is currently estimated at \$379,668. Therefore, any prevention intervention will be estimated to be cost-saving (reducing total healthcare costs) if its expense ratio is less than \$379,668 per infection averted. (<http://www.cdc.gov/hiv/prevention/ongoing/costeffectiveness/>)
 - A very recent CDC paper estimated that, although early diagnosis and treatment of HIV infection increases lifetime healthcare costs for an infected individual, this same effort will reduce by nearly 50% the number of new HIV infections transmitted. Therefore, efforts to improve early diagnosis and treatment of HIV are preventative and should be cost saving to the population at large. (Farnham et al. Updates of Lifetime Costs of Care and Quality of Life Estimates for HIV-Infected Persons in the United States: Late Versus Early Diagnosis and Entry into Care. *J Acquir Immune Defic Syndr* 2013 April 22 [Epub ahead of print].)
- For viral hepatitis prevention:
 - Hepatitis A and hepatitis B vaccines are both recommended childhood immunizations. Studies have confirmed that taken together the entire basket of routine childhood immunizations ultimately reduces health care costs. (e.g., Zhou F, Santoli J, Messonnier ML, Yusuf HR, Shefer A, Chu SY, et al. Economic evaluation of the 7-vaccine routine childhood immunization schedule in the United States, 2001. *Arch Pediatr Adolesc Med* 2005; 159:1136-44)
 - There is some evidence that screening for hepatitis C infection in high-risk populations is cost effective (not cost saving). (e.g., Linas et al. Cost-effective screening for acute hepatitis C virus infection in HIV-infected men who have sex with men. *Clin Infect Dis*. 2012;55(2):279-90.)

HRSA-LEE-5**5. How has HRSA worked with public and private partners to leverage limited federal resources to support HIV/AIDS and hepatitis testing activities?**

A: HRSA/HAB is working with grantees in the Special Projects of National Significance (SPNS) Hepatitis C Treatment Expansion initiative to increase provider capacity for treatment of hepatitis C among HIV+ individuals.

HRSA's Bureau of Primary Health Care (BPHC) funds the Lesbian, Gay, Transgender Health Education Center at Fenway Community Health Center, which is developing educational programs around viral hepatitis and HIV testing and treatment. HRSA/BPHC works closely with the National Healthcare for the Homeless Council on HIV, STD, and viral hepatitis testing and treatment. HRSA/BPHC works with the Association for Asian Pacific Community Health Organizations (AAPCHO), which is developing new Health Information Technology (HIT) strategies that increase screening for chronic hepatitis B and reduce the impact of hepatitis B among high-risk Asian American and Pacific Islander (AAPI) populations. In addition, HRSA/BPHC partners with the National Center for Health in Public Housing, which has hosted educational programs on hepatitis C.

HRSA also works closely with the Centers for Disease Control and Prevention (CDC) to promote HIV testing at the grantee level. CDC has developed the "Act Against AIDS" campaign using a combination of federal and private resources.

Ryan White:**HRSA-LEE-6****6. The Ryan White HIV/AIDS Program currently provides care, treatment and support services to nearly 550,000 people with HIV/AIDS in our country. With implementation of the Affordable Care Act and many people gaining coverage through private insurance and expanded Medicaid, how will this impact the Ryan White Program in the future?**

A: ACA will provide primary medical care coverage for many people living with HIV (PLWH) in states that expand Medicaid and private health insurance. However, the actual scope of coverage for Ryan White HIV/AIDS services in the context of expanded Medicaid program will be determined by states. It is likely that in many states, coverage for the Ryan White service categories will be included in the essential health benefits package and reflected in each state's individualized Medicaid, Basic Health Plans, and qualified health plans offered through the Marketplaces (aka Exchanges). We understand that the challenges of improving health outcomes for PLWH are best addressed by a comprehensive care management approach reflected in the Ryan White HIV/AIDS Program (RWP). The RWP will remain vital to ensuring that PLWH remain in care and on medications, which is essential to decreasing HIV/AIDS morbidity and mortality and preventing transmission of the disease. Many Ryan White Program services are not typically covered by private health insurance, and are not explicitly included in the essential health benefits (EHB) as defined by

the Affordable Care Act. For example, Ryan White Early Intervention Services such as referral services and linkage to care will not be covered under EHB. Other services that are critical to engaging and retaining people living with HIV (PLWH) in care such as medical case management, treatment adherence counseling and other core medical services such as adult dental and vision services are not required to be covered as essential health benefits. There will be continued need for these and other services provided through the Ryan White HIV/AIDS Program.

HRSA-LEE-7

7. Currently, about 70 percent of people in the Ryan White Program have some sort of health coverage, predominately from Medicaid or Medicare. Will health care reform impact their needs and their reliance on Ryan White services and programs?

A: An issue brief released by HHS/Assistant Secretary for Planning and Evaluation in February 2012 entitled *Medicare Beneficiary Savings and the Affordable Care Act* provides estimates of Medicare Parts A, B, and D savings from the Affordable Care Act to seniors and people living with disabilities enrolled in traditional Medicare. According to this issue brief, the ACA will favorably affect beneficiary expenditures in four ways: lowering part B premiums growth, lowering beneficiary copayments and coinsurance growth under Part A and B, closing the Medicare prescription drug coverage gap, and providing many preventive services to seniors at no additional cost. States have the option to enhance coverage in traditional Medicaid programs.

However, many Ryan White Program services are not typically covered by Medicare, Medicaid, or private health insurance, and are not explicitly included in the essential health benefits (EHB) as defined by the Affordable Care Act. Services that are critical to engaging and retaining people living with HIV (PLWH) in care such as medical case management, treatment adherence counseling, and other core medical services such as adult dental and vision services are not required to be covered as essential health benefits. There will be continued need for these and other services provided through the Ryan White HIV/AIDS Program. By keeping people living with HIV in care and on medications, the Ryan White program plays a critical role in preventing the spread of HIV epidemic, as people living with HIV who are on antiretrovirals and virally suppressed are much less likely to transmit the infection. Ryan White Program service utilization data show that one-third of the clients receiving medical case management services that include treatment adherence counseling in 2010 were Medicare beneficiaries or Medicaid recipients. Over 40 percent of the clients receiving RWP-funded medical nutrition therapy in 2010 were Medicare beneficiaries or Medicaid recipients. Clients with traditional Medicaid were more likely to receive RWP-funded home health care and home and community-based services.

HRSA-LEE-8

8. Massachusetts has already expanded health care coverage in their state. Can you explain how they utilize Ryan White Program funds for people with HIV in their state and the results that they have experienced?

A: The Massachusetts experience with the transition to health care reform has been very informative for how we think about the Ryan White Program (RWP) and ACA going forward.

Specifically, we have two examples of how the RWP and the Massachusetts (MA) Health Care Reform (HCR) experience intersect:

- As HCR has been implemented, MA has continued to demonstrate a commitment to supporting health care for its residents which means that they strategically utilized Ryan White funding to support insurance premiums assistance and coverage completion for core medical and support services that maintain PLWH in care - the end result being improved morbidity and mortality. Overall morbidity (newly diagnosed and reported cases) has decreased by 45 percent from 2006 to 2010 and mortality (deaths) has decreased by 44 percent between 2002 and 2008.
- The Boston Public Health Commission (the Part A grantee) applied for and has received a waiver of the Ryan White HIV/AIDS Program core medical services requirement that at least 75 percent of funds by a grantee must be spent on core medical services although the majority continues to be spent on medical case management and treatment adherence services. This flexibility in the context of ACA may, like in the case of MA, provide us with the tools and case studies on how the RWP may need to be applied in the future in other jurisdictions. By allowing Boston more flexibility to determine how to spend their grant dollars under their health reform program, they have managed to decrease their epidemic in the state.

HRSA-LEE-9

9. How are you preparing Ryan White Program grantees for implementation of the Affordable Care Act?

A: HRSA has been preparing Ryan White Program grantees for ACA implementation by bolstering our outreach and enrollment activities. Our recent activities include:

Communication Efforts

- Launched RWP-ACA Mailbox for grantees to submit ACA questions at: RWP-ACAQuestions@hrsa.gov.
- Launched ACA Webpage on HAB website "Ryan White and the Affordable Care Act: What You Need to Know" at: <http://hab.hrsa.gov/affordablecareact>.
- Launched ACA Section on TARGET Center site at: <https://careacttarget.org/library/affordable-care-act-and-ryan-white-program-learning-modules>.

Outreach and Enrollment

- Letter and chart posted on HAB ACA webpage to inform grantees about how they can use existing program resources to prepare for ACA implementation.
- Posted Key Provisions of ACA document for Ryan White Program Grantees on HAB ACA webpage.
- Posted non-exhaustive list of essential community providers (ECPs) from CMS on HAB ACA webpage.

New Policies

Newly posted Program policies 13-01 and 13-02 on the HAB ACA webpage:

- **13-01** – This policy clarification reiterates HRSA policy regarding Ryan White HIV/AIDS Program (RWHAP) clients who are currently eligible for Medicaid or will become eligible for Medicaid beginning on or after January 1, 2014.
- **13-02** – This policy clarification outlines the Ryan White HIV/AIDS Program (RWHAP) expectations for client eligibility assessment and clarifies the recertification requirements.

Grantee and Stakeholder Training

- Held first in a series of ACA-related webinars co-hosted with CMS on April 5th. The first webinar was titled “The Affordable Care Act and the Ryan White HIV/AIDS Program: Eligibility 101.” Over 570 participants connected by webinar and even more connected by phone (over 680) – these numbers are NOT mutually exclusive.

Development of Technical Assistance and Tools

- Working with HRSA Outreach and Enrollment Workgroup to ensure HRSA grantees are assisting clients to enroll in new health insurance options.
- Drafting FAQs for common ACA questions.
- Working with AIDS Education and Training Centers National Resource Center to develop toolkit to help grantees and providers enter into new Managed Care contracts.
- Initiated task under HAB TA Contract to develop other tools needed by grantees and RW clients.

- 1) **CDC: Have identified “HIV” as one of your winnable battles. Can you explain what you are doing to decrease the number of new infections, which has stood at 50,000 every year for the past several years?**

CDC-LEE-1-RESPONSE:

CDC programs have contributed to U.S. HIV prevention successes, including reductions in HIV among certain risk groups, reductions in HIV transmission rates, and increases in individual knowledge of HIV status. CDC’s most recent analysis of HIV incidence data reveal signs of an encouraging decrease in new HIV infection among heterosexual black women from 7,700 new

infections in 2008 to 6,100 in 2010 – a reduction of 21% -- and among females generally by 21% as well. In addition, HIV cases attributed to injecting drug use have continued to decline among both male and females over this same time period. Rates of HIV transmission, which is the number of new infections per year per 100 persons with HIV, have also declined. Nevertheless, much remains to be done.

CDC has undertaken a comprehensive approach to HIV prevention efforts that will move the United States beyond stabilizing to reducing the number of new HIV infections diagnosed each year. In 2011, CDC and its partners began pursuing a High-Impact Prevention (HIP) approach to reduce new HIV infections. By using combinations of scientifically proven, cost-effective, and scalable interventions targeted to the right populations in key geographic areas nationwide, HIP will increase the impact of HIV prevention efforts. HIP strategies include HIV testing and linkage to care, adherence of persons living with HIV to antiretroviral therapy, and prevention programs for persons living with HIV and their partners. CDC also implements various HIV testing campaigns to encourage HIV testing and knowing one's HIV status. While the testing campaigns carry wide appeal, certain campaigns are specifically tailored for a targeted audience, consisting of persons with demographic characteristics that are associated with a higher risk of HIV infection. In recent years, CDC has realigned funding opportunities to increase the effectiveness of reducing the number of HIV infections in the United States and to support the HIP approach. CDC's funding to health departments to support HIV prevention activities is now aligned so that funding to states and localities correlates with the prevalence of HIV in those geographic areas. In addition, CDC has provided funding to support HHS' Minority Health Initiative Care and Prevention in the United States (CAPUS) awards in eight jurisdictions. These awards are designed to promote partnerships between health departments and communities with a high prevalence of HIV to increase testing and linkage to and retention in care, particularly among racial and ethnic minority communities.

- 2) **It has recently been established that “treatment is prevention” meaning that if a person with HIV/AIDS is on treatment and retained in medical care, the virus in their system is reduced so low that possible transmission is substantially reduced. How are we doing in providing care and treatment to people with HIV/AIDS in the US? How can we improve this?**

CDC-LEE-2 RESPONSE:

Linkage to medical care is only one of a continuum of care services essential to HIV care and prevention. The breadth of engagement in HIV care includes diagnosis (HIV testing), linkage to and retention in HIV medical care, and ongoing HIV prevention interventions, including appropriately timed antiretroviral therapy (ART). According to CDC data, of the approximately 1.1 million Americans living with HIV, 82 percent (or 902,000) were diagnosed, 66 percent (or 726,000) were linked to HIV care, 37 percent (or 407,000) have stayed in HIV care, and 33 percent (363,000) are receiving treatment. Of all persons living with HIV, only 25% are successfully keeping their virus under control—the most important goal for maximizing an HIV-positive person's health, as well as reducing risk of transmission. CDC has shared this analysis publicly, and engaged in discussions concerning it with other agencies so that they can also act on it. These data demonstrate the need for CDC's ongoing efforts to strengthen linkage to and

retention in care among persons living with HIV. The need, however, is not only for clinical care, but also for behavioral counseling, sexual risk reduction interventions, and mental health and substance use services—all of which require efficient, effective, interventions by trained providers. In allocating funding for HIV prevention programs to state and local entities, CDC emphasizes the importance of not just treatment alone but a comprehensive approach toward prevention which includes sexual and drug behavioral change programs. Efforts are underway to improve the health outcomes for persons living with HIV and to reduce transmission of HIV to others.

QFRs from Congressman Harris

Impact of Sequestration

- 1) Did the CDC assist the White House in preparing the estimate on the impact of the sequester on vaccines for children?**

CDC-HARRIS-1 RESPONSE

Yes, CDC assisted with the development of these estimates.

- 2) The CDC claims the President's FY2012 proposed cuts would have not impacted the number of vaccines because the CDC had identified savings in the program. Can the CDC use the savings identified in the President's FY2012 budget justification to offset the sequester?**

CDC-HARRIS-2 RESPONSE

Under the FY 2013 Budget, there was a reduction directed primarily at one-time, non-vaccine purchase activities—including program operations and infrastructure improvement grants. The Budget policy was to use administrative flexibility and other policies to maintain vaccination levels. Further, the Budget takes into account increased insurance coverage of vaccinations under the Affordable Care Act. Unlike the FY 2013 budget request, which identifies targeted one-time initiatives, sequestration is an indiscriminate cut across all budgetary activities, including vaccine purchases.

In determining the estimated potential impact of sequestration on the Section 317 program, we used the FY 2012 funding level for vaccine purchases and calculated a 5 percent cut to that amount—approximately \$9 million. The amount sequestered was then divided by \$68, which is the per-person cost to cover the four vaccines the program focuses on: hepatitis B, influenza, Tdap, and MMR. This results in an estimated 135,000 fewer individuals receiving vaccinations. To get the state-by-state data, the same formula was used, but instead used the individual prorated amount of FY 2012 funding provided to each state.

ATSDR

- 3) The Agency for Toxic Substances and Disease Registry (ATSDR) is a federal public health agency managed as part of the CDC (under HHS). Since 2010, the EPA and ATSDR have conducted shale gas-related investigations.**

Would you agree that any consultation, assessment, or study relating to health impacts associated with oil and gas activities should be undertaken with a rigorous scientific approach that is consistent with ATSDR's Public Health Assessment Manual and HHS guidelines for government science? (Failure to put naturally occurring substances into the proper context is inconsistent with the ATSDR Manual.)

CDC-HARRIS-3 RESPONSE

All of ATSDR's findings in public health assessments use a rigorous scientific process that includes critical scientific analysis, internal agency clearance, and independent review. All of the health assessments conducted in areas with ongoing hydraulic fracturing activities have followed ATSDR's Public Health Assessment Manual including procedures for appropriately characterizing naturally-occurring substances.

3). Would you further agree that consultations relating to health risks from oil and gas activities, including work performed as part of the Interagency Working Group to Support Safe and Responsible Development of Unconventional Domestic Natural Gas Resources, should be considered "highly influential scientific assessments" and thereby subject to appropriate levels of transparency, rigor, and peer review?

CDC-HARRIS-3 RESPONSE:

ATSDR's site specific evaluations are not "highly influential scientific assessments" under the requirements of the Office of Management and Budget's peer review guidelines bulletin. The findings in these assessments only apply to the specific sites being assessed and cannot be easily generalized.

6). With the Chairman's permission, can you commit to this Committee that relevant HHS, CDC, and ATSDR officials will schedule a briefing to discuss your Agency's activities relating to the study of health impacts from shale gas development?

CDC-HARRIS-6 RESPONSE:

CDC has completed a hearing for this for the Energy and Commerce Committee and will be a witness at the April 26 hearing before the House Science and Transportation Committee. CDC can provide the requested briefing.

Community Preventive Services Task Force

7) The Community Preventive Services Task Force is described in its annual report as an "independent, nonfederal, unpaid panel of public health officials" that meets three times a year and is completely supported by CDC staff in terms of administration, research and technical needs. The Task Force has issued over one hundred policy prescriptions – some of them controversial – as if it were acting on behalf of the United States Government itself rather than of an unpaid panel.

8) What is the role of the Task Force, and what review process is in place regarding its policy recommendations? What is the research process utilized by the Task Force to arrive at its policy prescriptions?

CDC-HARRIS-8 RESPONSE:

Section 399U of the Public Health Service Act establishes the Task Force to “review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the Guide to Community Preventive Services (referred to in this section as the ‘Guide’), for individuals and organizations delivering population-based services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, schools, governmental public health agencies, Indian tribes, tribal organizations and urban Indian organizations, medical groups, Congress and other policymakers.”

The Act establishes the Task Force as an independent, expert group, and specifies the role of CDC to “provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.”

9) What are the Task Force’s funding sources and how much did it receive in each fiscal year beginning with 2004 through fiscal year 2013? How much has been provided via discretionary appropriations? How much mandatory funding has the Task Force received since its inception by fiscal year? A factsheet on Healthcare.gov indicates \$49 million was committed to the Task Force in FY 2011 under Title 4 of the Accountable Care Act, the Prevention and Public Health Fund. Is the PPHF an additional, ongoing source of Task Force funds in FY 2013? Do you anticipate additional funding for the Task Force in the President’s budget request for FY 2014? If so, at what dollar levels?

CDC-HARRIS-9 RESPONSE:

What are the Task Force’s funding sources and how much did it receive each fiscal year beginning in 2004 through fiscal year 2013?

Section 915 of the Public Health Service Act established the U.S. Preventive Services Task Force with a parallel legislative mandate to the Community Preventive Services Task Force.

The Task Force is an independent panel. Section 399U of the Public Health Service Act specifies the role of CDC to “provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.” In support of those efforts, Community Guide funding allocations from FY 2004 to FY 2013 are below:

Fiscal Year	Funding Allocation
FY 2013	Budget not yet received
FY 2012	\$10,500,000
FY 2011	\$8,177,000

FY 2010	\$6,630,000
FY 2009	\$1,737,000
FY 2008	\$1,831,000
FY 2007	\$1,796,000
FY 2006	\$1,886,000
FY 2005	\$1,587,000
FY 2004	\$1,400,000

How much has been provided via discretionary appropriations?

Since FY 2010, the Community Guide has been funded in part through the mandatory Prevention & Public Health Fund (PPHF). All other funds are discretionary. See below for PPHF funding levels.

How much mandatory funding has the Task Force received since its inception by fiscal year?

Prevention and Public Health Fund allocations to Community Guide

FY 2012	\$10,000,000
FY 2011	\$7,000,000
FY 2010	\$5,000,000
Total	\$22,000,000

Is the PPHF an additional, ongoing source of Task Force funds in FY 2013?

CDC has not received its allocation for the Prevention and Public Health Fund for FY 2013. The Community Guide received PPHF in FY 2010 through FY 2012 as shown in the above table.

Do you anticipate additional funding for the Task Force in the President's budget request for FY 2014? If so, at what dollar levels?

The FY 2014 Budget has not yet been released.

10) How does this independent, unpaid Community Preventive Services Task Force allocate its budget? Please specify amounts for overhead (staff and expenses), research grants, program support, outreach to stakeholders, and so forth. Who is in charge of planning and directing the Task Force's budget? Has the Task Force been affected by sequestration? If so, how much?

CDC – HARRIS – RESPONSE 10:

CDC is congressionally mandated to provide ongoing administrative, research, and technical assistance to the Community Preventive Services Task Force. Within CDC, the Epidemiology and Analysis Program Office is responsible for planning and executing the Community Guide budget. CDC has not released its FY 2013 operating plan levels. The budget associated with the Community Guide is allocated by the three functions that support the Task Force and that are outlined in the FY 2012 Congressional Justification. See the table below for a breakdown of the FY 2012 budget.

<i>FY2012 Budget</i>	
Systematic Review and Science	\$5,000,000
Dissemination and Implementation	\$2,700,000
Task Force and Operations	\$2,800,000
Total Expenses	\$10,500,000

11) Priorities listed in the 2012 Report to Congress include expanding the Task Force's review capacity by using external contractors for policy updates. Would Task Force members select these external contractors or would that be decided by CDC staff? Are full time CDC staffers inadequate for the job?

CDC-HARRIS- 11 RESPONSE:

Section 399U of the PHS Act calls upon CDC to "provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations." CDC's use of contractors to support these functions is in congruent with the departmental guidelines of precluding contractors from final authorization of any action that affects the financial standing of the government.

12) When the Task Force funds "cross-cutting" public health research as envisioned in the 2012 Report to Congress, what is the process for selecting research topics, who evaluates the proposals and who selects grantees?

CDC-HARRIS-12 RESPONSE:

The Community Preventive Services Task Force does not fund research. It does identify gaps in the evidence, which are available to inform the research priorities of the field. The Community Preventive Services Task Force prioritizes its systematic review work through a multi-stage process that involves input from a wide range of stakeholders, including Task Force Liaison agencies and organizations, federal agencies, practice- and business-based partners and stakeholders, and the public.

14) How do you define "cross-cutting" public health research? Is there any effort to coordinate with other federal agencies to ensure CDC is not duplicating the work of other government researchers or treading on their congressionally mandated jurisdictions?

CDC-HARRIS-RESPONSE 13:

The Community Preventive Services Task Force does not fund research. The Community Preventive Services Task Force routinely connects with the U.S. Preventive Services Task Force (USPSTF) to ensure work is complementary and not duplicative. In addition, prior to beginning a review, the Community Preventive Services Task Force searches the literature to identify any prior systematic reviews already completed. Many federal agencies (e.g. Department of Justice, Department of Transportation, and Department of Education) also participate on the coordination teams that conduct the systematic reviews of the evidence.

National Institute for Occupational Safety and Health

14) Several years ago the lone underground mine safety research laboratory operated by government under the management of CDC/NIOSH, was the Lake Lynn research facility in southwest Pennsylvania. However, it suffered a roof fall that caused all research activities to be terminated. Demolition activities have been initiated to return the property to the lessor.

CDC-HARRIS-14 RESPONSE:

No question was asked of CDC.

15) During discussions in an attempt to purchase the Lake Lynn facility CDC apparently gave assurances that a new location would be identified and that this was a priority. What is the status of your search efforts? Have you identified potential candidate locations and when do you expect to execute a purchase agreement to begin construction of a new underground mine safety and health research laboratory?

CDC-HARRIS-15 RESPONSE:

CDC is moving forward to replace the mine safety research facility. CDC has finalized program requirements for a replacement facility, and is conducting initial searches to identify existing properties or potential sites that meet the criteria on which to procure or construct a replacement facility. CDC will provide an update after an initial assessment is completed.

Vaccines for Children Program

16) In the June 2012 Health and Human Services Office of Inspector General report, "Vaccines for Children Program: Vulnerabilities in Vaccine Management," it was found that over the two week study period that vaccines stored by seventy-six percent of the health care workers, in the states that were studied, were exposed to inappropriate temperatures. OIG auditors found that over 20,000 vaccine doses were compromised, potentially leaving children unprotected and at risk from preventable diseases and potentially wasting government-purchased vaccines worth approximately \$800,000. In October 2012, the CDC issued interim storage and handling guidelines recommending that all providers of VFC vaccines purchase expensive refrigerators, in addition to digital monitoring equipment requiring additional staff training that could cost providers over \$10,000 to comply. Dr. Frieden, as a physician myself, I know that my health care provider

peers and constituents in Maryland are looking for solutions that will not be large financial and administrative burdens.

CDC-HARRIS-16 RESPONSE:

CDC understands the commitment grantees, providers, and partners all have to the VFC program as well as the time it takes to properly manage the program. CDC is working to identify ways to strengthen the program as well as streamline processes and support grantees and providers.

While the CDC works to identify these improvements to the program, grantees are encouraged to provide enhanced, regular communications to providers regarding tools and resources available to help providers comply with VFC requirements.

- CDC will work with our partners, including state health officials, immunization program managers, and professional organizations to research the challenges and barriers providers face in meeting VFC requirements and identify strategies to improve compliance.
- CDC will also work to improve the focus, clarity and utility of our educational materials, guidance documents, program requirements, and support materials for vaccine management, storage, and handling.
- CDC has begun working with key partners and stakeholders to identify other steps that need to be taken to address the findings in the report as well as develop longer-term strategies to help providers strengthen their capacity to appropriately store and handle vaccines.
- CDC develops technical assistance, and vaccine storage and handling education products including guidebooks, DVD training courses, and net conferences. Grantees and providers can get a complete list of available resources from CDC and can also visit the CDC's website at <http://www.cdc.gov/vaccines/hcp.htm>. One excellent resource is California's storage and handling guidelines and tools (<http://www.cdph.ca.gov/programs/immunize/Pages/VaccineStorageandHandling.aspx>)

17) Why is the CDC not pursuing actions, like those of other international aid organizations, which would monitor the individual vial instead of trying to control every environment that the vial is placed in? Couldn't this be cheaper in the end?

CDC-HARRIS-17 RESPONSE:

Monitors placed directly on vaccine vials have been used internationally by WHO and international organizations to determine whether or not a vial has been exposed for a defined period of time to a specific temperature, typically in the context of an immunization campaign. However, the technology currently available is not appropriate for monitoring the routine storage of vaccines in the United States.

If vaccine vial monitors were to be approved for use in the US, FDA would have to receive applications from a vaccine manufacturer for each specific vaccine. A substantial amount of additional data would be needed, both on the stability of each vaccine at different temperatures over time and on vaccine vial monitors and their validation. Furthermore, the technology behind VVMs would need to advance to collect and store information about temperature exposures; to incorporate information about the product expiration date; and to reduce the subjective judgment currently required for interpretation. There are also scientific concerns that data from the international use of these monitors in an immunization campaign in the field cannot be directly

extrapolated to use during routine vaccine storage and handling in the United States. Further, these monitors do not prevent vaccines from being exposed to inappropriate storage temperatures or the subsequent compromise of vaccine potency, and there is a potential for false reassurances provided by these monitors that may have unintended consequences on provider practices. CDC has talked with FDA about these issues and concerns and, as technology for vaccine vial monitors continues to evolve, CDC will continue dialog with FDA and vaccine manufacturers.

18) What other alternatives are you currently considering that will reduce administrative burdens on health care providers, health care costs, and the potential for patients to receive vaccines that have been compromised by temperature extremes up to the point of administration?

CDC-HARRIS-18 RESPONSE:

CDC is in the process of implementing substantial improvements in vaccine ordering and inventory management systems. Through changes in the vaccine ordering systems and processes, CDC is expecting to improve vaccine accounting in provider offices and forecasting of providers' vaccine supply needs. As a result, providers will have less expired and soon-to-be expired vaccines to manage.

19) While I acknowledge these interim guidelines are just recommendations, I am still concerned. Will healthcare providers who decide they cannot afford to follow those recommendations be open to increased medical liability if a child receives an ineffective vaccine?

CDC-HARRIS-19 RESPONSE:

As noted, these interim guidelines are recommendations. While we cannot speak to the issue of liability, we are cognizant of the concept of medical standard of care and its role in liability determination.

QFRs from Congressman Harris

HRSA's website states that it is "an agency of the U.S. Department of Health and Human Services, is the primary Federal agency for improving access to health care services for people who are uninsured, isolated or medically vulnerable." As a physician and a member of Congress who represents rural areas, I am concerned about looming physician shortages.

HRSA-HARRIS-1

1. Has HRSA looked into the impact on rural areas of the looming shortages of physician specialists such as neurosurgeons, neurologists, psychiatrists, and pediatricians?

A: HRSA tracks a range of health workforce issues on a regular basis, with a particular focus on the availability of clinicians in rural and underserved areas. This is done through the work of the Rural Health Research Center grant program as well as the National Center for Workforce Analysis. Ensuring access to specialty care has long been a challenge in rural communities. For the specialty areas noted in the question, such as neurology and

psychiatry, HRSA funds telehealth programs designed to help improve access to these services through the use of technology.

HRSA-HARRIS-2

2. Hospitals in rural areas across the country have begun to eliminate their labor and delivery services because of costs related to medical liability. Has HRSA examined this issue and if so, what actions is it taking?

A: Access to obstetrical care and specifically the ability of rural hospitals to provide labor and delivery services can be a challenge. We have seen data indicating that increasing numbers of small rural hospitals have ceased to provide labor and delivery services. There are a variety of potential factors that influence this including whether or not a hospital service area has enough volume to be economically viable. In other cases, there are concerns that the obstetrical providers see enough patients to maintain their skills and ensure quality. In yet other cases, rural hospitals may face challenges in attracting obstetrical providers. HRSA does provide grants to small rural hospitals to focus on quality and performance improvement which can help address some of these challenges. In addition, HRSA's Outreach grant programs can be used to support projects focused on obstetrical care.

Through CMMI's Partnership for Patients, 26 State, regional, national and hospital system organizations serve as Hospital Engagement Networks (HENs). These organizations help identify solutions already working to reduce hospital-acquired conditions, and work to spread them to other hospitals and health care providers.

- 1) **Can you provide specific examples of how the work of the HENs is actually reducing patient harm?**

CMS-CONGRESSMAN HARRIS-1 Answer: The Partnership for Patients initiative is a public-private partnership working to improve the quality, safety and affordability of health care for Medicare, Medicaid, and CHIP beneficiaries, and, by extension, for all Americans.

As you may know, Hospital Engagement Networks (HENs), as part of the Partnerships for Patients, work at the regional, State, national or hospital system level to help identify solutions already working and disseminate them to other hospitals and providers. Hospital Engagement Networks develop learning collaboratives for hospitals and engage in a wide array of initiatives and activities to spread effective interventions and rapidly improve patient safety. These two-year contracts, which may be extended for a third year, require Hospital Engagement Networks to conduct learning activities and make best practices available to partner hospitals in ten core areas of focus, although the contractors do not have to limit their work to this core set. The core areas of focus are: catheter-associated urinary tract infections, central line-associated blood stream infections, venous thromboembolism, ventilator-associated pneumonia, surgical site infections, pressure ulcers, adverse drug events, injuries from falls and immobility, obstetrical adverse events, and preventable readmissions.

We believe that we have made meaningful and significant progress towards the Partnership for Patient's goals. There is a measure called the 30-day all-cause readmission rate, which assesses readmissions to a hospital within 30 days of discharge. We have seen a drop in this measure

over the past five years from an average of 19 percent to 17.8 percent in the last half of 2012. This translates to about 70,000 fewer readmissions in 2012. We know that readmissions are extremely costly so this trend suggests that real savings are being realized. Over 3,700 hospitals are working to achieve these reductions using proven interventions and we think this focused sustained effort is going to lead to even more positive results.

2) Will contracts to Hospital Engagement Networks be extended to a third year?

CMS-CONGRESSMAN HARRIS-2 Answer: The Hospital Engagement Networks contract included a two year agreement with an option to continue through a third year. The contracts have not yet finished their second year, but CMS will review each contract to determine whether the contracts will be extended for the third option year.

QFRs from Ranking Member DeLauro

HRSA-DELAURO-1

- 1. Expansion of health centers has the potential for improving access to high-quality, cost-effective, primary care—including for people who will be gaining coverage through the Affordable Care Act.**

A: HRSA administers funding opportunities through the Health Center Program that increase and improve access to high-quality, cost effective, affordable primary care, including for those patients gaining coverage through the Affordable Care Act. Since the beginning of 2009, health centers have increased the total number of patients served by approximately 4 million people, increasing the number of patients served from 17.1 million to more than 21 million annually.

HRSA-DELAURO-2

- 2. How many grants, and in what amounts, has HRSA been able to provide in fiscal years 2010 through 2013 (to date) to support establishment of new health centers, new health center sites, expanded services at existing centers, and health center planning?**

A:

In FY 2010, under the Recovery Act, HRSA provided approximately \$250 million to support:

- 127 New Access Point grants to create new health centers and new service delivery sites for existing health centers; and
- 1,128 Increased Demand for Services grants to expand the service capacity of more than 1,100 existing health centers.

Under the Affordable Care Act, from FY 2011 through FY 2012, HRSA provided:

- \$158 million to support 286 New Access Point grants to create new health centers and new service delivery sites for existing health centers; and
- \$10 million to support 129 health center planning grants.

HRSA has also awarded grants to health centers for capital development purposes under both the Recovery Act and the Affordable Care Act. These include:

- The Recovery Act Capital Improvement Program (CIP) provided \$851 million in grants for more than 1,100 health centers nationwide. These grants supported the construction, repair and renovation of over 1,500 health center sites nationwide to help these centers expand and upgrade their existing facilities. More than 650 centers used the funds to upgrade equipment and purchase HIT systems, and nearly 400 health centers promoted the expansion and adoption of electronic health records.
- The Recovery Act Facility Investment Program (FIP) addressed major capital improvement needs in health centers, including renovation, modernization, and construction. In FY 2010, a total of \$520 million in Recovery Act funding was awarded to 86 CHCs in 30 states, the District of Columbia, and Puerto Rico.
- The Affordable Care Act Capital Development Program (CD) provided \$732 million to 144 CHCs across the country in FY 2011. These grants, like the FIP awards, allowed health centers to address major pressing construction and renovation needs and expand access to care.
- The Affordable Care Act Health Center Capital Development - Building Capacity Program (CD-BC) provided approximately \$629 million to 171 existing health centers across the country for longer-term projects to expand their facilities, hire more employees and serve more patients.
- The Affordable Care Act Health Center Capital Development - Immediate Facility Improvements Program (CD-IFI) provided approximately \$101 million to 230 existing health centers to address immediate facility needs.

HRSA is currently administering a competitive funding opportunity for Health Center Program New Access Point grants in FY 2013.

HRSA-DELAURO-3

3. How many applications for such grants has HRSA received? How large a backlog of unfunded applications do you have?

A: HRSA is in the process of receiving applications for the FY 2013 Health Center Program New Access Point funding opportunity. HRSA plans to award approximately 25 NAP awards for a total of \$19 million in FY 2013, but at this time the number of unfunded applications remaining at the end of FY 2013 is unknown.

HRSA-DELAURO-4

4. What do you see as the principal current and future shortages of health professionals to be addressed by HRSA's health workforce programs—including shortages of particular professions and specialties and shortages in particular areas and communities? What data and estimates support your assessment?

A: Three of the top priorities for HRSA's health workforce programs are: primary care, oral health, and behavioral health. While we are supporting efforts to increase the overall supply of these critical health providers, we are particularly concerned about the uneven distribution of these providers across the country. Through the designation of Health Professional

Shortage Areas (HPSAs) in collaboration with states and communities, we have identified communities with particularly high needs in each of these workforce areas. We are also developing an improved methodology to identify primary care shortage areas. In general, rural and inner city areas tend to face the greatest health workforce shortages and access problems. Through the development of the National Center for Health Workforce Analysis, authorized by the Affordable Care Act (ACA), we have expanded our data analysis and projections capabilities to better assess current and future health workforce needs. The National Center for Health Workforce Analysis is developing integrated projection methodologies for clinical specialties as well as for the health occupations and they have established a schedule for projections to be produced over the next several years.

HRSA-DELAURO-5

5. What problems are the health professions diversity programs designed to address? How do they do so? What evaluation data is available regarding the success of these programs?

A: The health professions diversity programs are designed to improve the recruitment and enhance the academic preparation of students from disadvantaged backgrounds into the health professions. This is a key strategy for increasing access to care across the country, but also to improve access and care in underserved areas. Evidence suggests that minority health professionals are more likely to serve in areas with a high proportion of uninsured and underrepresented racial and ethnic groups. Greater diversity among health professionals is also associated with improved access to care for racial and ethnic minority patients, greater patient choice and satisfaction, and better patient-clinician communication.

Program Evaluation Data

The Centers of Excellence (COE) Program seeks to increase the supply and quality of underrepresented minorities (URM) in the health professions workforce by providing grants to health professions schools and other public and nonprofit health or educational entities that meet the eligibility requirements described below. Funds support the development and implementation of structured training activities that are specifically designed to: enhance the academic performance of underrepresented minority students; increase the applicant pool of underrepresented minority students; and carry out student training in providing healthcare services so as to promote the interest of underrepresented minority students in the health professions. Data from the most recent academic year showed that grantees of the COE program offered over 100 different types of structured training programs between July 1, 2011 and June 30, 2012 to underrepresented minority students across the nation. The majority of structured training programs were intensive (*i.e.*, lasted over 180 clock hours) and reached a total of over 3,500 trainees. By the end of the academic year, a total of 1,894 individuals completed program requirements and 91 percent of these intend to pursue health professions training.

The Scholarships for Disadvantaged Students (SDS) program increases diversity in the health professions and nursing workforce by providing grants to eligible health professions and nursing schools for use in awarding scholarships to students from disadvantaged backgrounds with financial need. The SDS program aims to increase: 1) the number of

graduates practicing in primary care, 2) enrollment and retention of URMs, and 3) the number of graduates working in medically underserved communities. Greater diversity among health professionals is associated with improved access to care for racial and ethnic minority patients, greater patient choice and satisfaction, and better patient-clinician communication. In addition, evidence suggests that minority health professionals are more likely to serve in areas with a high proportion of uninsured and underrepresented racial and ethnic groups. Data from the most recent academic year showed that grantees of the SDS program supported a total of over 22,000 disadvantaged students—exceeding the program’s performance target of 18,000 by 22%. Analysis of performance data showed that, among students supported, over 13,000 were underrepresented minorities—exceeding the program’s performance target of 11,200 by 16%. Results from these analyses also showed that, of the total number of students supported, 6,145 completed their program. The most recently reported SDS data indicate that one out of every three SDS graduates was reported to have entered service in a medically underserved community.

The Nursing Workforce Diversity (NWD) program increases nursing education opportunities for individuals from disadvantaged backgrounds, including racial and ethnic minorities underrepresented among registered nurses, by supporting activities such as the provision of student stipends and scholarships, pre-entry preparation, advanced education preparation, and retention activities. The NWD program will increase nursing education opportunities for individuals from disadvantaged backgrounds to produce a more diverse nursing workforce. This outcome will help meet the increasing need for culturally aligned, quality health care for the nation’s rapidly diversifying population and help close the gap in health disparities. Data from the most recent academic year showed that grantees of the NWD program offered over 90 different types of structured training programs between July 1, 2011 and June 30, 2012 to underrepresented minority students across the nation. Through these training activities, grantees of the NWD program reached a total of over 4,800 trainees. By the end of the academic year, a total of 1,365 individuals completed program requirements and 84 percent of these intend to pursue health professions training.

HRSA-DELAURO-6

6. What needs are the primary care medicine and oral health training programs designed to address? How do the various funding streams available under these headings address these needs? What data are available regarding the impact of these programs on the supply and distribution of targeted health professionals?

A: The primary care medicine and oral health training programs address three priority areas: 1) increase capacity and improve distribution of the primary care workforce supply through enhanced education and training programs; 2) support innovations in health professions training that include team-based models of care founded on interprofessional education and clinical training experience; and 3) reduce health disparities and promote health equity by increasing healthcare workforce diversity. The programs also support primary care education that teaches care for vulnerable populations and prepares clinicians to practice in medically underserved communities. Additional areas of emphasis include community-based training, faculty development, and the integration of public health into primary care.

The Primary Care Training and Enhancement (PCTE) program supports competitive funding opportunities that develop and enrich the education of future primary care physicians, physician assistants, teachers, and researchers through curriculum development and enhancement and program expansion to ultimately strengthen the primary care workforce. PCTE is authorized by section 747(a) of the Public Health Service Act, as amended by section 5301 of the Patient Protection and Affordable Care Act (P. L. 111-148).

The Public Health and Prevention Fund, created by the Affordable Care Act, supported two programs to increase the number of physician and physician assistant students trained in primary care from 2010-2015: the Primary Care Residency Expansion and Expansion of Physician Assistant Training programs, respectively. These programs are increasing the number of clinicians prepared to enter primary care practice.

The Training in General, Pediatric, and Public Health Dentistry grant programs are authorized under section 748 of the Public Health Service Act. This program aims to enhance oral health care training and increase the supply of a qualified workforce to improve access to and the delivery of oral health care services to all individuals. Funding for this program supports grants or contracts to plan, develop, and operate, or participate in approved professional training programs in the fields of general, pediatric, or public health dentistry for dental students, residents, practicing dentists, dental hygienists, or other approved primary care dental trainees. The current funding opportunities are predoctoral training, postdoctoral training, dental faculty development, and dental faculty loan repayment programs.

The Grants to States to Support Oral Health Workforce Activities program is authorized under section 340G of the Public Health Service Act. This program provides funding to help States develop and implement innovative programs to address the dental workforce needs of designated dental health professional shortage areas in a manner that is appropriate to the States' individual needs. The statute provides twelve eligible grant activities and a thirteenth that allows the Secretary to fund innovative projects that are not specified in the law.

At this time, the outputs of these programs that we are tracking include the number of trainees, the number of graduates or program completers, the number of trainees receiving training in medically underserved areas, the number of graduates or program completers practicing in medically underserved areas, the number and percentage of graduates or program completers from minority and/or disadvantaged backgrounds, the number of primary care patients the trainees encounter, number of trainees receiving direct financial support, curriculum content, and training settings. Outcome data for the Grants to States to Support Oral Health Workforce Activities program are available for each of the eligible statutory activities.

HRSA-DELAURO-7

- 7. The President's fiscal year 2013 budget proposed a user fee for the section 340B drug pricing program. Please explain why this user fee is needed. What would this fee allow the Office of Pharmacy Affairs to do, and what would be the effect if this fee, or comparable funding, is not provided?**

A: The cost recovery fee is designed to ensure that some of the costs of administering the 340B Program are paid for with a small fraction of the received benefit. The cost recover fee would be paid by the 340B participating covered entities (not the manufacturers). The cost recovery fee will create a sustainable funding source to support the natural growth of the program and meet new program integrity responsibilities.

The request includes a 0.1 percent user fee. The program was expanded under the Affordable Care Act and will be phased in as regulations and policies are promulgated and systems are designed and implemented. Expanded responsibilities authorized under the Affordable Care Act include:

- Program oversight authority and responsibility, and expanded 340B drug discounts to certain free standing cancer hospitals, rural referral centers, sole community hospitals, critical access hospitals, and children's hospitals;
- Enhanced oversight that will include a civil monetary penalty for manufacturers that overcharge a covered entity for a 340B drug; and,
- Establishment of an administrative process for resolving disputes between covered entities and manufacturers.

Specific citations on Page 301,302 of the FY 2013 CJ:

HRSA requires significant additional ongoing funding sources to be able to administer the new authorities and responsibilities. Funds are also needed to address longstanding recommendations by the OIG to make major improvements in program integrity. The cost recovery fee provides the resources needed to address both long standing concerns and the expanded authorities, while reducing the government expenditure of taxpayer dollars. The cost recovery fee will ensure a reliable and continuous funding source for HRSA to fully administer the 340B Program and will allow HRSA to better monitor compliance among both manufacturers and covered entities.

HRSA-DELAURO-8

8. As you know I am a strong supporter of the Graduate Psychology Education program, especially its focus on training young psychologists to work with underserved populations. I have a number of requests related to the GPE program:

HRSA-DELAURO-8a

a. Please provide information on the number of participating graduate psychology education students for the past three years.

A: The Graduate Psychology Education (GPE) program is designed to close the gap in access to quality behavioral health care services by increasing the number of adequately prepared behavioral health providers who are able to provide care in underserved areas. The intent of this program underscores the need to improve access to competently-trained behavioral health providers, as well as to promote population-based behavioral health.

The GPE program has funded 20 grantees (primarily schools of health professions) for the past three years. In total, grantees of the GPE program trained a total of 688 students in Academic Year 2009-2010 (supported with FY 2009 funds); 710 students

in Academic Year 2010-2011 (supported with FY 2010); and 938 students in Academic Year 2011-2012 (supported with FY 2011 funds). These numbers are a combination of students who are enrolled in graduate-level psychology programs, as well as students in other health professions who receive clinical training in collaboration with the psychology training program.

Starting with Academic Year 2011-2012, we have begun collecting from our grantees individual-level data on each supported student. From this effort we found that of the 938 students trained in Academic Year 2011-2012 with support from the GPE program, 246 were graduate-level psychology students in the following fields:

- Clinical Psychology (77%)
- Counseling Psychology (16%)
- Other Psychology (7%)

HRSA-DELAURO-8b

b. Please provide information on the numbers and types of other health profession students with whom the psychology students are trained for the past three years.

A: The GPE Program's focus on interprofessional training integrates behavioral health, primary care, and public health into clinical education and practice to contribute to improved population health. Data regarding the field of study for GPE students were not collected until Academic Year 2011-2012. With the implementation of individual-level data requirements, BHPPr is now able to provide the following information for Academic Year 2011-2012:

- 672 out of the 938 students trained by grantees of the GPE program were in fields of study other than psychology and seeking interprofessional training.
- These fields included:
 - Audiology (0.4%)
 - Clinical Nurse Specialist in Psychiatric & Mental Health Care (0.2%)
 - Clinical Social Work (1.4%)
 - Family Medicine (7.2%)
 - General Internal Medicine (29%)
 - General Pediatrics (16.3%)
 - Occupational Therapy (0.8%)
 - Pastoral & Spiritual Care (1.6%)
 - Public Health (2.6%)
 - Speech Language Pathology (0.2%)
 - Other health-related field (36%)

HRSA-DELAURO-8c

c. Please provide information on the types of populations served including a total number of persons provided services as a result of the program.

A: GPE funds are awarded to eligible accredited health profession schools, universities, and other public or private nonprofit entities to plan, develop, operate or maintain graduate programs in mental and behavioral health practice to train psychologists to work with underserved populations. The program is designed to foster an integrated and interprofessional approach to addressing access to behavioral health care for underserved populations.

Data regarding populations served through clinical training sites are collected at the organizational level rather than the student level. Results for Academic Year 2011-2012 show that grantees used 120 different sites across the nation to provide psychology and interprofessional students with clinical and/or experiential training. Approximately one out of every two training sites used for the purposes of clinical training was located in either a medically underserved community (MUC) or a Health Professional Shortage Area (HPSA).

The following is the percentage of sites that reported serving specific types of vulnerable populations in Academic Year 2011-2012:

- Adolescents (11.1%)
- Children (10.4%)
- Chronically ill (8.8%)
- College students (2.7%)
- Homeless individuals (5.8%)
- Individuals with HIV/AIDS (5.7%)
- Individuals with mental health or substance abuse disorders (12.2%)
- Older adults (4.1%)
- Pregnant women and infants (10.4%)
- Migrant workers (5.0%)
- Returning war veterans (Iraq or Afghanistan) (1.9%)
- Veterans (1.1%)
- Victims of abuse or trauma (1.4%)
- Military and/or military families (8.8%)
- Unemployed (2.7%)
- Other Types of Populations (7.7%)

HRSA-DELAURO-9

9. Please provide the number and percentage of GPE trainees who remain to work with underserved populations after they become licensed to practice.

A: Grantees of the GPE program are required to provide information about post-graduation employment settings among graduates rather than the types of populations they serve. The most recent performance data showed that 32 out of the 110 graduates (29%) reported working in medically underserved communities post-graduation which, by definition, encompass several

types of underserved populations. The majority of graduates who reported employment in a medically underserved community (23 out of the 32) are currently pursuing a post-doctorate fellowship in clinical psychology.

HRSA-DELAURO-10

10. I understand that school psychologists are excluded from competing for GPE grants as well as other HRSA programs like the National Health Service Corps despite the fact that they are trained as health service psychologists and can work in the same health care settings as the other two types of health service psychologists: clinical and community. Can you explain the basis for this policy?

A: The GPE program will consult with the American Psychological Association to use terminology in our funding opportunity announcements that allow all types of psychology training programs to compete for GPE funding. The GPE program fosters the integration of behavioral health care into primary care through innovative program development and interdisciplinary training. The GPE program provides support to train and improve the number of clinically-trained behavioral health psychologists to serve underserved communities. Such communities include but are not limited to, populations in rural areas, children and adolescents, the elderly, victims of abuse, the chronically ill, disabled, returning war veterans, military personnel and their families, and tribal populations.

HRSA-DELAURO-11

11. As you know the GPE program is based on a foundation of interdisciplinary and interprofessional training. Does HRSA plan to use this model in developing policy for other grant programs designed to develop our future health care workforce? If so, please describe those efforts.

A: HRSA has advanced on many other fronts to support interprofessional training and practice in the health workforce. This goal is consistent with findings from the recent IOM report "Best Care at Lower Prices" which offers several recommended strategies that stress the important contribution of interprofessional practice to improving care and reducing costs.

Through grants in education and training, HRSA has invested in several activities to promote interprofessional clinical practice among nurses, front line workers, physicians, dentists, public health providers, and other clinical professionals. The Nurse Education, Practice, Quality and Retention Program supports projects that create and expand innovations in interprofessional collaborative practice that promote collaboration between nurses and other health professions and help nurses gain the necessary skills to lead and support team-based care. In addition, the Advanced Nursing Education Program supports projects that integrate technology into interprofessional education offerings for advanced practice nursing students who are joined by students in other health occupations.

In FY 2012, HRSA competitively awarded the University of Minnesota Academic Health Center to serve as the site for the National Center for Interprofessional Practice and Education. The Center is acting as a one-stop resource on interprofessional education and practice that also supports research, data collection and analysis. The key to this Center's success will be its ability to influence the training and education of our nation's future health professionals as well as the practice of current clinicians in their everyday patient

care. Students and health professionals will learn how team-based care can improve patient centeredness, patient safety, and reduce duplicative tests and procedures. In doing so, this effort will accelerate the transformation health care delivery that is often siloed by different providers and services, to one that values coordinated patient care. These goals are consistent with the ongoing implementation of the Affordable Care Act, which calls for the development of new healthcare organization and structures to promote team-based care, such as Accountable Care Organizations, patient-centered medical homes, and transitional care models.

HRSA is also supporting interprofessional development on the topic of Alzheimer's disease and related dementias and the FY2014 Budget request includes a continuation of this program. Specifically, this program is providing additional funding to 45 Geriatric Education Center Program grantees to develop evidence-based practice curricula related to Alzheimer's disease and dementia. Taking it one step further, these grantees are also using the curricula to train interprofessional teams of health care practitioners.

Another example of our work to move towards interprofessional practice is our recent launch of the Interprofessional Oral Health Clinical Competencies Project to explore how to close the chasm between medical and dental care. The project brings together oral health and primary care providers (such as physicians, physician assistants, nurse practitioners and nurse mid-wives), health systems leaders, and funders with the aim of enhancing physicians' ability to do oral health assessments in collaboration with dentists and other oral health providers.

HRSA-DELAURO-12

12. Regarding applying for a GPE grant, can an internship that is part of a consortium apply as a new program in order to avoid being penalized for other parts of the consortium of which the graduate students go into research and therefore make it difficult to meet the criteria for the Medically Underserved Area (MUA) preference?

A: Eligible applicant organizations can be part of a consortium that is accredited by the American Psychological Association (APA); thereby the members of the consortium are collectively accredited by the APA for the training provided to the interns. The authorizing legislation in sections 791 of the Public Health Service (PHS) Act provides that a funding preference be granted to any qualified applicant that meets the criteria for one of the MUC funding preferences: demonstrating high rate in service to MUC, demonstrating significant increase in service to MUC, or demonstrating a new program. Applicant organizations are required to both specifically request the MUC funding preference, and meet the specified criteria for the preference to be placed in a more competitive position among applications that could be funded.

QFRs from Ranking Member DeLauro

1) What are the principal programs and mechanisms by which CDC provides financial support to state and local health departments? Please provide, to the extent possible,

the amounts made available to health departments under these programs and mechanisms for each of fiscal years 2008 through 2012 and, to the extent known, 2013. What effect is sequestration expected to have on this funding?

CDC-DELAURO-1 Response:

CDC provides financial support to state and local health departments through grants and cooperative agreements. The table below presents the funding by principle programs or categories to health departments. Examples of the impact of sequestration could include the following: not issuing continuation awards, not awarding incremental funds on multi-year awards, or negotiating a reduction in the scope of awards to meet the constraints imposed by sequestration. Additionally, plans for new grants may be re-scoped, delayed, or canceled depending on the nature of the work and the availability of resources.

Funding Categories	FY 2010	FY 2011	FY 2012
Birth Defects and Developmental Disorders	\$ 19,619,654	\$16,171,231	\$19,787,466
Chronic Disease Prevention and Health Promotion	\$379,054,165	\$334,657,540	\$369,021,128
Environmental Health	\$63,060,379	\$37,463,834	\$23,995,835
Infectious Diseases	\$785,005,931	\$743,685,279	\$838,944,312
Injury Prevention and Control	\$46,876,842	\$43,303,486	\$43,193,085
Occupational Safety and Health	\$6,951,826	\$3,266,262	\$0
Public Health Preparedness and Emergency Response	\$630,483,627	\$540,519,998	\$549,321,989
Vaccines For Children	\$2,569,206,053	\$2,672,916,828	\$2,510,509,958

Source: CDC FY 2010- FY 2012 Grant Funding Profiles, CDC website, at <http://wwwn.cdc.gov/FundingProfiles/FundingProfilesRIA/>

State	CDC State Grants Profile (Dollars in thousands)		
	2010	2011	2012
Alabama	\$100,062	\$95,428	\$93,514
Alaska	\$36,491	\$37,566	\$38,820
American Samoa	\$3,357	\$3,090	\$3,488
Arizona	\$127,945	\$126,193	\$122,063
Arkansas	\$69,175	\$69,510	\$65,244

California	\$660,975	\$796,819	\$684,469
Colorado	\$100,407	\$99,304	\$99,074
Connecticut	\$68,240	\$69,866	\$66,705
Delaware	\$25,373	\$25,875	\$30,281
District of Columbia	\$98,802	\$88,787	\$91,209
Federated States of Micronesia	\$3,638	\$3,654	\$2,930
Florida	\$303,548	\$305,262	\$314,363
Georgia	\$236,234	\$228,752	\$212,478
Guam	\$6,582	\$6,321	\$6,484
Hawaii	\$35,054	\$35,198	\$32,222
Idaho	\$40,892	\$35,630	\$34,903
Illinois	\$253,082	\$250,525	\$257,153
Indiana	\$120,667	\$97,769	\$89,666
Iowa	\$55,849	\$61,380	\$63,418
Kansas	\$46,961	\$52,630	\$51,503
Kentucky	\$72,200	\$77,012	\$77,279
Louisiana	\$116,221	\$107,865	\$103,142
Maine	\$32,867	\$35,171	\$39,946
Marshall Islands	\$2,472	\$2,360	\$2,552
Maryland	\$157,348	\$152,501	\$138,402
Massachusetts	\$138,622	\$142,234	\$139,390
Michigan	\$177,352	\$174,383	\$169,499
Minnesota	\$90,737	\$96,656	\$95,782
Mississippi	\$72,168	\$74,777	\$74,979
Missouri	\$97,949	\$102,907	\$101,820
Montana	\$25,460	\$30,412	\$29,819
Nebraska	\$41,132	\$45,411	\$42,125
Nevada	\$54,100	\$56,400	\$58,779
New Hampshire	\$29,762	\$28,832	\$28,651
New Jersey	\$144,937	\$149,232	\$144,925
New Mexico	\$59,979	\$68,198	\$70,250
New York	\$562,802	\$473,290	\$463,529
North Carolina	\$183,901	\$176,829	\$175,698
North Dakota	\$19,355	\$20,451	\$21,055
Northern Mariana Islands	\$4,064	\$3,641	\$4,591
Ohio	\$161,036	\$163,919	\$163,521
Oklahoma	\$82,838	\$89,544	\$84,813
Oregon	\$69,199	\$70,646	\$76,661
Pennsylvania	\$188,700	\$192,550	\$196,649
Puerto Rico	\$77,854	\$90,956	\$94,366
Republic Of Palau	\$2,537	\$2,891	\$2,952
Rhode Island	\$32,869	\$34,535	\$31,961

South Carolina	\$100,448	\$96,384	\$100,756
South Dakota	\$24,007	\$25,352	\$24,397
Tennessee	\$116,145	\$112,622	\$110,507
Texas	\$531,437	\$523,439	\$520,770
Utah	\$55,563	\$54,890	\$55,357
Vermont	\$21,921	\$23,794	\$21,110
Virgin Islands	\$6,096	\$5,869	\$4,745
Virginia	\$113,912	\$116,157	\$115,111
Washington	\$143,488	\$168,426	\$158,136
West Virginia	\$43,317	\$45,822	\$46,508
Wisconsin	\$89,415	\$93,799	\$90,650
Wyoming	\$19,539	\$18,833	\$15,696
Grand Total	\$6,357,083	\$6,438,548	\$6,256,869

This table includes selected CDC grants and cooperative agreements provided to health departments, universities, and other public and private agencies within each state.

- 3) I understand that CDC recently issued a Funding Opportunity Announcement providing a common application process for several chronic disease prevention programs. Please explain this consolidated process and the benefits that it is intended to produce, as well as what mechanisms will be used for maintaining the identity of, and accountability for, the separate funding streams involved.**

CDC-DELAURO-2 RESPONSE:

CDC's strategy is to capitalize on the complementary nature of the respective program strategies to develop cross-cutting strategies and expertise to achieve measurable impact; provide core funding to all states to support heart disease, diabetes, school health and nutrition, physical activity and obesity program activities; provide competitive funding to approximately 25 states to support the implementation of enhanced chronic disease prevention and health promotion strategies; and, maintain fidelity to current categorical appropriation funding levels and performance targets. We plan to bring together four programs whose current cooperative agreements will end in FY 2013: Heart Disease and Stroke Prevention; Nutrition, Physical Activity, and Obesity; School Health; and Diabetes. Funded activities will result in measurable impacts to address school health, nutrition and physical activity risk factors, obesity, diabetes, and heart disease and stroke prevention. States will advance the goals of categorical funding lines, while tracking funding and performance accordingly. The short-term outcomes of the program will be to: (1) Improve state, community, worksite, school, and early childhood education environments to promote and reinforce health and healthful behaviors across the life span related to diabetes, cardiovascular health, physical activity, healthful foods and beverages, obesity, and breastfeeding (2) Improve effective delivery and use of quality clinical and other preventive services aimed at preventing and managing hypertension and diabetes (3) Increase community-clinical linkages to support prevention, self-management, and control of diabetes, hypertension, and obesity. The program's long-term goals will be improved prevention and control of hypertension, diabetes, and overweight and obesity.

- 4) Funding for the Childhood Lead Poisoning Prevention program has been reduced from \$35 million in fiscal year 2010 to just \$2 million in fiscal year 2012. What activities have been eliminated as a result of that cut, and what has been the effect of those eliminations? What activities have been continued? In your view, does lead poisoning remain a health problem warranting continued public health interventions?**

CDC-DELAURO-3 Response:

CDC continues to provide national expertise and analyses of childhood lead poisoning prevention. CDC remains committed to train and consult with state and local agencies and stakeholders in healthy homes and lead poisoning prevention. CDC will continue to monitor trends in childhood blood lead levels if states provide data and by analyzing the National Health and Nutrition Examination Survey. CDC will also provide epidemiological and laboratory quality control support.

Although the number of children with elevated blood lead levels has declined dramatically over the last four decades, there remains an estimated 535,000 (2.6 percent) of U. S. children aged 1-5 years with blood lead levels greater than or equal to the reference value of 5 micrograms per deciliter. Any exposure to lead is harmful to children's health. Children who are exposed to lead will suffer at least a \$3,000 loss in lifetime productivity for each 1ug/dL increase in blood-lead level. Lead poisoning prevention resources should be targeted to areas and communities where children are most at risk.

- 4) What does CDC need to do in order to modernize its capacity for detection and tracking of foodborne illnesses and to carry out its responsibilities under the Food Safety Modernization Act? How much progress has been made in these efforts and what more needs to be done?**

CDC-DELAURO-4 RESPONSE:

We need to invest in the capacity of public health to detect, investigate, stop and prevent foodborne outbreaks. These investments will help restore and improve federal, state and local capacity to monitor foodborne illness and respond to outbreaks.

Priority areas of investment include:

- 1) Preserving the capacity of our public health laboratory network to track infections and detect outbreak in the next few years, as new diagnostic technologies are adapted in the medical laboratories to diagnose infections.
- 2) Expanding the number of states participating in the Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE) which work together to develop, assess and implement model public health practices and tools for rapid and efficient outbreak detection and response.
- 3) Funding fully the Integrated Food Safety Centers of Excellence to serve as a resource for local, state and federal public health professionals to respond to outbreaks of foodborne illness.
- 4) Increasing funding support for all state public health agencies to maintain critical capacity to enhance the national foodborne surveillance, outbreak detection and response systems.

- 5) Intensifying efforts to provide information for policy by determining which foods make us sick. CDC works closely with FDA and USDA/FSIS to create advanced statistical models that attribute illnesses to food categories so the regulatory agencies and food industries can better focus their efforts to prevent contamination of food where it is most effective.

For CDC to carry out its responsibilities under the Food Safety Modernization Act (FSMA), and to strengthen the capacity in the local and state public health departments that are our critical partners, we will need to maintain and upgrade the PulseNet system that detects dispersed outbreaks as hospital and clinical laboratories turn to diagnostic methods that do not depend on growing the bacteria in culture on a Petri dish. We also need to do more to attribute illnesses to specific food commodity groups to help target prevention efforts through an interagency consortium that has begun this large task, and to integrate surveillance systems that help monitor the effectiveness of food safety prevention measures.

The response to outbreaks can be improved. We need to improve the timeliness of outbreak detection and response which depends on evaluating and optimizing the practices that can make response faster. This has already begun in the FoodCORE sites (in the state of Connecticut and six other sites), where the cost and impact of innovative new practices is evaluated, and the most successful practices are being described. Supporting FSMA's Integrated Food Safety Centers of Excellence will help disseminate and train other states in the best practices. These Centers will serve a critical role in transferring best practices and tools in food safety surveillance and outbreak response to state and local public health program staff and the food industry through training and regional capacity support.

Finally, to address the longer term need to modernize its capacity for detection, tracking and control of many infectious illnesses, CDC and its public health partners will require rapid, sustained growth in advanced molecular technology and bioinformatics. This is critical to keep pace with scientific advances in rapid reading and decoding of large blocks of DNA from pathogens that are revolutionizing disease detection and investigation. Making use of this technology for public health depends on having sufficient laboratory and computing infrastructure in the field of bioinformatics, as well as highly skilled experts to manage, analyze, evaluate, and gain new information from large amounts of biological data. CDC has started a few pilot bioinformatics projects that provide some initial data; however, CDC has not been able to develop the molecular technology and bioinformatics capacity to keep pace with rapid changes in molecular science. This new technological capacity is critical to support the detection, tracking and investigation of many infections, including foodborne ones.

5) Please explain the function and purposes of the Environmental Health Tracking Network. What results and successes have been achieved by the Network over the past several years?

CDC-DELAURO-5 Response:

The Environmental Public Health Tracking Network is a dynamic, web-based system that tracks and reports environmental hazards and the health problems that may be related to them (www.ephtracking.cdc.gov). With tracking, public health officials can apply the same "disease

detective” skills used in infectious disease surveillance to respond quickly, often within hours, to locate hazard sources or answer residents’ concerns.

To date, the tracking network includes 17 datasets, 34 indicators, and over 300 measures. Over the past year, CDC added biomonitoring data to the National Health and Nutrition Examination Survey, animated maps to show disease trends over 10 years, and created a tool to model how changes in air pollution levels impact death rates. This year, CDC hopes to add NASA satellite air quality data, additional heart attack data, and pesticide data. The tracking network also hosts data for other CDC programs such as Built Environment, Climate and Health, and Developmental Disabilities. These data are available to the public only on the tracking network. CDC funds 24 state and local tracking programs. In the past seven years, state and local health officials reported using the tracking network more than 160 times to prevent sickness and the loss of life. These public health actions required use of the tracking network to determine disease impacts, detect trends, recognize unusual disease patterns, and identify the most affected people and places.

State-by-state success stories are available on CDC’s website:

<http://www.cdc.gov/nceh/tracking/successstories.htm>

- 6) The President recently proposed expanding the National Violent Death Reporting System (NVDRS). Please explain how this system works, the information it provides, and how that information is being put to use. What benefits would be expected from expanding the NVDRS to additional states?**

CDC-DELAURO-RESPONSE 6:

NVDRS is the only state-based violent death reporting system that pools information from multiple data sources—including death certificates, coroner/medical examiner reports, and law enforcement reports—to obtain the most comprehensive data available on homicides and suicides, as well as unintentional firearm injury. NVDRS collects data on all mechanisms of violent injury (such as blunt force trauma and poisonings). NVDRS is also the only data system on homicide that collects information from data sources outside of law enforcement and that has the capacity to link to hospital and other health records. The goal of the system is to gather information about the circumstances surrounding violent deaths and to provide insights into why violent deaths occur and how they can be prevented. NVDRS data help inform violence prevention efforts by providing important details on demographics, method of injury, victim-suspect relationship, and precipitating circumstances such as health and financial stressors. NVDRS-funded states use NVDRS data to inform violence prevention activities and address risk factors for homicides and suicides in their states. Two examples include:

- In Oregon, NVDRS data were used to help develop and better target suicide prevention programs for older adults. Almost 50% of men 65 years of age or older who died by suicide were reported to have a depressed mood before death, with only a small proportion of these men receiving treatment. As a result, Oregon developed primary care recommendations so that suicidal behavior and ideation are better diagnosed and older adults receive appropriate treatment.
- Beginning in October 2010, police officers from seven police departments in Oklahoma responding to domestic violence calls conduct a brief lethality assessment. If they determine the victim is at high risk, immediate coordination with the local

domestic violence service provider occurs. NVDRS data are being used to detect any increases or decreases in intimate partner homicides as a result of the intervention.

NVDRS is not a nationally-representative system, as it currently includes only 18 states. The President has proposed that an additional \$20 million be provided to NVDRS to enhance and expand this system to all 50 states and Washington, D.C. Expanding NVDRS nationwide will mean that for the first time researchers and officials across the entire country will be able to assess the characteristics of violent deaths at the national, state, and local levels and to track trends and progress. Having NVDRS in every state will allow each state to better identify future prevention opportunities, such as determining where an intervention might have prevented deaths. In addition, the system will allow CDC scientists and others to understand and monitor trends in special populations, such as active duty military and former members of the military.

7) Concerns have been raised about possible use of CDC grant or cooperative agreement funds for improper lobbying. What actions does CDC take to ensure that recipients observe all legal restrictions regarding use of funds for lobbying? Has CDC (or other agencies of the Department of HHS) looked into any allegations of violations of the anti-lobbying rules? If so, what has been the result?

CDC-DELAURO-7 RESPONSE

CDC is committed to ensuring the proper use of federal funds, and to ensuring awardees' compliance with all applicable restrictions on lobbying. Over the course of the CPPW program, CDC has worked hard to ensure the proper use of appropriated funds, and to ensure awardees' compliance with all applicable regulations and statutes related to lobbying activities.

CDC's policy prohibits lobbying at the federal, state, and local levels. These restrictions apply to all CDC grants, including the CPPW program (initiated in 2009 with funding from the Recovery Act, with nearly all activity completed). All CDC awardees are informed at multiple junctures about the federal laws relating to use of federal funds, including applicable anti-lobbying provisions. CDC's *Additional Requirement 12, "Lobbying Restrictions"* (AR-12) stated CDC's policy at the time of CPPW awards prohibiting awardees from using any appropriated federal funds for "any activity designed to influence action in regard to a particular piece of pending legislation." As noted below, we have revised the AR-12 to reflect new language in the FY 12 appropriations law.

In addition to making these restrictions part of grant awards, for the CPPW program CDC staff provided numerous reminders and conducted trainings for CPPW awardees on these prohibitions in order to ensure awardees understood the limits on use of the awards. These steps included an initial pre-award teleconference; presentations at the CPPW Communities kick-off meeting in April 2010; and multiple training sessions during the grant period of performance, including a mandatory meeting for all program managers and principal investigators to review the prohibitions outlined in AR-12.

In addition to educating awardees, CDC has regularly monitored awardee performance in order to ensure that federal funds are used effectively and appropriately. CDC staff have interacted with awardees every month to ensure that they were implementing the activities and strategies

set forth in the awardee's work plan and that awardees were adhering to administrative requirements, including provisions relating to lobbying prohibitions. In addition, CDC staff has monitored the use of federal funds by awardees using tools such as onsite reviews and risk mitigation plans.

CDC has asserted continuing oversight of CPPW and other grantees, and has reviewed all suggestions and evidence of inappropriate activities by grantees. In addition, in June 2012 the HHS Inspector proposed a set of recommendations that CDC could take to clarify guidance for grantees and to clarify misleading statements about activities by grantees. The HHS Inspector General recommended that CDC:

- Review its guidance and other posted materials on CDC's website;
- Clarify any misleading statements about lobbying activities by grantees under the CPPW program;
- Train employees, as necessary, and
- Provide updated and more detailed guidance to grantees describing how to avoid violating these statutory provisions. Such guidance should also advise grantees concerning new restrictions on lobbying contained in the FY 2012 HHS appropriations.

CDC has fully implemented each of the HHS Inspector General recommendations. These steps have included:

- Developed more detailed anti-lobbying guidance for CDC staff, which was broadly disseminated to senior leadership, management and policy officials, and CDC project officers. This guidance updated and expanded upon previously available material to reflect changes in the FY 12 appropriations law and to provide more detailed examples to help clarify restricted activities.

8) On March 30, 2012, the Institute of Medicine issued a report on epilepsy titled *Epilepsy Across the Spectrum: Promoting Health and Understanding*. Provide a summary of the recommendations in which the CDC is in whole or part the agency responsible for implementation, and the approximate funding needed to implement each recommendation.
CDC-DELAURO-8 RESPONSE

This report was released after the March 5 hearing. CDC would be glad to discuss the report with Representative DeLauro.

NIH-DeLauro-1. Please describe the steps being taken by NIH in response to funding reductions under the sequestration order issued on March 1, including the effects (and anticipated effects) on grants and other mechanisms of support for research and research training as well as on intramural programs and other NIH activities.

Answer. NIH is taking every step to mitigate the impacts of the funding reductions under the sequestration order issued on March 1, 2013.

Based on NIH's initial analysis, all grants and cooperative agreement awards may be affected. NIH anticipates that reductions may be spread throughout all mechanisms, and are unlikely to be excessively concentrated in a single mechanism. The distribution of reductions within the

Institutes and Centers may vary, based on individual circumstances in the IC portfolios. Further information was provided to NIH grantees and contractors by Dr. Sally Rockey, Deputy Director for Extramural Research, through letters available at <http://grants.nih.gov/grants/financial/index.htm> (“Sequestration Letter to Grantees” and “Sequestration Letter All NIH Contractors”).

NIH-DeLauro-2. Please summarize the NIH Fiscal Policy for Grant Awards for each fiscal year from 2010 through 2013, including policies regarding costs-of-living adjustments—or reductions—to non-competing awards, size of new awards, future year cost-of-living adjustments to new awards, and other key policies. How were policies for fiscal year 2013 affected by sequestration?

Answer. Updates to the NIH Fiscal Policy for Grant Awards are announced annually in the NIH Guide to Grants and Contracts. They are archived on the NIH Extramural Financial Operations website (<http://grants.nih.gov/grants/financial/index.htm#Res12>). Following are links to the Notices published from 2010 through 2013, and a short summary of the provisions in each. Each NIH Institute and Center (IC) establishes fiscal policies consistent with these NIH-wide policies according to its specific scientific and programmatic imperatives.

- FY 2010 - <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-039.html>
 - Non-competing research grant awards were adjusted to ensure compliance with a 2 percent inflation allowance.
 - The average cost of competing grants was permitted to increase by 2 percent over the FY 2009 level.
- FY 2011 - <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-068.html>
 - Modular and non-modular research grant awards, from all ICs, with the exception of the National Cancer Institute (NCI), were reduced to 1 percent below the FY 2010 award level.
 - NCI modular and non-modular research grants were reduced 3 percent below the FY 2010 award level.
 - For all ICs, inflationary adjustments for recurring costs on non-competing research grant awards in FY 2012 and beyond were set at the 2 percent level; calculations were based on the adjusted FY 2011 level.
 - Consistent with the policy for non-competing awards, future inflationary adjustments for recurring costs on competing research grant awards were provided at 2 percent.
- FY 2012 - <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-036.html>
 - Non-competing awards were issued without cost of living/inflationary adjustments in FY 2012; however, adjustments for special needs (such as equipment or added personnel) could be accommodated.
 - Inflationary increases for future year commitments were discontinued for all competing and non-competing research grant awards issued in FY 2012.

NIH made efforts to keep the average size of awards constant at FY 2011 levels or lower. For new and competing grants, NIH awarding ICs developed funding principles consistent with overall NIH goals, considering the funds provided to their IC in FY 2012.

- FY 2013 – this year’s final Fiscal Policy is being developed. NIH published a Notice about NIH operations under the continuing resolution (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-002.html>), indicating that until FY 2013 appropriations are enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90 percent of the previously committed level). This is consistent with NIH practice under previous continuing resolutions.

NIH’s operation plan in the event of sequestration was announced in <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-043.html>, suggesting that NIH will reduce the final FY 2013 funding levels of non-competing continuation grants and expects to make fewer competing awards to allow the agency to meet the available budget allocation. Each IC will assess allocations within their portfolio to minimize the effects of sequestration on scientific impact. The IC-specific fiscal policies are being developed and will be announced on the IC’s funding strategy page (links collated at <http://grants.nih.gov/grants/financial/index.htm>).

NIH-DeLauro-3. Please provide a history of funding levels and number of awards supported under the Ruth L. Kirschstein National Research Service Awards program for fiscal years 2002 through 2012 and the anticipated amounts for 2013. How have the estimated 2013 amounts been affected by sequestration? How have stipend levels changed over the 2002 through 2013 period?

Answer. The table below depicts funding amounts, number of awards, and the number of full-time trainee positions (FTTP) supported under the NIH Ruth L. Kirschstein National Research Service Awards (NRSA) program for fiscal years (FY) 2002 through 2013. Amounts and counts displayed for FY 2002 through FY 2012 represent actual results. The FY 2013 figures reflect anticipated levels that account for sequestration; a 3.2 percent reduction in FY 2013 funding available for the NRSA program, compared to the amount obligated in FY 2012, will support fewer or smaller awards and consequently will support fewer trainees and fellows. Relying on the relatively stable historical relationship between number of grants awarded and FTTPs, the FY 2013 NRSA training program is projected to fund 85 fewer awards and 468 fewer trainees and fellows in FY 2013 compared to FY 2012.

Ruth L. Kirschstein National Research Service Awards (NRSA) Training Program			
(Dollars in Thousands)			
FY	Funding Level	Number of Awards	Number of Trainees
2002	\$ 650,686	1,503	16,843
2003	\$ 711,441	1,652	17,313
2004	\$ 740,506	1,714	17,595
2005	\$ 743,861	1,706	17,372
2006	\$ 748,642	1,687	17,325
2007	\$ 781,909	1,774	17,596
2008	\$ 770,480	1,699	17,318
2009	\$ 776,193	1,653	17,290
2010	\$ 775,186	1,703	17,150
2011	\$ 771,766	1,601	16,888
2012	\$ 761,934	1,629	16,305
2013*	\$ 737,336	1,544	15,837

* Number of awards is derived from the 5-year historical average of the ratio of number of trainees (FTTP) compared to number of awards (2008-2012).

Stipend rates have changed between FY 2002 and FY 2012 to partially offset the cost of living as required by Title 42-USC-288.

Stipend rate adjustments continue a long-term strategy that NIH has used to align stipend levels more closely to salaries that could be earned in related occupations. The table below compares official stipend rates for pre- and post-doctoral levels between FY 2002 and FY 2012 (FY 2013 stipend rates are the same as in FY 2012). Stipend rates have increased by between 10 percent and 26 percent, depending upon the recipient's level of training, with dollar equivalent increases ranging from approximately \$3,900 to over \$8,500.

Ruth L. Kirschstein-NRSA Stipend Level Change

Level	Actual 2002	Actual 2012	Cumulative Change	
			Dollars	Percent
Pre-doc	18,156	22,032	3,876	21.3%
Post-doc Level 0	31,092	39,264	8,172	26.3%
Post-doc Level 1	32,820	41,364	8,544	26.0%
Post-doc Level 2	38,712	44,340	5,628	14.5%
Post-doc Level 3	40,692	46,092	5,400	13.3%
Post-doc Level 4	42,648	47,820	5,172	12.1%
Post-doc Level 5	44,616	49,884	5,268	11.8%
Post-doc Level 6	46,584	51,582	4,998	10.7%
Post-doc Level 7	48,852	54,180	5,328	10.9%

NIH-DeLauro-4. Section 217 of the fiscal year 2013 appropriations bill approved by the House Labor-HHS-Education Subcommittee last year would have prohibited use of any discretionary appropriations in the bill to support patient-centered outcomes research. I have several questions related to that prohibition.

NIH-DeLauro-4a. How much patient-centered outcomes research has NIH supported in the past three years and what are the purposes and benefits of that research?

Answer. Patient-centered outcomes research (PCOR) compares different medical treatments and interventions to provide evidence on which strategies are most effective in different populations and situations in order to allow patients and their care providers to make sound health care decisions. Similar research funded by NIH is referred to as comparative effectiveness research (CER). CER studies compare different interventions and strategies to prevent, diagnose, treat, and monitor diseases and conditions. These studies generate knowledge about which interventions are most effective for which patients under specific circumstances. NIH's CER portfolio includes landmark studies that directly support the improvement of health. Over the last three fiscal years (FY 2010-FY 2012), NIH supported a total of \$2.0 billion in CER (the FY 2010 figure included ARRA funding).

The benefits of CER are exemplified in the following examples:

- The Diabetes Prevention Program (DPP), which revealed that lifestyle changes (diet and exercise) were more effective than medication (metformin) in preventing the onset of Type 2 diabetes in adults with pre-diabetes.
- The Sudden Cardiac Death in Heart Failure (SCDHeFT), trial, which demonstrated that implantation of automated defibrillators improves survival in adults with heart failure. Since its publication, the use of defibrillators has substantially increased and heart failure mortality rates have declined.
- The Comparison of Age-Related Macular Degeneration Treatment Trials (CATT), which demonstrated that two commonly used medications have equivalent effects on visual acuity and that an imaging test, optical coherence tomography, could be used to administer therapy on an "as needed" basis rather than on a routine basis.

NIH-DeLauro-4b. How does the NIH mission and research portfolio in this area differ from that of AHRQ, and what is done to prevent overlap and duplication?

Answer. NIH and the Agency for Healthcare Research and Quality (AHRQ) have different and complementary research missions. NIH's mission is to seek fundamental knowledge about human health and disease and to apply the knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. AHRQ's mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. Our portfolios of comparative effectiveness research (CER) may relate to the same health problem, but the questions we pursue about the problem and the approach we take to increase understanding of it will differ. For example, whereas an NIH CER study will involve a clinical trial designed to address a fundamental question about the effectiveness of two interventions, AHRQ will support a research review to look at all the available evidence about the benefits and harms of each intervention for different groups of people. For example, both NIH and AHRQ have done CER on the prevention of sudden death due to heart disease. The Sudden Cardiac Death in Heart Failure Trial (<http://www.nejm.org/doi/full/10.1056/NEJMoa043399>) exemplifies the approach NIH takes. The trial, which involved thousands of patients with congestive heart failure, compared the effectiveness of a device called an implantable cardioverter-defibrillator (ICD) and an antiarrhythmia drug in preventing sudden death from cardiac arrest. The study demonstrated that the defibrillator reduced mortality by 23 percent whereas the drug had no favorable effect on survival. AHRQ's contribution was to carry out a systematic review of the scientific literature resulting from many research studies--including the findings from the NIH trial--on the efficacy, effectiveness, and safety of ICDs compared to a different type of therapy for arrhythmia. AHRQ's research produced an important evidence report (<http://www.ahrq.gov/downloads/pub/evidence/pdf/defib/defib.pdf>) that confirmed the value of defibrillators in saving lives in appropriately selected patients. The agencies' distinct missions and approaches prevent redundancy of effort, and ongoing communication and collaboration help ensure that the knowledge generated by each agency is complementary.

NIH-DeLauro-4c. What would be the effect on NIH research if the prohibition in section 217 of the fiscal year 2013 House subcommittee bill were to be enacted?

Answer. Under that prohibition, if interpreted to include CER, NIH might be unable to continue to support important research that helps improve the health of the nation. In FY 2012, NIH funded 1,071 CER projects totaling nearly \$600 million. In addition, if the prohibition took effect upon enactment, it could require ongoing research to be halted. Interrupting clinical trials in mid-stream would not only be a waste of resources, it could also have adverse impacts for enrolled subjects. The following are examples of CER studies that NIH might not be able to support:

- The Systolic Blood Pressure Intervention Trial (SPRINT) is a randomized, multi-center clinical trial to determine whether treating systolic blood pressure (SBP) to a lower goal than is currently recommended further reduces cardiovascular disease (CVD) morbidity and mortality. The trial, which began recruiting patients in FY 2010, aims to reach 10,000 participants. High blood pressure affects nearly 1 in 3 American adults. It is one

of the most common conditions among middle-aged and older adults and is a leading risk factor for stroke, heart disease, kidney failure, and other conditions and a key contributor to the development and progression of chronic kidney disease. Therefore, the results of the SPRINT study could have a profound effect on public health.

- The Comparison of Radiation Therapy Regimens in Combination with Chemotherapy in Treating Young Patients With Newly Diagnosed Standard-Risk Medulloblastoma study (http://cancer.gov/clinicaltrials/search/view?cdrid=365506&version=healthprofessional#AlternateTitle_CDR0000365506) is a Phase III trial comparing standard-dose radiation therapy to reduced-dose craniospinal (head and spine) radiation therapy. This trial is enrolling up to approximately 510 patients between 3 and 21 years of age, with treatment available at 191 study locations across the country. It is important to determine whether we can achieve effective treatments for medulloblastoma while minimizing radiation exposure, and to learn the best and most effective ways to direct the dose of radiation to the brain. This knowledge will allow for the development of therapies with reduced toxicities and improved quality of life by limiting both short and long-term side effects.
- The ongoing Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) CER study is conducted at 15 clinical centers. A total of 704 children and adolescents are enrolled and randomized to one of three treatment arms: (1) metformin alone, (2) metformin plus rosiglitazone, and (3) metformin plus an intensive lifestyle intervention called the TODAY Lifestyle Program (TLP). Participants are followed a minimum of two years. The recent and precipitous rises in rates of type 2 diabetes and in obesity—the primary risk factor for diabetes—in the pediatric population have important ramifications for our health care system. Previous research of treatment and prevention of type 2 diabetes targeted mainly adults. The STOPP-T2D consortium represents one of the first large-scale federally funded efforts to conduct studies to further our knowledge and understanding of these problems and their solution in children and adolescents.

NIH-DeLauro-5. The fiscal year 2013 appropriations bill approved by the subcommittee last year included language (under the “Office of the Director” appropriation) instructing NIH to allocate 90 percent of appropriated funds to extramural activities, 10 percent to intramural activities and at least 55 percent toward basic science activities. Several questions in connection with that proposal:

NIH-DeLauro-5a. What have been the relative percentages of NIH appropriations spent on extramural and intramural research activities over the period from fiscal year 2002 through fiscal year 2012?

Answer. The relative percentages of NIH appropriations invested in Extramural Research (ER) and Intramural Research (IR) for the period of fiscal years (FY) 2002 through FY 2012 are displayed in the table below.

Fiscal Year	Extramural Research	Intramural Research
2002	81.6%	9.6%
2003	79.8%	9.6%
2004	81.4%	9.5%
2005	80.6%	9.6%
2006	81.4%	9.6%
2007	81.5%	10.5%
2008	82.5%	10.5%
2009	82.2%	10.7%
2010	81.8%	10.7%
2011	81.9%	10.9%
2012	81.6%	11.0%

Note: */ Extramural and Intramural research exclude that portion of the NIH budget that supports common costs such as facilities, construction, repair, or maintenance as well as policy directives and administrative functions funded by the Office of the Director account.

The calculated annual percentage reflects the distribution of funds obligated across all ER grant and contract mechanisms (RPGs, Research Centers, Other Research, R&D Contracts and NRSA Training) and the amount obligated by the IR budget mechanism.

NIH-DeLauro-5b. How are the extramural and intramural categories defined for these reporting purposes? Are there activities that are included in neither category? Have there been any changes in concepts or classification of activities since 2002 that would affect year-to-year comparisons?

Answer. Extramural research includes grants and research & development (R&D) contracts awarded to institutions outside of NIH, such as colleges and universities, medical colleges, state and local governments, and private industry. Intramural research is conducted at NIH's in-house laboratories funded by the IR budget mechanism.

Traditionally, IR has been defined as laboratory and clinical programs conducted by government employees and trainees who initiate the research with general supervision by scientific leaders. In FY 2007, most of the National Library of Medicine (NLM) budget, which exists to support NIH extramural grantees and other scientists throughout the world, was realigned to the IR mechanism, increasing the proportion of the NIH budget defined as IR by almost one percent. In addition, in recent years some existing activities that were IR in nature but not funded by that mechanism have been reclassified to IR, e.g., the Therapeutics for Rare and Neglected Diseases (TRND) program at the National Center for Advancing Translational Sciences (NCATS), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) perinatal study in Detroit. While these changes have increased the IR percentage, they represent more accurate measurement rather than growth in IR activities.

Infrastructure maintenance, repair and construction budgeted for under the Buildings & Facilities (B&F) mechanism is usually not included in either ER or IR segments. There is no simple correlation of B&F to IR since ER programs also depend to varying degrees on personnel and other resources hosted by NIH facilities. In the same vein, NIH policy direction, program evaluation, financial, legal, acquisitions and related administrative functions whose costs are in the Office of the Director (OD) appropriation are also not included in either ER or IR segments.

NIH-DeLauro-5c. What are the broad purposes of the NIH intramural program and what strengths does it offer as compared to extramural research? What are some of the principal recent research achievements of the intramural program?

Answer. The most important aspect of the Intramural Research Program (IRP) is its emphasis on high-risk, high-reward research. This takes place in an environment conducive to research that cannot be readily funded or accomplished in traditional academia; and this is made possible through a vast and advanced technology infrastructure of shared resources, a broad range of expertise comprising more than 1,000 principal investigators and 4,000 highly selected postdoctoral fellows, and the world's largest clinical hospital to foster the cycle of research from patient studies to laboratory work to bedside cures.

Coupled with relatively stable funding and intellectual freedom, this framework enables the pursuit of projects beyond the scope of what is reasonably fundable elsewhere, such as the ability to start long-term research projects, such as vaccine development, or to change directions quickly when the opportunity or need arises, such as in a public health emergency.

IR complements ER in crucial ways, often providing accomplished scientists in academia and the private sector with the basic science and research tools that they need to further our mutual pursuit of treatments and cures. The IRP has been, and remains, a model for other federal laboratories, for research foundations, and for other governments who seek to establish research laboratories.

IR results leading to clinical advances from the past few years alone include the HPV "anti-cancer" vaccine, a treatment for multiple sclerosis, gene therapy to restore salivary gland function, immunotoxins to treat common cancers, and vaccines for Ebola and Marburg viruses. Historic discoveries that have emerged from the NIH IRP—such as the use of fluoride to prevent tooth decay, the use of lithium to manage bipolar mental illness, the development of blood tests to detect HIV and hepatitis, the first AIDS drugs, and vaccines against hepatitis and Hemophilus influenza, among others—have repaid many times over in public health savings the total past investment, and any foreseeable future investment, in this program.

Very recent, major breakthroughs include:

- * success in engineering T-cells to attack leukemia in 3 of 3 children tested (2013)
- * development of non-invasive MRI to accurately detect unrecognized heart attacks (2012)
- * first implantation of bone marrow stromal cells in a research participant (2012)
- * an MRI-guided, catheter-based, "closed-chest" alternative to open-chest surgery (2011)

* discovery that ketamine provides a fast, robust, and sustained antidepressant effect, including reduction of suicidal thoughts within minutes (2010)

* advances in a universal vaccine with a new approach that has produced protection against 16 different influenza strains seen over the last 70 years (2010)

As one concrete example of an intramural strength, consider Parkinson's disease. NIH researchers have an unparalleled record in Parkinson's disease basic research, particularly in understanding the genetic basis of this disorder. NIH scientists found mutations at three of the six known genetic regions associated with Parkinson's disease, including the identification of mutations in a gene called LRRK2, which underlie approximately 20,000 to 40,000 cases of Parkinson's disease in the United States. This work was only possible with agile and stable funding, which enabled scientists to quickly mobilize resources and collaborators for rapid identification of these mutations. As the mutations were identified, researchers were able to work easily across institutes bringing together experts to jointly solve complex problems and then provide data to the entire scientific community studying neurodegenerative diseases. These findings have revolutionized our understanding of Parkinson's disease, previously thought of as a non-genetic disease, and has offered insights into the disease process, leading to improved screening and animal models, and highlighting potential points of therapeutic intervention.

Another strength is the IRP's ability to study rare and undiagnosed diseases, which would be difficult to fund through the extramural process and for which industry often has little commercial interest. While such diseases aren't so rare when considering, collectively, upwards of 10 percent of the U.S. population are affected by rare diseases, these conditions often express themselves in overt ways—such as accelerated aging, rapid weight gain, intense mood or personality traits, or extreme immune system reaction—and thus provide keen insight into the cause and treatment of common diseases. The NIH IRP is the world leader in the characterization and treatment of rare diseases. And the NIH Clinical Center (CC), where treatments are administered, often is the last and best hope for children and adults with rare and undiagnosed diseases.

NIH-DeLauro-5d. Does NIH currently have a policy with respect to division of funds between extramural and intramural activities?

Answer. Decisions concerning the division of funds between extramural and intramural activities reside within each NIH Institute and Center (IC), and not centrally. Thus, each IC makes its own allocation, usually slightly below or slightly higher than 10 percent of its total budget, varying each year.

The ICs each have a formal planning process for the allocation of their funds, and each IC provides a written description of this process annually to the NIH Director. This policy was adopted in 1995 at the recommendation of the External Advisory Committee of the Director's Advisory Committee in 1994. The decision process resides at the IC level for numerous reasons, such as: differing missions for each IC; the evolving scientific opportunities and needs in each IC's subject range; the changing technologies and expertise in any given field

of research year to year; new training needs (as witnessed most recently in NIH's effort to train more clinical researchers); and Congressional mandates.

Decisions concerning funding allocation are made annually based largely on cost effectiveness: what is most feasible internally in established, federal labs with a critical mass of accomplished investigators across a variety of disciplines benefiting from shared resources and economies of scale; and what is most feasible externally at specialized research institutes with their own sets of strengths.

Although the importance of the NIH IRP has been repeatedly reaffirmed, the precise percentage of its funding allocation has long been discussed. The recent level is considered to be adequate to maintain an all-important critical mass of investigators and shared resources.

NIH-DeLauro-5e. Would the proposed limits of 90 percent and 10 percent require reductions in the extramural or intramural portfolio relative to recent levels? If so, what would you see as the effects, both positive and negative, of such a change?

Answer. Since the intramural budget line as currently defined exceeds 10 percent of the total NIH budget, significant and damaging cuts in IR would need to be instituted to reach the 10 percent level. In the short term, these could not be achieved without major elimination of programs, personnel reductions, and reductions in discretionary funds that would impair the ability of remaining scientists to conduct meaningful research.

NIH-DeLauro-5f. Roughly what percentage of NIH appropriations has been spent on basic science each year since fiscal year 2002?

Answer.

Fiscal Year	Basic*
2002 Actual	58.8%
2003 Actual	56.1%
2004 Actual	54.9%
2005 Actual	57.4%
2006 Actual	56.5%
2007 Actual	55.5%
2008 Actual	55.4%
2009 Actual	54.3%
2010 Actual	53.5%
2011 Actual	53.8%
2012 Actual	53.2%
2013 Estimate	53.2%
2014 PB	53.0%

Note: */ Percentages exclude amounts allocated for facilities and training.

NIH-DeLauro-5g. How does NIH define this “basic science” category, and what kinds of activities are not included in it?

Answer. Basic Research is defined as systematic study directed toward fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind. Basic research, however, may include activities with broad applications in mind. Activities such as construction and rehabilitation, conduct of education and training and applied research are not included.

NIH-DeLauro-5h. Does NIH have a policy with respect to a target percentage of funds to be directed toward basic science activities?

Answer. NIH does not have an explicit policy with respect to a target percentage of funds to be directed toward basic science activities. More than half of NIH’s funding has been devoted to basic research over the last 20 years.

NIH-DeLauro-5i. Would the proposed floor of 55 percent require a reallocation of funds toward basic science, relative to recent levels? If so, what would you see as the effects, both positive and negative, of this change?

Answer. Since current spending on basic research is approximately 53 percent, a floor of 55 percent would require a shift of about two percent out of applied research. In practice, such a floor would be difficult if not impossible to implement: there is no process to achieve such a target in the NIH portfolio.

NIH-DeLauro-6. The fiscal year 2013 appropriations bill approved by the subcommittee last year included language under the National Center for Advancing Translational Sciences (NCATS) directing that actions be taken to ensure that activities of NCATS “do not create duplication, redundancy or competition with industry”. What steps have been taken, or are being taken, to avoid such duplication, redundancy or competition? More generally, what do you see as the relationship between NIH translational science efforts and those of industry?

Answer. NCATS focuses on the general (i.e., not disease-specific) scientific and operational issues that underpin all translational science, in order to make this process more efficient and thus empower the research community (public and private) to be more efficient. NCATS’ work is generally in the “precompetitive” space where industry and NIH/academia have long collaborated to mutual benefit, and in the translational space which is concerned with how interventions demonstrated to be useful can be efficiently disseminated to benefit patients. Put simply, NCATS is focused on the many system-wide problems that are currently unaddressed and are holding back the translational process, not on problems which can be and are the focus of industry. NCATS continues the tradition of NIH research—providing a foundation for improvements in human health upon which industry can build.

In addition, NCATS has put in place many specific initiatives to prevent duplication, redundancy, and competition with industry. One such initiative is to ensure that industry is

aware of the activities being undertaken and planned by NCATS and to offer an opportunity for industry to provide input. Therefore, NCATS is planning to post a Notice in the Federal Register seeking comments on the methods it is using to ensure that the public, including private industry, is both aware of and able to provide input on its activities and planned initiatives.

Another way to prevent duplication, redundancy, and competition with industry is to form partnerships so that both sides are aware of each other's activities. NCATS has done this in a number of ways, such as during the development of the Discovering New Therapeutic Uses for Existing Molecules initiative, where NCATS formed unprecedented partnerships with eight pharmaceutical companies for this program. Since its launch, additional companies have inquired about joining the initiative and will be considered upon completion of the pilot phase. NCATS also continually seeks partners through Collaborative Research and Development Agreements (CRADA) to facilitate the development and commercialization of technologies.

Regarding the relationship between NIH's translational science efforts and those of industry, NCATS is positioned to be an unparalleled resource to address the challenges of intervention development. NCATS emphasizes partnership, innovation, and deliverables, relying on the power of data and tools to develop, demonstrate, and disseminate improvements in every dimension of translational science. In this way, the newest NIH Center is partnering with and complementing — not competing with — the work of other NIH Institutes and Centers, the private sector, and the nonprofit community.

Collaborations among government, academia, industry and nonprofit patient organizations are crucial for successful translation of research; this process is so multifaceted that no single organization can succeed alone. To this end, NCATS leads innovative and collaborative approaches in translational science that are crosscutting and broadly applicable to the scientific community. The Center convenes expert teams from diverse scientific disciplines and constituencies in an effort to reduce, remove, or bypass significant bottlenecks across the entire continuum of translational research, including efficacy, toxicity, data sharing, biomarkers, clinical trials, regulatory science, and training.

In order to address the many complex and varied needs of patients, translational research must be conducted as a team effort. It is essential that partners from academia, government, industry, advocacy groups, and related fields each learn from research information shared among them, add to this research from their own expertise, and work together to translate this research into practice for the benefit of all. NCATS is a new and distinctly different member of the translational research ecosystem, purposely designed to complement and be informed by the efforts of industry and others in order to catalyze the development of interventions that improve the health of the American people.

NIH-DeLauro-7. Concerns have been raised, including by the Institute of Medicine, about problems with clinical trials, including the length of time often needed to complete trials and the costs, delays and failures associated with enrollment of patients. What actions has NIH been taking to examine and address these and other problems and to improve the systems for clinical trials supported by NIH?

Answer. In House Report 112-331, of the Consolidated Appropriations Act of 2012 (Public Law 112-74), Congress directed the National Institutes of Health (NIH) to conduct a review of the applicability of 12 recommendations in a 2010 Institute of Medicine (IOM) report about the Cooperative Group Program of the National Cancer Institute (NCI) to all clinical trials funded by NIH. The IOM report, *A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program*, was commissioned by NCI. In response, the NIH Office of the Director (OD) gathered information from Institutes and Centers (IC) on the applicability of the recommendations to their clinical trial portfolios, and a report was submitted to Congress in March 2013.

A trans-NIH Clinical Trials Working Group (CTWG) has been formed to consider the range of issues and concerns related to the agency's role in the stewardship, leadership, and management of clinical trials and clinical trial networks; evaluate the options for NIH actions; and make recommendations to the NIH Director to enhance the quality and transparency of NIH-supported clinical trials. The CTWG began meeting in February 2013 and is scheduled to make recommendations to the NIH Director later this year.

NIH-DeLauro-8. In January, the National Academy of Sciences and Institute of Medicine released "U.S. Health in International Perspective: Shorter Lives, Poorer Health." The report found that Americans are in poorer health and living shorter lives than people in many other high-income countries and that this health disadvantage is pervasive across populations regardless of age or socio-economic status. Further, the report suggested that the reasons for our nation's lagging numbers are rooted in behavioral and social factors. Now that we have these findings, how is the NIH planning to respond to its recommendations?

Answer. The "U.S. Health in International Perspective: Shorter Lives, Poorer Health" report was important in that it confirmed previously reported findings indicating that the major contributors to the U.S. health disadvantage are behavioral and social factors rather than biological factors. The findings suggest that we need to redouble our efforts in the prevention and treatment of behaviors such as smoking, overeating, unprotected sex, and drug use and abuse, and, indeed, NIH is investing in research to address all of the key areas of concern identified in the report. For example, NIH supports a broad portfolio of basic, clinical, and translational research to understand the complex interplay of factors influencing obesity and diabetes.

NIH is responding to the recommendations in a number of ways. For example, to contribute to broader efforts to communicate with international partners to improve the quality and consistency of data sources available for cross-national comparisons, NIH is exploring issues of data fidelity and harmonization with the National Committee on Vital and Health Statistics and the Office of the Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services. To help develop more refined analytic methods in study designs for cross national health research, NIH's National Institute on Aging (NIA) is supporting cross-nationally comparable datasets that can be harnessed to study research questions related to the factors most significantly affecting U.S. health and contributing to our health disadvantage. These datasets include the Health and Retirement Study, English Longitudinal Study on Ageing, Survey of

Health, Ageing and Retirement in Europe (SHARE), and the Human Mortality Data Base. A cross-cutting effort has been initiated to enhance innovative research methodologies for behavioral and social sciences, including methodology for international comparisons. To advance understanding of the factors responsible for the U.S. health disadvantage and potential solutions, NIA is funding studies on the reasons behind the divergent trends that have been observed in health and longevity at older ages and is soliciting additional research ideas on this topic. Still other research opportunities in this area are being explored by the Office of Behavioral and Social Science Research (OBSSR), the Fogarty International Center (FIC), and the Eunice Kennedy Shriver National Institute on Child Health and Human Development (NICHD).

THURSDAY, MARCH 14, 2013.

**ADDRESSING SOCIAL SECURITY ADMINISTRATION'S
MANAGEMENT CHALLENGES IN A FISCALLY CON-
STRAINED ENVIRONMENT**

WITNESS

**CAROLYN COLVIN, ACTING COMMISSIONER, SOCIAL SECURITY AD-
MINISTRATION**

Mr. KINGSTON. Well, welcome. This is actually the way Ms. DeLauro and I like it. [Laughter.]

We get to ask all the questions.

It is great to have you here. I welcome Commissioner Colvin here. I know you will be managing the Social Security Administration I guess until further notice, and we are delighted to be working with you.

A couple things that we are concerned about is 2 years ago we directed the Social Security Administration in the fiscal year 2012 omnibus develop, with assistance of the National Academy of Public Administration, a strategic plan to direct how the agency's service delivery approach should evolve in response to a number of pressures. Like any other multi-billion dollar operation, a large service delivery organization needs to understand where it is headed and how it plans to tackle the well-known and unknown challenges ahead. It is, therefore, extremely difficult for me to understand why the Social Security Administration has refused to follow the direction of Congress and develop a truly long-range strategic plan in consultation with the well-respected NAPA.

Social Security needs to long-term plan more than ever. A large number of employees are retiring. We actually had some incredible testimony yesterday from some of the folks involved in the aging advocacy forum, and something like—I cannot remember the number—10,000 people a day will start retiring and that by 2050, 19,000,000 of the population will be over 65 years old. And it is just staggering when we look at the graying of America, although I know I think people prefer the word “silvering” of America. “The silver tide,” or what is the name for it?

So I understand the needs and the pressures on funding, but what we really do not have as clearly as I think the committee would like is a vision in terms of where the agency is going and how it is going to deal with this. And we all know Social Security is extremely difficult to reform, otherwise we would have done it. It is enormously popular. It is a universal program, and making changes—there is always a constituency group that says too far, too fast, not me, not in that direction. But the reality is we do need to have a thoughtful focus on where Social Security is going to be in 10 years, 15, 20, 30 years.

So I am looking forward to this hearing.

And with that, I will yield to Ms. DeLauro.

Ms. DELAURO. Thanks very much, Mr. Chairman.

I want to say thank you to our witness for joining us and thank you for everything that you are doing at the Social Security Administration.

Social Security is the ultimate legislative expression of the shared values of this Nation. For over 75 years, it has tied generation to generation. It ensures that seniors have a secure retirement after decades of service to their community. And it provides a safety net for those who can no longer work due to an accident or to disability.

As soon as the first Social Security check was issued, poverty amongst the elderly began to drop. There were 30 percent of elderly Americans in the 1950's who were in poverty. Today it is about 10 percent. Two out of three seniors today rely on Social Security as the prime source of monthly income, including three-quarters of all elderly women. Women live longer than men. Sorry, Jack. That is a fact of life. We live longer.

Mr. KINGSTON. If you would yield to me. If you want to live longer in a world without men, that is your business. That will be your loss. It will not be as fun or as confusing. [Laughter.]

We have had this technical mike problem. It is because of sequestration, let the record show. [Laughter.]

Ms. DELAURO. Without doubt.

Speaking of sequestration, the decision to let that go through in my view puts the basic functions of Social Security at risk. These are cuts that come at a time when agencies have been dealing with funding that has not kept up with inflation or demand over the years. In the case of Social Security, funding over the past 2 fiscal years for routine operations has been essentially flat. In each of these years, the funding level provided was below the President's request by \$924,000,000, or about 8 percent. The cuts have an impact on our ability to serve seniors, to ensure that they get the proper benefits they have earned. Efforts to prevent waste, fraud, and abuse to ensure that benefits only go to eligible individuals have not been fully funded. The Budget Control Act permits additional funding to be provided above the spending caps for continuing disability reviews and SSI redeterminations. If we had fully funded this in 2012, it would have provided an additional \$140,000,000 for program integrity.

The 2013 House subcommittee provided none of the funding, cut this work by about \$483,000,000, and while the claims are that we want to save money by cutting out program waste and inefficiencies, rhetoric is not matched by action. Rather, it suggests that people would prefer to see Social Security falter in its basic responsibilities to America.

We need to be clear. The only thing SSA uses its funding for is to get Social Security benefits to the seniors and others who deserve them in a timely fashion. We are talking about retirees that have worked their entire lives for retirement benefits, individuals with disabilities, and seniors who live in poverty. Right now, people are waiting desperately for resources they deserve, earned, or they need to get by. With these deep cuts, fewer applications will be

processed, backlogs will grow, more erroneous payments will be made, and people will have to wait even longer in offices to have their phone calls answered. The Social Security Administration is already understaffed, and these cuts will only make things worse.

Due to limited resources, the Social Security Administration has already taken measures such as curbing hiring and closing offices.

Meanwhile, a record number of individuals filed retirement claims in 2012, and while the Social Security agency should be applauded for completing 820,000 disability appeals this last year, the backlog grew by 29,000. It still grew by 29,000. Despite the recent progress, the average wait for a disability appeals hearing is nearly 1 year.

I also understand that the agency has taken advantage of technology to curb and cushion some of the effects of these deep cuts. We want to hear about those efforts. In fact, though, technology can only go so far since much of the work is lengthy, it is complicated, and it requires individual attention, the kind of work that demands a trained, knowledgeable employee, a real person, if you will, working with the beneficiary to assist him.

So a combination of more work, fewer staff has really stretched the agency, and unfortunately, the future looks bleak. In less than 10 years, the cuts made through existing BCA caps will take non-defense discretionary spending to the lowest level on record as a share of GDP.

Some people are demanding further reductions in caps, which would mean that the shortfalls will just get worse. My view is that we simply cannot do that and properly provide our seniors and others with the benefits they deserve.

Let me just say a quick thank you to you for what you are working to do to make the SSA more modern, efficient, the use of technology to become more advanced to ensure that people get the benefits that they have earned. I welcome you today and hope that you can help the subcommittee to understand the impact of these budget policies on our seniors and families. Thank you so much for being here.

Ms. COLVIN. Chairman Kingston, Ranking Member DeLauro, I want to thank you for inviting me to discuss our service delivery challenges and what we must do to successfully manage them.

I am Social Security's Acting Commissioner.

At Social Security, we are responsible for administering some of the Nation's largest and most successful programs. We also administer programs providing an economic lifeline for the most vulnerable among us. Last year, we paid over \$800,000,000,000 to almost 65,000,000 beneficiaries. We take great pride in helping the American people by providing some peace of mind during important transitions in their lives. These transitions may include retirement, surviving the loss of a family member, or coping with severe disabilities. While the faces and circumstances of our customers vary, our commitment to serve them never changes.

Over the years, Congress has asked us to take on more responsibilities and challenges. Time and again, we have succeeded when given adequate, predictable funding. Most recently when Congress asked us to reduce the time it takes for an individual to get a hearing decision and gave us the funding to meet that objective, we de-

livered. In addition, when Congress gave us funding to ramp up program integrity, we dedicated those resources to tools that deliver an excellent rate of return for the American taxpayer. In fact, recent estimates suggest that continuing disability reviews save \$9 for every dollar invested, and Supplemental Security Income (SSI) redeterminations save about \$6 for every dollar invested.

But in this difficult fiscal climate, our ability to serve the public has suffered. Over the past 2 years, we have operated at funding levels nearly \$1,000,000,000 below the President's budget. Sequestration further threatens our ability to serve the public. At this time, we cannot adequately invest in the information technology that would help us reach more of our customers. Further, we have lost many of our Federal and State employees through attrition.

To get by, we have consolidated 41 field offices and closed 490 contact stations. We have also abandoned plans to open new hearing offices and a new teleservice center. The result is deteriorating service nationwide. Wait times are going up in our field offices and hearing offices, and those who call our 800 number have to wait longer.

Predictably, the American people are frustrated. Longer waits can lead to dangerous behavior. More and more we receive reports of receive frustrated customers threatening and assaulting our employees and other members of the public. Just last month, in Representative Simpson's district, a visitor to the Boise office told one of our employees, "If I get denied, I am pretty sure I am going to lose it and hurt people or even shoot someone." In Casa Grande, Arizona, someone even set off an explosive device in one of our offices.

Still, we focus on what we have always focused on, conscientiously and compassionately serving our customers. They are, after all, to us people, not numbers. They are a grandmother seeking a replacement Medicare card, a worker of 30 years applying for hard-earned retirement benefits, and a wounded warrior in need of disability benefits because of severe Posttraumatic Stress Disorder. We will never lose sight of our customers. We remain committed to serving them with care, diligence, and skill.

However, without sufficient, predictable funding, we can only do so much. In this day and age, Americans increasingly want to do more business with us online, and doing more business online makes sense for the taxpayer. Our online services are the highest rated in the public and private sectors, but with limited funding, we cannot do much more than maintain the information technology that we have.

Moreover, without sufficient, predictable funding, we cannot invest in our best asset, the employees of Social Security. If we do not have enough staff to keep up with the work, the public can expect to wait longer in our offices, on the phone, and for disability decisions. The quality of decisions will also suffer without resources to invest in training.

Of course, we recognize that fiscal belt-tightening means making tough choices. We may need to further reduce office hours, close offices, defer workloads, and take other cost-saving measures that will sadly delay services to the public even more. We will do what we can to manage these cuts fairly.

However, if Congress makes a greater investment in our agency and the millions of people we serve, we will do what we have always done. We will deliver. We will invest in information technology and in our employees. We will continue to streamline our business processes and our rules. We will maintain Social Security as one of the most efficient and effective agencies in the Federal Government, one with an administrative overhead that is a mere 1.5 percent of all the payments that it makes.

Thank you for the opportunity to appear before you today. I will be happy to answer any questions you have.



COMMITTEE ON APPROPRIATIONS

**SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES,
EDUCATION, AND RELATED AGENCIES**

UNITED STATES HOUSE OF REPRESENTATIVES

MARCH 14, 2013

STATEMENT FOR THE RECORD

**CAROLYN W. COLVIN
ACTING COMMISSIONER
SOCIAL SECURITY ADMINISTRATION**

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to update you on our service delivery challenges and what we must do to successfully manage them.

The Social Security Administration (SSA) historically has been a “can-do” agency. Over the years, Congress has asked us to provide the American people with quality service in a timely and effective manner. Our work includes not only our core mission of administering Social Security and Supplemental Security Income (SSI), but also requires the employees in our 1,200 community-based field offices to assist individuals in other areas ranging from applying for Medicare to clarifying their immigration and work authorization status. While we recognize the very important role we play in helping people, and are proud of the service we provide, I must warn you that these levels of service cannot be sustained if we are underfunded.

When we receive adequate, sustained, and predictable funding, our record shows that we deliver on the investment. Unarguably, our most recent success has been drastically reducing the hearings backlog. We are considered among the most efficient and effective agencies in the Federal Government—achieving great success when our “can-do” attitude is matched with sufficient resources. As I will explain further, we are under continuing stress and need your assistance to allow us to maintain the quality service the American people deserve and have come to expect.

Program Overview

The Old-Age, Survivors, and Disability Insurance (OASDI) program, commonly referred to as “Social Security,” protects against loss of earnings due to retirement, death, and disability. Workers, their employers, and self-employed persons finance Social Security through payroll taxes. We also administer the SSI program, funded by general revenues, which provides cash assistance to aged, blind, and disabled persons with very limited means.

In addition to administering these core programs, we handle lesser-known but critical services that bring millions of people to our field offices or prompt them to call us each year. We issue replacement Medicare cards, help administer the Medicare low-income subsidy program, and verify information for other Federal and State programs.

When the American people turn to us for any of these vital services, they expect us to deliver a quality product, and we do everything within our power to deliver it. Whether our customer is a grandmother who asks for a replacement Medicare card, a worker applying for retirement insurance benefits, or an indigent mother with a severely disabled child needing SSI, our purpose is the same: to conscientiously and compassionately serve our customers.

We pride ourselves on delivering caring, high-quality services for all of our customers, although that has become more challenging over the past several years. A large part of that challenge is due to the increased workloads caused by the aging of the Baby Boomers, economic downturns, and the growing demand for us to verify information for other programs. Tighter budgets have exacerbated our ability to serve members of the public who need our services.

If we are to succeed in our mission to serve our current beneficiaries and all Americans seeking help through other important programs, we need sustained, predictable funding that will allow us to hire and train highly-qualified employees to reach an optimal staffing level, having lost many employees through attrition since fiscal year (FY) 2011. Sufficient funding also will allow us to make the right investments in technology to help us to be as efficient as possible, saving time for both the agency and public.

Our employees are our best asset when it comes to serving the public. They have responded heroically to serve every person who comes through our front door or calls us—even as dwindling resources mean we have far fewer employees available to serve the public. In fact, since FY 2011, average daily visitors per employee have increased by 4 percent. In the offices with the highest employee attrition (over 10 percent), average daily visitors per employee have increased by 16 percent.

Shrinking resources and workforce, and rising workloads have resulted in people waiting much longer—and becoming increasingly frustrated. On those increasing occasions when frustration spills over into aggression or even violence, our employees, as well as members of the public, are at risk. Since FY 2011, our employees have been exposed to a nearly 20 percent increase in threats. We owe it to our employees and the people they serve to do everything we can to protect and support them.

Adequate funding enables us to invest in tools and technology, which are vital for delivering quality service. Technology benefits our customers by providing more options to do business with us over the Internet or through self-service kiosks. We must build upon the success of our online tools and recently released *mySocialSecurity*, which provides Internet users a secure way to do business with us. As we perfect these self-service options, we can add more business functions to them, which free our employees to focus on complex work and the customers who most need our help.

Another important part of customer-centric service delivery is partnering with other agencies. Many of those we serve are eligible for benefits and services from other Federal and State agencies. We owe it to our customers—who include Wounded Warriors and homeless veterans—to strengthen our relationships with agencies like the Department of Defense (DoD) and the Department of Veterans Affairs (VA). Coordinating our services with other agencies helps ensure that the most vulnerable among us do not slip through the safety net that Congress created for them. However, without adequate resources, these partnerships will be much harder to sustain.

Looking ahead, we recognize the current fiscal environment may mean reduced resources for us to administer Social Security and SSI. Consequently we—and Congress—will face tough choices and trade-offs. Insufficient resources may mean further reductions in office hours, deferred workloads, and other cost-saving activities that will sadly delay services to our applicants and beneficiaries. We will do what we can to spread out any additional budget cuts across our organization in a way that is manageable for all of our customers and fundamentally fair. We will also do what is best for our employees who have struggled to cover more and more

work. Our goal is to provide balanced service with the resources that we receive. With additional resources, we could hire more, invest in technology that will help us work smarter and faster, and deliver an overall better product to the American people. We have shown time and again that we are a good investment for the American taxpayer.

The Services We Provide and the Challenges We Face

Few government agencies touch as many people as we do. The programs we administer provide a financial safety net for millions of Americans, and many consider them the most successful large-scale Federal programs in our Nation's history. The responsibilities with which we have been entrusted are significant. In FY 2012, we:

- Paid over \$800 billion to almost 65 million beneficiaries;
- Handled over 56 million transactions on our National 800 Number Network;
- Received over 65 million calls to field offices nationwide;
- Served about 45 million visitors in over 1,200 field offices nationwide;
- Completed over 8 million claims for benefits and 820,000 hearing dispositions;
- Handled almost 25 million changes to beneficiary records;
- Issued about 17 million new and replacement Social Security cards;
- Posted over 245 million wage reports;
- Handled over 15,000 disability cases in Federal District Courts;
- Completed over 443,000 full medical continuing disability reviews (CDR); and
- Completed over 2.6 million non-medical redeterminations of SSI eligibility.

We accomplish these tasks, and others, through a nationwide workforce of about 80,000 Federal and State employees. Our employees' number one challenge and priority is to deliver the highest quality service they can to our customers.

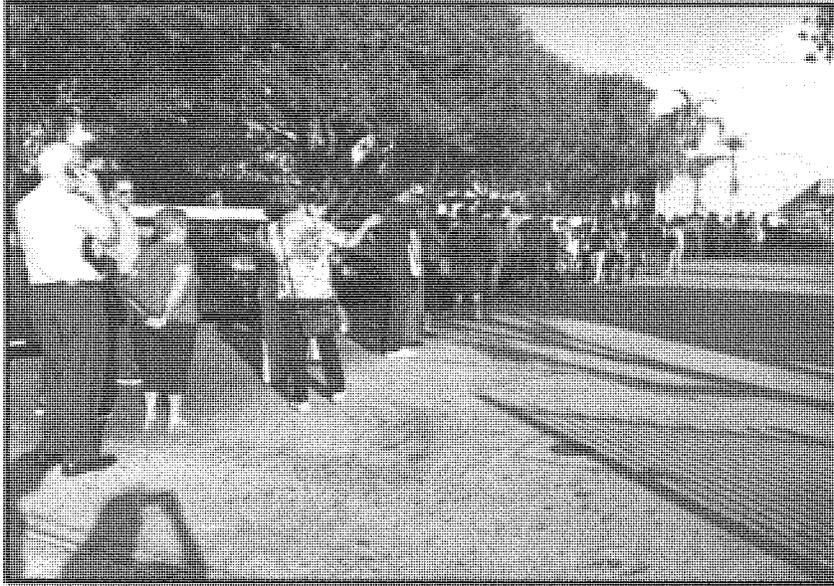
Delivering excellence has meant different things at different times. We must change along with our customers' needs, including their preferences for ways of doing business with us. When we first established our field office structure in 1936, there was only face-to-face service. We processed our claims on paper, without computers, and we housed our ever-growing files across the country, making it difficult, if not impossible, to share work between offices.

Now, our customers increasingly embrace and expect the use of online services. In addition to providing better service, our online services save our employees time, allowing them to work on other issues and workloads. In fact, our online claims applications are critical to allowing us to keep up with a surge in retirement and disability claims.

As we change to meet the public's service preferences, we must ensure that we provide excellent service for those who prefer to speak to us on the phone or face-to-face. We are committed to not leaving any of our customers behind in pursuit of new technologies, and we must do everything within our power to serve them in an easily accessible way. However, managing our transition to online processes is a very difficult balancing act, especially in the current fiscal climate and as we see growing numbers of claims.

The current budget situation is exacerbating the negative effects of over two straight years of funding levels nearly a billion dollars below the President's budget requests. With fewer employees to serve our customers, we are seeing serious signs of service deterioration. Examples include:

- This week, close to 12,000 visitors to our field offices will have to wait over 2 hours to be served, a figure that has almost tripled in just the last 4 months;
- The average wait time for field office visitors without an appointment increasing by 40 percent, from just 21 minutes in FY 2010 to about 30 minutes through January of FY 2013;
- Our 800-number average busy rate increasing from 4.6 percent of all calls in FY 2010 (which equates to 2.6 million calls) to about 15 percent of all calls through January of FY 2013 (which equates to 3.3 million calls and puts us on-pace for a projected 10.5 million calls for FY 2013); and
- Our average speed of answer for the 800-number more than doubling from about 3.5 minutes in FY 2010 to over 7.5 minutes through January of FY 2013.



Above: The public waits to enter our Miami (South), Florida office on January 8, 2013.

We have done everything within our power to minimize the effects on our customers, including enacting several cost-saving measures. We have:

- Consolidated 41 field offices and closed 490 contact stations since FY 2010, in addition to foregoing plans to open eight needed new hearings offices and a new teleservice center;
- Reduced the hours that our field offices are open to the public to complete late-day interviews without using overtime;
- Developed an acquisitions savings plan that realized over \$460 million in savings in FYs 2010 and 2011;
- Reduced travel in accordance with the President's Executive Order on Promoting Efficient Spending, which has saved \$28.6 million since FY 2010;
- Eliminated unnecessary spending in areas such as printing, supplies, and relocation, which has saved \$52.4 million since FY 2010; and
- Reduced agency-sponsored conferences from 112 in FY 2010 to 13 in FY 2012, saving over \$7 million.

However, the core of our work is people-based. If we do not have enough employees to keep up, our customers can expect to wait longer in our offices, on the phone, and for disability decisions at all levels. At the estimated sequestration level, we would operate with \$11.134 billion in FY 2013 for our Limitation on Administrative Expenses account, a decrease of \$386 million from our current continuing resolution operating level of \$11.520 billion. At this stage of our planning, sequestration will result in the loss of over 3,400 employees due to attrition in FY 2013 that we would be unable to replace.

As a result, we estimate that pending levels of initial disability claims will rise by over 140,000 claims, and on average, applicants will have to wait about 2 weeks longer for a decision on an initial disability claim and nearly a month longer for a disability hearing decision. Visitors in our field offices will wait significantly longer, and callers to our 800-number will wait almost 10 minutes for us to answer.

These service issues have created unfortunate and potentially dangerous consequences. As customers have had to wait longer and longer for services, we are seeing an increasing number of threats to our employees, guards, and members of the public in our offices. In 2012, our offices received and processed nearly 4,000 incidents of threat or violence against our employees, guards, and facilities. In several assaults, weapons were used, and on November 30, 2012, our Casa Grande, Arizona office was attacked by an individual using an incendiary device. In just the first 3 weeks of this year, we experienced over 500 incidents, many of which were directed towards our employees.

We expect that the tight fiscal climate will persist, and we are realistic about the tough choices we will continue to face. Even if we receive the same amount of, or slightly higher, funding compared to FY 2012, we will lack adequate funding to replace all the employees we expect to lose due to attrition. This diminishing return is because many of our fixed costs—e.g., salaries, health care benefits, rent, postage, guards—will continue to rise each year and consume a larger part of our fixed budget, leaving insufficient funding to hire new employees. Staffing losses are already creating uneven service across the Nation, and the disparities will grow without adequate, sustained, and predictable funding.

We are evaluating how we can best deliver services to our customers given the current environment. We will make smart, balanced choices about how we deploy the resources that we receive. With funding at the current continuing resolution level for the full year, we would be able to hire about 2,000 employees between now and the end of the fiscal year to replace critical losses and to help mitigate the effects on the public. However, in this fiscal environment and in spite of all our best efforts, we know we will not be able to timely complete all of the work for which we are responsible.

Initial Disability Claims and Hearings Backlog

We are trying to keep pace with the elevated level of new disability claims. Over the past five years, the initial disability claims we received increased by about a third. Due to significant increases in employee productivity, technology, and policy improvements, we have so far been able to keep pace with this workload and while maintaining—and even improving—quality.

Our easy-to-use online application for applying for disability, retirement, and Medicare—iClaim—has been a huge success. Applicants can now file for benefits online at their own pace and on their own schedule. The percentage of applications filed online continues to increase. In FY 2012, more than 1.1 million Social Security Disability Insurance (SSDI) claimants, or 38.5 percent of SSDI claimants, filed online, which was almost 8 times greater than in FY 2007, prior to iClaim. Through January 2013, 43.3 percent of SSDI claimants filed online.

We continually identify ways to streamline the disability claims process. Since last April, adults who file online now have the option of electronically signing and submitting the authorization form we use to obtain evidence. Over 94 percent of eligible adults have chosen to electronically submit the authorization form. Ultimately, we expect this improvement will further reduce processing times by eliminating the need for mailing paper authorization forms.

We know we cannot just focus our efforts on speed. Quality is integral to our disability processes. We have developed and implemented the electronic Claims Analysis Tool (eCAT), a web-based application, to help State disability determination services (DDS) examiners apply policies correctly throughout the disability decision-making process. eCAT uses “intelligent pathing,” which prompts users to consider the appropriate questions based on the unique characteristics of each case. We fully implemented eCAT last year and made it mandatory for use in every DDS.

We continue to make significant progress in developing the Disability Case Processing System (DCPS). DCPS will replace the 54 different systems that support the DDSs with 1 national system based on state-of-the-art technology. This system will include eCAT. Additionally, DCPS will allow us to systematically support policy changes in a faster way, and it will promote more consistency among the DDSs. DCPS will also provide efficiencies that will make it easier to modify our system, making changes in 1 rather than 54. We expect that the new system will improve documentation of our decisions. We are testing the initial version of DCPS, released in September 2012, in the Idaho DDS. We are incrementally increasing functionality and plan to expand to the Illinois DDS in April 2013 and the Missouri DDS in July 2013.

We rely upon doctors, hospitals, and others in the health care field to timely provide the millions of medical records that we need. Traditionally, this has been a very time-consuming, paperbound part of the disability decision process. We are leveraging the rapid developments of electronic health records and health IT in the medical community to improve our disability business processes. However, with the advent of standards-based computer exchanges, we have successfully shown that, with the consent of our claimants, we can nearly instantaneously access medical records. As health IT becomes the industry standard, the volume of medical records that we receive through health IT will rapidly increase, and the speed and accuracy of our disability decisions should improve significantly. We, along with Congress, will have much improved management information to support further enhancements to the disability process. We are working very closely with the Department of Health and Human Services' Office of the National Coordinator for Health IT and with the Centers for Medicare and Medicaid Services to align our work with the national strategy for health IT. In addition, we are working with DoD and VA to implement health IT exchanges to improve our collection of medical records.

Streamlining and updating our business processes will help us to decide claims more quickly without disadvantaging the claimant. Last year, we issued a rule to give our adjudicators greater flexibility in how they analyze disability cases. In certain cases, if we find that a claimant is able to do other work based solely on his or her age, education, and residual functional capacity, we can deny the claim without requiring—as our prior rule did—the adjudicator to determine whether the claimant is able to perform his or her past relevant work.

The President's 2013 Budget proposed another program simplification called the Work Incentives Simplification Pilot (WISP). The current set of work incentive policies and post-entitlement procedures has become very difficult for the public to understand and for us to administer effectively. The goal of WISP is to conduct a test of simplified SSDI work rules, subject to rigorous evaluation protocols, which may encourage beneficiaries to work, reduce our administrative costs, and help eliminate improper payments.

To help us identify disability cases that we should clearly allow, we continue to update the Listing of Impairments (Listings). The Listings describe for each major body system the impairments considered severe enough to prevent an adult from working or, for children, impairments that cause marked and severe functional limitations. We have completed comprehensive body system listing revisions for 10 of the 14 adult and childhood body systems and plan to complete the rest by the end of FY 2014.

We are successfully using the Compassionate Allowances and Quick Disability Determinations processes to fast-track disability determinations for individuals who are obviously severely disabled. Since October 2009, we have used these processes to expedite claims for over 510,000 disability claimants, while maintaining a very high accuracy rate and processing the cases in days or weeks, rather than months. Approving clearly eligible claimants early in the process benefits persons with severe disabilities and, at the same time, allows us to focus our attention on the more ambiguous cases. We continuously research other conditions to identify those we should capture under our Compassionate Allowances or our Quick Disability Determinations processes.

To make consistent, better-informed decisions on whether claimants meet our disability criteria, we have started the difficult process of overhauling our main vocational tool, the Dictionary of Occupational Titles, which the Department of Labor (DOL) largely stopped updating in the late 1970s. We are working with DOL to collect new data for occupations at the detailed occupational level. In July 2012, we signed an interagency agreement with the Bureau of Labor Statistics to pilot the collection of detailed occupational information that could support a new Occupational Information System that would address our needs.

We also partner with the National Institutes of Health (NIH), which allows us to work with each of NIH's 27 institutes to support our disability program research and development. In 2008, we executed an interagency agreement with NIH's Clinical Research Center to conduct short- and long-term research on improving the disability determination process. Under this agreement, NIH analyzes our existing data to provide recommendations for expanding the list of Compassionate Allowances and updating the Listings. The collaboration has also informed our efforts to incorporate functional information into the disability criteria.

We have worked hard to reduce the hearings backlog. Our results illustrate the enormous good that can be achieved with a dedicated commitment of resources to an important agency workload. With more judges and employees to decide cases, as well as wider use of video hearings, we reduced average processing time from an all-time high of 532 days in August 2008 to a low of 340 days in October 2011. However, because of cutbacks in the budget, average processing time started trending upwards in FY 2012 and is currently at 382 days. Without adequate funding, our gains in this area will soon be a distant memory.

Improving quality is also a crucial part of our efforts to improve our appeals processes. With additional staffing and funding to invest in systems that capture structured data, we have been able to not just review hearing-level decisions, but also analyze them for adjudicative trends, patterns of errors, and other anomalies. Our analysis has led us to develop and then refine tools such as "How MI Doing?" and the electronic Bench Book, which provide detailed information to our adjudicators and help them improve their accuracy and policy compliance. In 2010, we established the Division of Quality within the Office of Appellate Operations. Through its review of a random sample of fully favorable unappealed hearing-level decisions, the Division of Quality has been able to examine how our administrative law judges (ALJ) and hearing offices are adjudicating cases. These reviews have led to the agency restructuring its training programs, materials, tools, and software to better support our ALJs and hearing offices. Together, these efforts to improve quality have driven a dramatic decline in programmatic errors and unexpected outcomes, resulting in substantial cost savings and a decrease in overpayments to claimants.

Moreover, our agency still suffers from a shortage of ALJs. While we have hired over 850 new ALJs since FY 2007, historically high ALJ attrition and dramatic workload growth leave us short on adjudicatory capacity. The Office of Personnel Management's ALJ register is virtually exhausted and we will end FY 2013 far short of our hiring target.

Though we have attempted to meet our ALJ hiring needs by doubling our number of senior ALJs, we will not be able to make further progress on reducing our backlog until we get more ALJs. Hearing requests continue to come in at high levels in FY 2013, but we do not expect to

have the ability to hire ALJs until the third or fourth quarter of FY 2014. Until we can hire more ALJs, reducing our average processing time will be impossible. For now, the best we can deliver is a stable average processing time.

Finally, as we have reduced processing times for hearings and the hearing backlog itself, we have seen a significant increase in Federal District Court filings whereby claimants appeal unfavorable decisions. In FY 2012, 16,831 cases were filed in the Federal District Courts, which represent a 7.7 percent increase over the 14,236 filings of FY 2011 and an 18 percent increase over the 12,952 filings of FY 2010. We anticipate even more court filings in FY 2013, possibly as many as 18,600. While attorney productivity in the briefing of these cases has increased by 8 percent since 2010, we will be hard-pressed to meet the court deadlines of such a growing caseload.

Program Integrity Work

We are committed to protecting program dollars from waste, fraud, and abuse. We must maintain the public's trust by effective stewardship of program dollars and administrative resources. Our ability to identify and pursue improper payments is ultimately determined by available resources.

I am pleased to report that our hard-working, dedicated employees continue to improve our efforts to prevent, detect, and recover improper payments. As a result, the Social Security program is among the most accurate in the Federal Government. However, despite our high accuracy rates, due to the sheer size of our programs, even a small percentage of inaccuracies results in billions of dollars of improper payments. Further reducing our error rates is difficult due to our programs' complexities.

Each year, we complete periodic medical reevaluations, or CDRs, to determine if beneficiaries are still disabled. We also perform SSI redeterminations to review non-medical factors, such as income and other non-home resources. These reviews save billions of program dollars with only a small investment of administrative funds. In the past few years, we have substantially increased the number of CDRs and SSI redeterminations.

In FY 2012, we completed more than 440,000 or over 100 percent more SSDI and SSI medical CDRs than we did in 2007. For the FY 2013 President's Budget, we estimated that every dollar spent on CDRs will yield about \$9 in program savings over 10 years, including savings accruing to Medicare and Medicaid. We have also significantly increased the number of SSI childhood CDRs that we complete each year. In FY 2012, we completed over 150 percent more of these cases than we did in FY 2011.

The Budget Control Act of 2011 (BCA) authorized a level of program integrity funding that would have allowed us to complete 569,000 medical CDRs in FY 2012—a 65 percent increase over the FY 2011 CDR level. The Administration strongly supports the program integrity cap adjustments authorized by the BCA, which would put Social Security on a 10-year path to eliminate the backlog in program integrity reviews. Unfortunately, our FY 2012 appropriations did not provide the BCA level of funding for program integrity work; therefore, we were able to

complete only 443,000 medical CDRs in FY 2012. If we had received funding for CDRs in FY 2012 at the full BCA funding level as compared to what was actually funded, we estimate OASDI, SSI, Medicare and Medicaid program savings of roughly an additional \$800 million in FYs 2012-22 under FY 2013 Budget assumptions.

The President's Budget requests \$1 billion for SSA program integrity in FY 2013, which would allow us to complete the BCA levels of program integrity, including 650,000 medical CDRs. However, under the current continuing resolution, we expect to complete only 435,000.

In FY 2012, we completed 2.6 million SSI redeterminations or 150 percent more than we completed in FY 2007. For the FY 2013 President's Budget, we estimated that every dollar spent on SSI redeterminations will yield about \$6 in program savings over 10 years, including savings for the Medicaid program.

We are always looking for smarter ways to handle our work. We developed a predictive model that selects the most advantageous cases to consider for work reviews to decrease improper payments in the SSDI program. The model prioritizes a workload of more than half-a-million cases per year, for which we must evaluate earnings.

At the end of FY 2011, we nationally implemented an initiative called Access to Financial Institutions (AFI). AFI enables us to check the bank accounts of SSI applicants and recipients to determine if their assets exceed our program eligibility requirements. Assuming we had used our current account verification process on a long-term basis, the account verifications we would complete in FY 2013 would yield an estimated \$365 million in lifetime SSI program savings consistent with a return on investment of about \$9 to \$1.

Building upon our AFI success, we are exploring the use of commercial databases to help us identify undisclosed non-home real property held by SSI applicants and recipients. This automated approach has the potential of helping us uncover unreported assets that may result in ineligibility for SSI payments.

We continue to expand our SSI Telephone Wage Reporting System. This system has allowed us to increase the volume and timeliness of wage reports we receive, therefore, reducing wage-related errors. These telephone reports generally are accurate and require no additional evidence, which saves time in our field offices.

Similarly, we have begun testing an SSI Mobile Wage Reporting application for smartphones, which allows recipients and representative payees to use their smartphones to report monthly wage information at their convenience. This alternate method of wage reporting will help reduce delays between a recipient's reporting an income change and the update to our systems. We have offered the mobile application to a small number of users and will gradually expand its availability. We expect new tools such as these for wage reporting will help reduce improper SSI payments.

In response to the growing problem posed by identity theft and direct deposit fraud, we have expanded measures to protect our beneficiaries' payments. Beneficiaries can request a block to

prevent changes to their records to optimize security access and prevent criminals from re-directing payments to a fraudulent account. Since implementing this service in November 2012, nearly 7,000 beneficiaries have taken advantage of this option. To date, we have prevented 941 potential fraud attempts. We will continue to devise ways to prevent fraud and collaborate with the Office of the Inspector General to protect our customers' payments and identities.

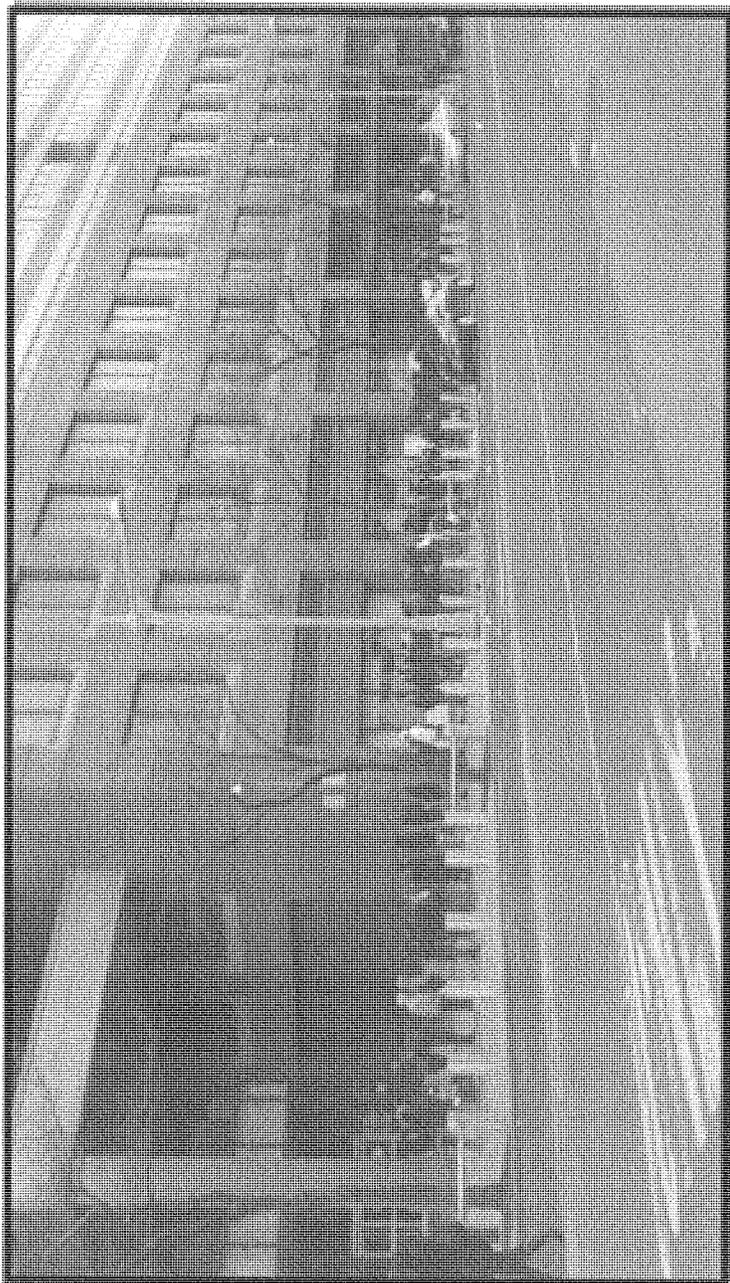
Conclusion

Thank you for this opportunity to update you on our service delivery challenges and what we must do to successfully manage them. We believe serving the public successfully begins with evaluating the range of customer experiences at SSA. Whenever a customer asks for help, we must do everything within our power to deliver a quality product.

Over the past few years, in this fiscal climate, it has grown increasingly difficult for us to provide high-quality service to all of our customers on all of our service fronts. With the resources we receive, we must invest in all of our employees across all areas of the agency, giving them the tools they need to make the right decision the first time. Expanding upon our partnerships with other agencies will also help ensure that none of our customers slip through the safety net. By offering our customers more options to do business with us over the Internet or through self-service kiosks, we can further energize our service delivery and make it more customer-centric.

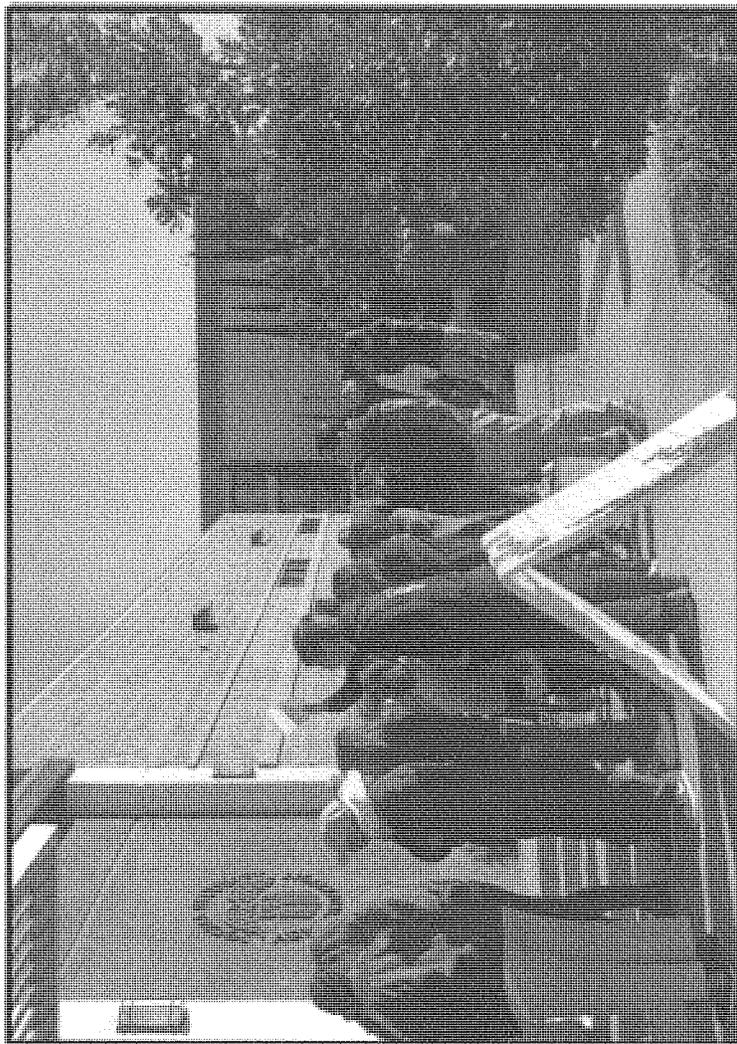
While we cannot be everything to everyone, we will do the best with the resources we have. Service suffers as a result of inadequate funding and we continue to face tough choices and trade-offs. However, we will do what we can to spread out any additional budget cuts across our organization in a way that is manageable for all of our customers and employees and in a way that is fundamentally fair. What Congress can do to help us is to provide us with adequate, sustained, and predictable funding. We could hire more, invest in the technology that will help us work smarter and faster, and deliver an overall better product—a quality return on investment to the American people.

Appendix A



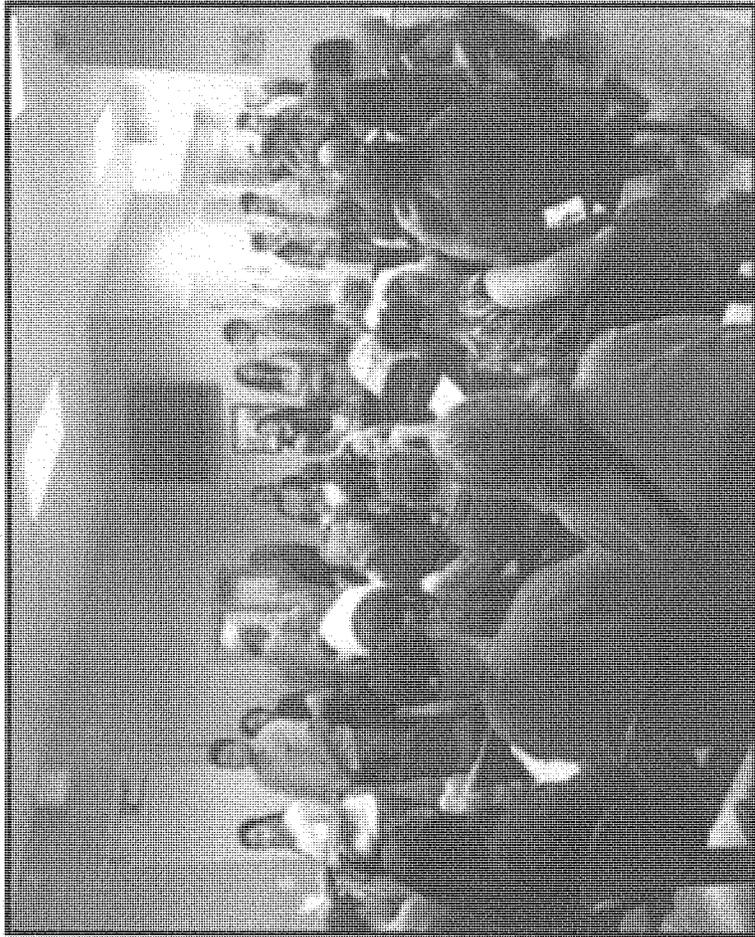
Above: The public waits outside the Queens Card Center in New York, New York on February 19, 2013.

Appendix B



Above: The public waits outside our Anaheim, California office on January 17, 2013.

Appendix C



Above: The public waits for service in our Ferrine, Florida office on January 8, 2013.

Mr. KINGSTON. Thank you very much, Ms. Colvin.

I wanted to get something clear in my mind. You have something like \$100,000,000 to \$200,000,000 in IT carryover funds that are accessible to you. Correct?

Ms. COLVIN. Yes, we do have carryover funds available.

Mr. KINGSTON. But I think you just said—and I actually was having trouble finding—because I think your testimony was not quite tracking the complete written testimony. But I think you said something like without sufficient funds to implement some of the high-tech—

Ms. COLVIN. Yes.

Mr. KINGSTON. But you have \$100,000,000 to \$200,000,000 sitting there.

Ms. COLVIN. Well, that certainly is nowhere near the dollars that we need to be able to do both maintenance of our systems, as well as additional online services and improvements in applications.

Mr. KINGSTON. How much will that take?

Ms. COLVIN. I would have to get back to you with a specific number. But right now at the sequestration level, we—

Mr. KINGSTON. Well, let me interrupt you a minute. Shouldn't you know how much you need? And the reason why I asked is—

Ms. COLVIN. I have it. I do not have it right here.

Mr. KINGSTON. But somebody here would know. Right?

Ms. COLVIN. I do not think so. It depends upon what we are going to do. When we get an allocation, we lay out what our plan for the year is going to be, what new applications we expect to do, what modernization, what our maintenance costs will be. So we always submit a budget that indicates the amount that we are going to—I mean, if we were to submit to you everything that we would like to do, the funding would be just not possible. So what we do is try to, each year, look at what we think is reasonable and make a request. So if you want to know what we submitted in our 2013 request, I can provide you with that figure.

Mr. KINGSTON. That would be helpful to me.

[The information follows:]

The fiscal year (FY) 2013 President's Budget assumed \$857 million for our Information Technology Systems budget.

Mr. KINGSTON. And it gets back to my opening statement on the centralized plan.

Ms. COLVIN. Let me speak to that, if you would like.

Mr. KINGSTON. Please.

Ms. COLVIN. We were advised by our attorneys, when we received our appropriation, that we could not do a single source contract, that it would be in violation of the procurement law.

So based on that, what we did was develop a service delivery plan with in-house staff. We consulted with the staff of this committee to get their input. We have used that input and the input of various other stakeholders—the advisory board, and advocacy groups, et cetera—and we have developed a draft plan. It is still in the works, but it will be posted on the Federal Register hopefully this week and it will ask for comments. We expect that the staff will probably offer further comments, and then we would expect to finalize it.

Certainly strategic planning is something that we need to focus on more in the agency. That is certainly something that I am very much interested in as the Acting Commissioner. So this plan was developed under Commissioner Astrue. I expect, once that is submitted, that I will begin a further planning process in the agency during the interim that I am there.

Mr. KINGSTON. And are you dealing with the National Academy of Public Administration?

Ms. COLVIN. No, we are not. As I indicated, our attorneys said we could not do sole source, that there were many other organizations out there that had the capacity to do this. And so unless I get a different legal opinion, I do not think that I would feel comfortable doing anything differently.

Mr. KINGSTON. I need a clarification. Maybe staff can help me on it on your side of the table or mine.

But if it was stipulated in the fiscal year 2012 law to work with them, why would that be a violation of the law?

Ms. COLVIN. I have been informed that the Competition and Contracting Act of 1984 requires us to obtain full and open competition through the use of competitive procedures when we contract for goods and services. And we do not believe that the language expressly authorized us to do that.

Now, this is very technical. I would be very happy—

Mr. KINGSTON. No, no.

Ms. COLVIN [continuing]. To provide you a more complete response for the record, if you would like.

But I know we have had a lot of discussions with the committee staff, and I think the conclusion was that the language was not sufficient to allow us to do a sole source competition—I mean, non-competition contract.

Mr. KINGSTON. All right.

Ms. COLVIN. Would you like something further?

Mr. KINGSTON. Yes. I think that would be helpful.

Ms. COLVIN. All right. We will do that.

[The information follows:]

In the Statement of Managers in the conference report (H.R. Rep. No. 112-331) that accompanied the Consolidated Appropriations Act of Fiscal Year 2012, the conferees “provide[d] SSA with up to \$500,000 to contract with [NAPA] to develop and submit a report proposing a long-range strategic plan for SSA’s consideration.”

The Competition in Contracting Act of 1984 (CICA) requires us to “obtain full and open competition through the use of competitive procedures” when we acquire goods and services. 41 U.S.C. § 3301(a). The law provides an exception to use non-competitive procedures when “a statute expressly authorizes or requires that the procurement be made ... from a specified source” 41 U.S.C. § 3304(a)(5).

We do not believe that the language of the Statement of Managers in the conference report allows us to use non-competitive procedures to procure the services of NAPA. This is because the Statement of Managers is not, in and of itself, a statute since it is not legislation passed by both Houses of Congress and signed by the President. Rather, the Statement of Managers is a type of legislative history. The Congressional Research Service (CRS) has noted that a Statement of Managers “explains the various elements of the conferees’ agreement in relation to the positions that the House and Senate had committed to the conference committee.... Like standing committee reports accompanying bills, joint explanatory statements may prove informative as legislative history.” *Conference Reports and Joint Explanatory Statements*, CRS 98-382 (May 10, 2011).

In analyzing the legal effect of legislative history in the context of an agency’s appropriations, the Supreme Court adopted the analysis of the Comptroller General on whether legislative history legally binds an agency:

[A] fundamental principle of appropriations law is that where “Congress merely appropriates lump-sum amounts without statutorily restricting what can be done with those funds, a clear inference arises that it does not intend to impose legally binding restrictions, and *indicia in committee reports and other legislative history as to how the funds should or are expected to be spent do not establish any legal requirements on*” the agency.

Lincoln v. Vigil, 508 U.S. 182, 192 (1993), quoting *LTV Aerospace Corp.*, 55 Comp. Gen. 307, 319 (1975) (emphasis added).

Moreover, even if we considered the Statement of Managers to be a statute, pursuant to 41 U.S.C. § 3105, a provision of law may not be construed as requiring a new contract ... to be awarded to a specified non-Federal Government entity unless the provision of law specifically –

(1) refers to this section [of the CICA];

(2) identifies the particular non-Federal Government entity involved; and

(3) states that the award to that entity is required by the provision of law in contravention of the policy set forth in subsection (a) [which requires that a project identified in legislation be awarded through merit-based selection procedures].

41 U.S.C. § 3105(c).

The Statement of Managers, even if considered a statute, does not meet the requirements of 41 U.S.C. § 3105(c).

For the above reasons, we concluded that the award of a sole-source contract to NAPA based on the language in the Statement of Managers would be contrary to the requirements of CICA.

Mr. KINGSTON. And I will yield to Ms. DeLauro.

Ms. DELAURO. You have mentioned some of these facts, if you will, in your testimony.

But Commissioner, let me ask you about the number of closed field offices. The closures, as I understand it, will respond to the pressure of dealing with flat funding you pointed out, which has been eroded by inflation. Again, now we see sequestration, new cuts, stagnant funding levels. Just in a couple of areas, tell us a little bit more about what you have already done in terms of office closures. Is closing additional offices something that the Social Security Administration is looking at to achieve the cuts required by sequestration? Let me start there.

And I do not know. I think we ought to make a list available probably to all Members about the Social Security offices that have been closed in their communities and what is pending as it regards this effort. I think they ought to have that information.

So tell me about the office closures. I want to also ask you about recent staffing trends, and will you have to terminate any employees or implement furloughs under sequestration? But let's start with the office closures.

Ms. COLVIN. Thank you, Ms. DeLauro.

I would like to first say that we have had to make some really tough and undesirable decisions over the last 2 years. In 1989, we received the President's budget. For 2010 and 2011, we received \$1,000,000,000 less. And so that meant we had to make some very difficult decisions.

One of those was that because we had such high attrition, many of our offices were viable because we did not have sufficient staff to be able to staff them. And in those areas where we had offices that were nearby, we consolidated offices and moved those staffs together. And we did work with the community. We did notify individual members whose districts would be impacted. We have closed 41 since then. We closed 490 contact stations.

Ms. DELAURO. What is a contact station?

Ms. COLVIN. That is where we would have one individual who staffed that facility and would go there maybe 1 day a week or 2 days a week or on a schedule so that people would know when someone would be there and they could, in fact, go there.

With the use of videoconferencing and some of the Internet usage, we felt that we could no longer keep contact stations open. It did not make good business sense.

We have closed 490. We probably have another 40 or so that we expect to close, and there will probably be a small number that will remain open. We can give you the specifics on that, if you would like.

This was not something that we did lightly, but we have continued to try to serve our customers in those areas. We realize that everyone is not going to use the Internet. They are not going to have access to it. They are not going to feel comfortable using it. So we are going to always have to have field offices. But we have lost significant numbers of staff over the last 2 years both at the State and local level. So we just cannot do that.

In the testimony, you should have pictures of long lines at some of our offices. People wait from 30 minutes to 2 hours. That is not

the type of service that we are proud of, nor is it the type of service that someone who has paid for an earned benefit deserves. But we do not have the ability to do anything differently.

Ms. DELAURO. Will you have to close additional offices, additional contact stations, if the sequester continues?

Ms. COLVIN. We may. That is an option. My absolute last alternative is to furlough staff because we have lost so many already. We have to have staff to do the work. We also expect another 3,000-plus persons who will attrit out of the system this year, and we had hoped to be able to fill some of those critical positions. But we are not certain yet what we will be able to do there. So, yes, there is a possibility that we may have to close offices.

As you know, we have also reduced our office hours that we serve the public. We have reduced it by a full hour, Monday, Tuesday, Thursdays, and Fridays, and a half day on Wednesdays because we do not have overtime. And staff have to have time to adjudicate the cases. Even though we do work online, it still requires a human being to review the application, make sure it is accurate, and then to adjudicate the case. And we have other post-entitlement work.

But more importantly, we have program integrity work that we have to do. If we do not do that, we keep people on the rolls who should not be there.

Ms. DELAURO. My time has run out. But I am going to ask you later about some of the limitations of technology in terms of a personal commitment.

Thank you, Mr. Chairman.

Mr. KINGSTON. Mr. Joyce.

Mr. JOYCE. Good morning, Commissioner Colvin.

Ms. COLVIN. Good morning, sir.

Mr. JOYCE. Thank you for your testimony here today.

I was wondering if a disability claim is denied, someone has a right to appeal, and the appellate process can take more than a year. What, if anything, has your agency been doing to try to speed that process up?

Ms. COLVIN. Thank you for that question.

Congress was very generous in funding us to reduce the hearings backlog, and as I say, we deliver when you fund us. And as a result, we started with a processing time in the hearing offices of over 500 days. I think it was 555. We were down to about 350, 357. I will give you the exact numbers in writing.

[The information follows:]

At the height of the backlog in August 2008 our hearing offices had an average processing time of 532 days. We reduced the average processing time down to 340 days by October 2011.

Ms. COLVIN. And our goal was 270. But as a result now of the cuts, that number is going back up. But we made tremendous progress in reducing that number. As I said, it was over 500 when we received the funding from you, and now it is down to less than a year. That is still too long, but I mean, we did do what we said we would do based on the funding that you made available to us.

Mr. JOYCE. Thank you.

I yield back.

Mr. KINGSTON. Ms. Lee.

Ms. LEE. Thank you very much.

Good morning. Good to see you.

Ms. COLVIN. Good morning.

Ms. LEE. Let me first say thank you for being here and thank you for doing a tremendous job under very dire circumstances really.

My mother actually is a retired Social Security employee. She worked for Social Security 20 years. She is 88 years old now.

Ms. COLVIN. And we certainly thank her for her services. The strength of our organization is our employees.

Ms. LEE. Yes, I tell you. And I come from Oakland, California, and we have some wonderful employees and it is just a great operation. And I just hate to see and to hear all of the, I say, assaults that you are under and attacks.

First, you have had to downgrade the service in terms of staff hours. You just laid out the day's hours. Now you have got on top of that sequestration.

Let me ask you. What demographic is this going to hit the worst?

And secondly, what is the morale like with your employees at this point? I mean, this seems like a heavy-duty burden that you all are carrying. And it really concerns me because the Social Security offices are the offices of last resort for so many people just to be able to live their daily lives. And now with the kinds of cuts and trauma that the agency is facing, you know, I am really worried about what is taking place.

Ms. COLVIN. Thank you, Congresswoman Lee.

We are very concerned. We are an agency under stress. And as I mentioned before, the employees are heroic in their performance. Caseloads have increased. We cannot give them overtime. We have not given them training. There is no travel. And yet, they still serve in a compassionate and caring way. We serve those people who are most at risk. Congress recognized the need for a safety net, and we have the Social Security program.

But we also provide other services. In addition to our core services, we provide the Medicare cards. We process those. We process Medicare Part D and because so many of the local and State benefits require verification of benefits, many, many of our customers come to get verification of benefits. So we really are a basic safety net service in the community.

I would say that there is no one demographic that is impacted. All of the seniors of this country are impacted, all of the disabled, survivors. People who come to us come when there is some transition in their life, normally not a good transition.

And we have tried to stem the tide. We have had great efficiencies with our IT investments. We continue to improve those. And by the way, our Internet applications are rated the best in Government and best in the private sector. But you still need a human being. You have to be able to review these applications to make sure they are accurate, and you also have to go back and contact people, and you have to adjudicate. So there is a tremendous need for staff. We are way down below where we were 2 years ago, and yet we are at a time when the baby boomers are aging out and people are reaching their disability-prone years. And so our workloads are going up tremendously.

So we have proven time and time again that when you give us adequate, sustained, and predictable resources, we deliver. I remember back when I was here in the 1990's, 1994 to 2001. Congress gave us 7 years, multiple years, of funding for the CDRs. We did every CDR and had no backlog. We knew what we had to do. We knew what our timeframe was. We knew what our funding was going to be, and we delivered. You asked us to reduce the disability backlog. You gave us the funding. We delivered.

So we are an agency that when you invest in us, you get your money's worth plus more. When you invest \$1 in a CDR, you get \$9 back. When you invest \$1 in a redetermination, you get \$6 back. And I do not think there is any Federal agency or private agency that has an overhead of 1.5 percent of its expenditures.

Ms. LEE. But even when we do not invest where we should, you still deliver under dire circumstances.

Ms. COLVIN. Yes, but we cannot anymore. We cannot anymore. We are a "can do" agency, and it hurts an employee to have to close the door and people have to come back a second day.

Ms. LEE. So what is their morale like?

Ms. COLVIN. It is very low. It is very low. Fortunately, because they are committed to public service, they still try to do what they can do, but you see higher stresses as a result of more illness. We have an older workforce. We have major challenges.

Mr. KINGSTON. Thank you. The gentlewoman's time has expired.

You know, I have to say, though, while I understand and I am hearing you, you have 17 employees who are full-time union representatives, paid by the taxpayers to do nothing but union activities—17. And then you have 1,463 who do part-time union activities, paid for by the taxpayers. It is \$14,000,000. It is such a disturbing thing to taxpayers.

I am hearing you say, well, we cannot pay claims. But I would suspect—I am not sure, but I would suspect if you asked those people standing in line, Democrat, Republican, liberal, conservative, do you know that 17 employees at Social Security are full-time union and that it costs about \$14,000,000 a year that you are paying for, do you feel good about that, or would they say why don't they do that on their own time. And you know, I know there is a statute on that, but I do not ever hear administrators like you saying, you know, I want you to know this is a problem.

Now, that is nothing—nothing—compared to what the GAO said the overpayments were on SSI, \$3,300,000,000. Let me repeat that to my friends. \$3,300,000,000 in overpayments. How much of that money has been recovered? And that is a GAO report which you have seen.

Ms. COLVIN. And it is an accurate report.

Let me, first of all, say that we take, first of all, preventing overpayments and then collecting them very seriously. In fact, as the deputy during the time that I was a deputy and certainly now as Acting Commissioner, I have been personally involved in improper payments. Our accuracy rate for improper payments in our title II program, which is less complex—you have the age, you have the quarters, you get a benefit—is 99.8 percent. You cannot get better than that. In SSI, it is 92.7 percent.

So we have been making tremendous strides in our accuracy rate. The problem is just one-tenth of a percent can result in \$50,000,000. So we are taking major steps to increase the accuracy rate.

Mr. KINGSTON. It sounds a little bit like, well, you know, the reductions, if you look at those as percentages, those would be small too, and yet we have spent a lot of time this morning talking about those. But \$3,300,000,000 is big money, and that is only 1 year, by the way, as you know.

Ms. COLVIN. Absolutely.

Mr. KINGSTON. Only 1 year. So if it is 8 percent and 8 percent is a small amount, that is still huge money, \$3,300,000,000 in a 1-year period of time.

Ms. COLVIN. The SSI program is very complex—very complex. Some of our biggest challenges are individuals reporting their changes in assets and wages. We have instituted a program called—well, it is Access to Financial Institutions—where now we are able to work with the banks and go out and identify any assets that individuals have not reported. And that has been very effective. As our budget allows, I will continue to reduce the threshold so that we can do more and more of that. And we are removing individuals because they have, in fact, not reported all of their resources.

We also have instituted a telephone wage reporting system where individuals can report their wages so that we can learn early because, as you know, we do not get the wage reports but once a year, although there has been a proposal in the President's budget to get it quarterly because the earlier we get it, the quicker we can check. So the agency is very aggressive, in preventing overpayments.

We have the CDI units, which are our Cooperative Disability Units, where we work with our Office of Inspector General to identify any potential fraudulent cases so that we can prevent anything from happening before it happens. We focus on aggressively going after any dollars that are overpaid.

I will say we also focus on under payments. We have individuals who should have been paid more, but because of the complexity of the program, we have not been able to do that. But that is a high priority.

Mr. KINGSTON. How much of the \$3,300,000,000 in 1 year overpayment for SSI has been recovered?

Ms. COLVIN. I can provide you that for the record, but you will see that our numbers have increased each year.

[The information follows:]

Below is our SSI overpayment collections for the last five fiscal years:

- FY 2008—\$1,059,600,000
- FY 2009—\$1,102,600,000
- FY 2010—\$1,168,900,000
- FY 2011—\$1,171,400,000
- FY 2012—\$1,202,200,000.

Mr. KINGSTON. Thank you. My time has expired.

Ms. DELAURO. It is not the question I was going to ask, but I cannot stay out of this discussion because I just find it very interesting.

Mr. KINGSTON. I had a feeling.

Ms. DELAURO. Oh, yes. I just find it so, so interesting that my majority counterpart has—we are always eager to bring up waste, fraud, and abuse. Quite frankly, we are not interested when it comes to other areas of the budget like crop insurance or any other way, but that is a fact of life.

However, when we come to funding the efforts that would allow for this redetermination or for the continuing disability reviews, the subcommittee has a very dismal record.

Example. 2012, Budget Control Act explicitly provided an exemption in the caps for program integrity at SSA at \$623,000,000. The enacted level was \$140,000,000 less than was permitted.

The 2013 House bill that barely made it to the subcommittee, provided no additional BCA-permitted funding. Zero. Zero for program integrity. \$751,000,000 less than was permitted.

According to the chief actuary at the SSA, the lack of funding in the House subcommittee bill would have cost approximately \$5,000,000,000 to \$6,000,000,000 over the long run. Each dollar spent, as the Commissioner has pointed out, for the program integrity saves between \$6 and \$9 on average.

I would encourage my colleagues to provide the funding for program integrity so that in fact we can see what those redeterminations cough up or the reviews cough up so that we can save money and cut out whether it is an overpayment, whether it is an underpayment, or whatever it is. You cannot have it both ways. You cannot make a determination that you do not want to provide the money and then say, my God, you are losing money. And that has been the case over and over and over again. And if this subcommittee wants to do its job, it would provide this agency with that money for program integrity—it is what it is all about—instead of complaining about program waste.

I just will mention this. I will bring it up in another context. And that is I hope my colleagues on the other side of the aisle will help us to uncover the 26 people who get at least \$1,000,000 in a premium subsidy from crop insurance, and in fact, they have no asset test, no threshold levels in income or anything else. We cannot even find out who they are. Nobody will make it public. So I am going to enlist my colleagues when we are talking about this issue and trying to find those folks who are getting this money which we cannot account for.

You do not have to comment on that. I have got about a minute or so left here.

Mr. KINGSTON. Let the record show your microphone is working fine now. [Laughter.]

Ms. DELAURO. Yes, indeedy. Yes, indeedy.

I just want to ask you this question, and then I am going to have to dash to the Ag Committee, but I will come back.

In terms of what you talked about, a skilled labor force at Social Security over the long term, how long does it take to train an employee? What are the limitations of the technology in terms of the complex nature of some of the cases that we are talking about here?

Ms. COLVIN. We have determined that it takes well over a year for a new claims examiner to be qualified to adjudicate a case. And

we provide very intensive training. In addition, they are assigned to a mentor. These are very, very complex cases. The cases that are less complex have been automated. SSI is certainly our most difficult program to administer, and we do have a long-range plan to try to automate that also, but that is very complex. But you are talking about looking at all of the information that has been provided and then other medical information in adjudicating a case.

As you know, the disability process starts at the State level with the disability examiners, and we are very concerned because we have not hired anyone in those positions over the last 2 years. And so as we are losing the more seasoned examiners. We know that even if we hire today, it is going to take us about a year to have a proficient staff person there.

Mr. KINGSTON. Mr. Joyce.

Mr. JOYCE. Thank you, Chairman Kingston.

Commissioner, I would like to follow up on something the chairman brought up with you, and maybe I missed it in your answer. But what is the threshold amount at which you start to look for overpayments?

Ms. COLVIN. What is the threshold amount?

Mr. JOYCE. Yes. You said there was a threshold, but I did not hear a number.

Ms. COLVIN. No, I do not recall saying there is a threshold. We go after any overpayment. We do not have a minimum number that we would look for. What we do is review a case to see if the information that we received is accurate, and then if it is not, it means that we have overpaid that individual. It could be a month's overpayment, 2 months overpayment. We would pursue that.

Now, I do not know if you are referencing the fact that there could be a waiver under extenuating circumstances, but we generally pursue all overpayments.

Mr. JOYCE. Well, I am sorry. I just heard you say the word "threshold," but I did not hear the amount.

Ms. COLVIN. Are you talking about overpayments specifically?

Mr. JOYCE. Yes. That is what you are looking for is people that you have overpaid.

Ms. COLVIN. Yes. Well, we would pursue all of those.

Mr. JOYCE. And I also wanted to follow up. In an NPR testimony, former Commissioner Astrue mentioned that the program needs to adapt to the times. Do you agree?

Ms. COLVIN. I am not certain what his reference was when he said "adapt to the times." Do you know what he was referencing?

Mr. JOYCE. Well, that the program is maybe running a 1980's program when we are in 2013. That is the way I took the comment. I was wondering if you had any ideas about that.

Ms. COLVIN. Well, if he was speaking of the disability program, we are always looking at medical advancements. We are looking at policy changes that need to occur. We are in the midst right now of updating our medical listings. In some instances, those medical listings had not been updated for many, many years. We now have updated, I believe, 10 of the 14, and we are on a cycle where we will update those every 3 years so that as medical advances occur, the listings would reflect those medical advances. I think you certainly have to constantly be attentive to the changes both in tech-

nology and in the medical community. And I know that is happening on an ongoing basis.

I would suggest that the program is not the same as when it was originally implemented. Even Congress has made many changes over the years to try to keep up with the changes that they believed were necessary.

Mr. JOYCE. So you agree that something needs to be done then to continue working forward and make it this—

Ms. COLVIN. We have research that is going on internally and externally. So we are always looking for ways to improve the program to make it more appropriate and relevant to today's needs. I would say that is something that is ongoing. Yes.

Mr. JOYCE. And efficient?

Ms. COLVIN. I think it is efficient. I think that clearly there are always pros and cons. Sometimes Congress agrees and sometimes it does not. But you know, you all make the laws and we try to implement them at Social Security.

Mr. JOYCE. Thank you.

I yield back my time.

Mr. KINGSTON. Thank you, Mr. Joyce.

Ms. Lee.

Ms. LEE. Thank you.

I wanted to go back to this whole issue of online activity. The digital divide is still very real in many parts of the country in many of our communities, and while we have to move toward technology—I understand that and you all are doing a really great job—I wanted to find out if you have certain online requirements. For instance, oftentimes employers will not accept a resume unless that resume is submitted online. Well, a lot of people in my district cannot submit resumes because they do not have a computer. They go to the library. There is a long wait. Then they have to leave and do other things. Do you have any requirements for online-specific response?

And then the other issue is how are you addressing—given your cutbacks and given the stresses that your employees are dealing with now, how are you calibrating that so that people who do not have access to computers are still able to receive the services that they deserve?

Ms. COLVIN. Thank you, Ms. Lee.

We recognize that we are going to always have customers who will not choose to work with us online. We are almost at 50 percent of our claimants using online services. So that is about 50 percent who are not. And so we expect that some people will always want to call in by phone or walk into the office to have face-to-face services. We do not expect that we will ever have a system where we will not have that.

What online services allow us to do is two things. One, it allows us to meet customer expectations because some customers really want to be served in the privacy of their home, and they do not want to come to the office. Two, because we get certain efficiencies with online services, it allows us to be more efficient, to be able to process cases faster, and to keep up with the increasing workloads. So there is always going to be a balance.

But we do not require anyone to use online services. We make them aware of it. We encourage them to use it. And certainly as the populations get younger and younger, they will, in fact, want to use online services.

Ms. LEE. Okay. Thank you very much. So there is no requirement for any service to be accessed online.

Ms. COLVIN. You are thinking of direct deposit, which is a Treasury requirement. We do not require that you do online services.

Ms. LEE. Are you still mailing checks?

Ms. COLVIN. The Treasury Department requires that you have the direct deposit. There are a number of individuals who still have not signed up for direct deposit. Treasury has assured us that they will still get their paper check, but they are out of compliance. So they will still encourage them to move to direct deposit. They do have a waiver for individuals who do not want to do direct deposit, particularly those who are older, 90 and older.

Ms. LEE. I know a lot of people who do not want direct deposit.

Ms. COLVIN. Right. But Treasury at this point has said that they will still get their paper checks. I do not know how long.

Ms. LEE. They will get their—

Ms. COLVIN. Yes. Treasury has said that they will.

Ms. LEE. Once Treasury says that is it, direct deposit, then we have to go to Treasury—

Ms. COLVIN. Yes.

Ms. LEE. Because that is a big issue. That is a big issue.

Ms. COLVIN. It is. And we are working with Treasury. We are letting them know the issues that develop from our perspective. But it is a statute, and it is a Treasury requirement.

Ms. LEE. Thank you.

Mr. KINGSTON. Mr. Womack.

Mr. WOMACK. Thank you, Mr. Chairman. Sorry I am late. I had a previous hearing that I was attending.

If I go back over some material that has already been covered, I certainly apologize up front.

I am going to confine my line of questions toward automation because this is an agency that I think has benefitted from and can continue to benefit from our capacity to utilize the automated technology that is out there and maybe that we have yet to see. So I am kind of asking at a 30,000-foot level. Are we continuing to do the things necessary to ensure that we are maximizing our technological capability without sacrificing privacy and matters of privacy that can be compromised? And then I will follow up on that.

Ms. COLVIN. Thank you, Mr. Womack.

We believe that technology is the one thing that has allowed us to consistently see a 4 percent production increase each year for the last 5 years. Certainly with the loss of staff that we have had and the increasing workloads, we would not have been able to keep up without automation.

About 50 percent of our applications now for disability and retirement are filed online, and that number continues to go up. It is probably about 48 percent, but it continues to go up. And we are constantly bringing on new applications. People can file for retirement and disability online. With My Social Security now they can get their earnings statement online. They can do a change of ad-

dress, direct deposit, and other things of that nature. And we are constantly developing additional applications.

A great part of our workload is individuals coming into the offices for benefit verification because they need that to get local and State benefits, and we work with those local and State entities. We now have the ability to provide the benefit verification online. We have just started that. So now we need to make sure that the providers and local governments will, in fact, go online rather than send their individuals into the office.

We have an IT plan relative to how we would roll out increased online services, but right now, we are operating within the agency, at what we call, it's "lights on," minimum that is necessary to keep us running. We do not have an allocation in this existing budget to do new applications. I think the number that—we have about \$850,000,000 in the IT budget now. We would need money above and beyond that amount to do additional applications.

My desire is to try to at least keep the things that we have in place going. For instance, we are bringing up a major system, Disability Case Processing System, where instead of having 54 separate State Disability Determination Services (DDS) systems, we will have one system that is Federal. That will speed things up. It will make it consistent. That is going to cost money.

Now, we have budgeted that each year. We would certainly expect that would be there each year because we developed a long-term plan. And that is what we do when we are looking at systems that we can bring up.

But again, unless we have sustained and predictable funding, it is very difficult to plan because, you know, IT is not something you can do overnight. And so you have got to have some sense of what your budget is going to be from year to year. So it is difficult, but we certainly are trying to do the very thing that you have asked are we doing.

Mr. WOMACK. This year my wife received a—and I am not real sure how she got this, whether it was the paper statement that came in the mail, the calculation that shows your Social Security. I cannot remember what you call that. We used to get those. But this year, all of a sudden, another name showed up—I guess it was called an alias that she might have gone by—showed up with a different income stream, and it was a very complicated thing. But it just appeared out of nowhere. And I am not asking for any help in deconflicting that because we have already taken steps to do that. There is a basis for my question.

Now, there were some coincidental things about it. The name was the same. General location, geographic location of the State was the same, where they were from, and both of their parents—two different people—by the same name had a father that had an initial H and D. And so all of a sudden, boom, it gets plugged in as part of her earnings record. It benefitted the other person greatly, not so good for my wife.

That said, how does that happen? And do we have enough defense in depth of our automated systems so that we are able to discern something that is about to go plugged in on somebody's earnings record that should not be there? And is there a way that those things can be flagged? Because her earnings record was pretty con-

sistent for years and years and years and years and years, and then all of a sudden, something appears out of the blue. It threw us for a loop.

And I know there are a lot of people out there that probably are caught up particularly with stolen identities and what have you. There are a lot of people caught up in this kind of a scenario, and it bothers me that they may not know what to do.

Ms. COLVIN. This scenario we are very concerned about. We know that people are always trying to hack into the systems. We certainly take security measures. We right now are reviewing our authentication process. As you know, My Social Security has not been up that long. We have had tremendous response, but we are looking at the authentication process to see if we need to make it more vigorous and more robust. So we are always looking at that.

We work with our Office of Inspector General if they identify any cases that are the kinds of cases that you are talking about to do an analysis to determine what happened, how it happened, and how to prevent it from happening again.

We realize that we have an awful lot of data Personally Identifiable Information (PII) and we do everything that we can to protect that data. To say we have never had a breach, I do not think I could say that. But I will tell you that protecting PII has the highest priority in the agency. We have reviews that are done by an outside auditor each year. We have inside reviews that are done by our own staff, and then we have the OIG reviews. But this is an area we focus on.

Mr. WOMACK. Thank you very much.

I yield back.

Mr. KINGSTON. The gentleman's time has expired.

I wanted to, number one, make sure that on this fraud thing, that we are taking it very, very seriously—a fraud or overpayment. You know, I am outraged about 26 people who I am not even sure what Ms. DeLauro meant on the crop insurance. But frankly, we should pursue them. The school lunch program has a 16 percent error rate. The school breakfast program has a 26 percent error rate. Lord knows the Pentagon procurement system is broken and needs lots of attention. I think the military can play the game as well as anybody when it comes to moving funds around and making things very confusing.

But we as Democrats and Republicans and Independents are charged with the job that I do not think we are taking as seriously as we should be. There is a lot more common ground than we want to give ourselves credit for. If we cannot agree on overpayments and error rates and fraud, then this country has no hope, and if this country has no hope, the world has no hope. I just feel very strongly about it. When I go home and I talk about this, this is just unbelievable that we cannot sincerely have a shared outrage about this.

You know, as a Republican conservative, certainly I understand these 14 union employees. None of them would probably vote Republican. We understand that this is a political deal. And it is a statute. You cannot do anything about it and I cannot get anything about it but get frustrated. \$14,000,000 for union activities on the

taxpayer dime. But you know, maybe we cannot change that immediately for partisan reasons.

But why can we not really go after the overpayment with a great zeal and just a great fervor? I mean, why can we just not say—you know the old expression, partisanship ends at the water's edge. The President is about to go to Israel. He met with us yesterday. I am glad he is going. But why can partisanship not end when it comes to over payment and fraud and abuse and inefficiencies? And to me, it seems like there should be a culture.

I will ask you this, and I know I am lecturing. I do not mean to lecture, but I am getting it off my chest, which I hope we all feel some common ground with.

SSI claims, according to your testimony, have gone up 38 percent since 2007. Do you really believe in your heart of hearts that that many people have become disabled? Or is it, as folks tell me on the street, their unemployment ran out and that gives them an opportunity for a more permanent income stream. And I am not saying they are not desperate. But do we really believe—and I will ask you. Do you share any of my outrage on that 38 percent increase since 2007 in SSI? Is that merely coincidence?

Ms. COLVIN. Well, Mr. Kingston, the SSA actuaries indicate that the increase is due to the changing demographics, that it is due to the aging of the baby boomers. It is due to the people reaching their disability-prone years, and that some of it is due to unemployment, but that that is due to the fact that individuals who normally would qualify for disability under our listings try to stay in the workforce and they do as long as they can, and they reach a point where they just are no longer able to because of their disability.

So I am not seeing anything to suggest that—I mean, we certainly try to apply the disability law according to the standards. We have quality reviews. The accuracy rate in the DDSs still remains high.

Mr. KINGSTON. I mean, you are not on trial here.

Ms. COLVIN. No, but I am telling you what I understand.

Mr. KINGSTON. I mean, you are not on trial and this is not your fault.

Ms. COLVIN. I understand.

Mr. KINGSTON. But do you really believe this is because of changing demographics? I mean, I know you can get an actuary, just like a lawyer, to give you a lot of answers, and I am not saying you did that at all.

Ms. COLVIN. Well, if you ask me do I believe as an individual, I would say yes. I worked with the disability population at the local and State level. When I was in Maryland, I was responsible for that population, when I was in Montgomery County, at the local level. If you look at the disabilities under which they come, it is no different than the Social Security Disability Insurance (SSDI) population except that they come based on income as opposed to the fact that they paid into the system. I did not see a difference.

Mr. KINGSTON. Well, then you probably have the breakdown of that 38 percent, how many, say, are over 50 years old, how many are under.

Ms. COLVIN. We would have that.

Mr. KINGSTON. And what is that?

Ms. COLVIN. Oh, I do not know it in my head. I will be happy to give it to you for the record.

[The information follows:]

[Please note that the 38.5 percent in my testimony referred to the percentage of SSDI claimants who filed online, which was almost 8 times greater than FY 2007. For a thorough discussion of the demographics affecting the Social Security Disability program, please see Stephen Goss's recent testimony before the House Committee on Ways and Means, Subcommittee on Social Security at http://www.socialsecurity.gov/OACT/testimony/HouseWM_20130314.pdf.

The requested information follows:]

Number of Beneficiaries (in Thousands) Under and Over Age 50 in Selected Years

Year	SSDI		SSI	
	< Age 50	Ages 50+	< Age 50	Ages 50+
1980	785	2,072	852	1,109
2010	2,513	5,691	2,602	2,718
2012	2,548	6,316	2,669	2,975

Percent of Beneficiaries Under and Over Age 50 in Selected Years

Year	SSDI		SSI	
	< Age 50	Ages 50+	< Age 50	Ages 50+
1980	27%	73%	43%	57%
2010	31%	69%	49%	51%
2012	29%	71%	47%	53%

SS Area Population (in Millions) for Selected Age Groups in Selected Years

Year	SS Area Population		
	< Age 50	Ages 50-64	Ages 65+
1980	174.7	34.2	26.2
2010	215.0	59.1	41.1
2012	215.3	61.5	43.3

Notes:

1. SSDI figures include disabled worker beneficiaries in current payment status, as of December of each year.

2. SSI figures include adult blind and disabled recipients with Federal Benefits in current payment status, as of December of each year.
3. SS area population is estimated as of July 1 each year. The population comprises: (1) residents of the 50 States and the District of Columbia (adjusted for net census undercount); (2) civilian residents of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands; (3) Federal civilian employees and persons in the U.S. Armed Forces abroad and their dependents; (4) non-citizens living abroad who are insured for Social Security benefits; and (5) all other U.S. citizens abroad.

Mr. KINGSTON. But you would know in your head that it is consistent because you are saying that it is a demographic change. So you had to have something more than a gut instinct.

Ms. COLVIN. No. I am saying that as people get older, they become more prone to disabilities. So if you look at the population, you can see that.

Now, for children or younger people who are on the disability rolls, some research would suggest that it is due to the fact that as you get larger numbers and you see more coming on because of mental health issues, et cetera, that can be because it is more readily identified. I would be happy to share with you the research studies that have been done in that area. But I am not seeing anything that—

Mr. KINGSTON. Okay. I would like to see it because it is so interesting to me.

Ms. COLVIN. We would be happy to do that.
[The information follows:]

Below is a link to recent testimony by SSA's chief actuary, Stephen C. Goss. Below that is a list of research papers, conducted by SSA staff, that address Chairman Kingston's question about demographics and the influence of unemployment on benefit seeking. For each paper, we have provided a citation, an abstract, and a link, where available, to the full paper.

"The Financing Challenges Facing the Social Security Disability Insurance Program"

By Stephen C. Goss, Chief Actuary, Social Security Administration. House Committee on Ways and Means, Subcommittee on Social Security. March 14, 2013.

http://www.ssa.gov/oact/testimony/HouseWM_20130314.pdf

"Factors Affecting Initial Disability Allowance Rates for the Disability Insurance and Supplemental Security Income Programs: The Role of the Demographic and Diagnostic Composition of Applicants and Local Labor Market Conditions"

By Kalman Rupp. *Social Security Bulletin*, Vol. 72 No. 4, 2012.

Various factors outside the control of decision makers may affect the rate at which disability applications are allowed or denied during the initial step of eligibility determination in the Social Security Disability Insurance (DI) and Supplemental Security Income (SSI) programs. In this article, using individual-level data on applications, I estimate the role of three important factors—the demographic characteristics of applicants, the diagnostic mix of applicants, and the local unemployment rate—in affecting the probability of an initial allowance and state allowance rates. I use a random sample of initial determinations from 1993 through 2008 and a fixed-effects multiple regression framework. The empirical results show that the demographic and diagnostic characteristics of applicants and the local unemployment rate substantially affect the initial allowance rate. An increase in the local unemployment rate tends to be associated with a decrease in the initial allowance rate. This negative relationship holds for adult DI and SSI applicants and for SSI childhood applicants.

<http://www.ssa.gov/policy/docs/ssb/v72n4/v72n4p11.html>

Disability Benefit Coverage and Program Interactions in the Working-Age Population

By Kalman Rupp, Paul S. Davies, and Alexander Strand. Social Security Bulletin, Vol. 68 No. 1 2008.

It is widely known that about three-fourths of the working-age population is insured for Disability Insurance (DI), but the substantial role played by the Supplemental Security Income (SSI) program in providing disability benefit coverage is not well understood. Using data from the 1996 panel of the Survey of Income and Program Participation (SIPP) we find that over one-third (36 percent) of the working-age population is covered by SSI in the event of a severe disability. Three important implications follow: (1) SSI increases the overall coverage of the working-age population; (2) SSI enhances the bundle of cash benefits available to disabled individuals; and (3) interactions with other public programs—most notably the SSI path to Medicaid coverage—also enhance the safety net. Ignoring these implications could lead to inaccurate inferences in analytic studies.

<http://www.ssa.gov/policy/docs/ssb/v68n1/68n1p1.html>

How Policy Variables Influence the Timing of Applications for Social Security Disability Insurance

By Richard V. Burkhauser, J. S. Butler, and Robert R. Weathers II. Social Security Bulletin, Vol. 64 No. 1, April 2002.

The onset of a work-limiting health condition may lead workers to reevaluate their lifetime work path. This article analyzes the impact of policy variables—employer accommodations, state Social Security Disability Insurance (DI) acceptance rates, and DI benefits—on the timing of DI applications for such workers.

<http://www.ssa.gov/policy/docs/ssb/v64n1/v64n1p52.pdf>

Mr. KINGSTON. You know, I always say to people back home you can say what you want about Members of Congress, but we do get lots of information and lots of opinions. And certainly, you know, when I am back home, this is one of the opinions that I have gotten consistently that people have moved towards as a pot of money or a stream of money and, again, just because of the unemployment situation. So it is interesting to me that your conclusion is completely different, and your conclusion is presumably backed up by facts. So I would like to see the demographic breakdown that this is just the aging of America rather than this is the gaming of America, you might say. I think it would be very interesting to know. Well, I get a different opinion on the street I got to tell you.

Let me ask you this, though. If I am right, are we in the same boat that you would share my outrage if I am right? And if I am wrong, I will say, golly, I am wrong and I would tell you.

Ms. COLVIN. As I mentioned before, we take fraud very seriously within the agency. In fact, our employees that I commend for the work that they do are usually our first line of defense. When someone comes in and based on the information that they are provided or information that they have obtained, that they are attempting to get a benefit that they are not entitled to, we are very aggressive in referring that case to the Inspector General.

I will say also that SSA has always been very focused on fraud detection and prevention. When I was here in 1998 as the Deputy Commissioner for Operations, I instituted the existing CDI units, which is a partnership between SSA and OIG because we wanted to be very aggressive in going after any individual who might be trying to commit fraud. And that was 12 years ago, and now it has even been intensified.

So this is an agency that believes if a person is entitled to a benefit, they should get it, but if they are not entitled to a benefit, that we should do everything under the law to see that they do not get it. And if they got one fraudulently, we should aggressively go after them for fraud. So we do that.

Mr. KINGSTON. So as founder of this—what did you call it? I know my time is way over, Mr. Joyce. I appreciate your patience.

Ms. COLVIN. Cooperative Disability Unit, CDI.

Mr. KINGSTON. I am reaching out.

Ms. COLVIN. I understand.

Mr. KINGSTON. We are on the same page then. We would be on the same page on the outrage of somebody who is—

Ms. COLVIN. Yes, absolutely.

Mr. KINGSTON. If there is any hope between some of the division in this town, I think we should be able to come together over somebody who is taking advantage of a benefit that should be going to somebody else who, as you pointed out, might be getting underpaid.

Ms. COLVIN. Absolutely.

Mr. KINGSTON. Or one of your employees who has been in the system for 20–25 years and just is frustrated to death right now.

Mr. JOYCE.

Mr. JOYCE. Thank you, Chairman.

I would like to follow up on your questions. One of the things that you were talking about with this designation of the dis-

ability—if someone is under 50, does that continue on for the rest of their lifetime—that payment?

Ms. COLVIN. That is a good question. No, sir. That is why the CDR is so important. Based on the disability, we diary a case and we determine when that case should be reviewed again, and that is what triggers our continuing disability review. So we would then review that case at an appropriate time to determine if there has been any medical improvement that would now disqualify that individual. Or if it is an SSI case, and they are on the rolls, we would look at the medical piece, but we also look at the asset piece to see if they are still financially eligible based on income. So we do that on a regular basis. And that is why the continuing disability reviews and the redeterminations are so important.

Mr. JOYCE. How long into the future do you look then? A year, 2 years out after they—

Ms. COLVIN. It depends upon the type of disability if medical improvement is expected. We do CDR's every 3, 5, or 7 years depending upon the type of disability.

Mr. JOYCE. And what, if any, investigation is taken to see if they have mislead your agency to the disability?

Ms. COLVIN. Well, that would be where you would be verifying the medical information, or you would be verifying the asset information. So we would verify that.

Mr. JOYCE. With the ones with the disability that might be coming because they have run out of unemployment, can you tell whether or not their unemployment ran out and now they are applying for the disability?

Ms. COLVIN. I do not know the answer to that question.

Mr. JOYCE. So there is nothing that would indicate or trigger for you that perhaps this person was gaming the system?

Ms. COLVIN. You mean because they previously received unemployment?

Mr. JOYCE. Right and that expired. Now, all of a sudden, they come over—

Ms. COLVIN. We are not looking at whether or not they previously got unemployment. We are looking at whether or not they meet the standard, the definition of disability. So there is a very extensive review process to make that adjudication determination.

Mr. KINGSTON. Will the gentleman yield?

Mr. JOYCE. Yes.

Mr. KINGSTON. A question on that. When 43 percent of them do it online, how do you know—do you get a doctor verification?

Ms. COLVIN. Oh, that is just the initial application. They still have to be physically seen.

[CLERK'S NOTE.—Later corrected to "They have to get an extra medical review by a physician or a consultant."]

Mr. KINGSTON. Okay.

Ms. COLVIN. Yes. We were saying that it happens to save time.

Mr. KINGSTON. Yes, but it is just the initial.

Ms. COLVIN. Yes.

Mr. KINGSTON. Okay. I yield back.

Ms. COLVIN. They still have to be seen. Yes.

[CLERK'S NOTE.—Later corrected to delete "They still have to be seen, yes."]

They cannot get a determination just by something that is written. They have got to have an entire medical review by a physician or a consultant.

Mr. JOYCE. So that would be an independent review by your agency after they bring in their documentation from their primary care physician.

Ms. COLVIN. Yes. All of that information is given to the disability examiner at the DDS level who then has to review that. In some instances, they may require an additional medical consultant. They may require the individuals to see a physician of our choice, but you have all of that. There is a whole series of steps that one must go through in order to receive a medical determination.

Mr. JOYCE. If you know, what percentage of those are denied and what percentage of those who apply are accepted?

Ms. COLVIN. I can get that information for you. I do not know the percentage of denials and acceptance.

I understand that at the initial allowance rate, it is 30 percent that are allowed.

Mr. JOYCE. And 70 percent denied.

Ms. COLVIN. Yes.

Mr. JOYCE. Thank you.

I yield back.

Mr. KINGSTON. Thank you.

While you were gone, Ms. DeLauro, I pledged to locate those 26 farmers. [Laughter.]

Mr. KINGSTON. Even if they are all from the great State of Georgia or Connecticut.

Ms. DELAURO. And I hope—and I know you hope as well—that they are all farmers.

Mr. KINGSTON. They are probably not. They are probably doctors. [Laughter.]

Ms. DELAURO. I am sorry I was not here for the beginning of the discussion, but I would like to have you walk us through the disability claims process, if you would not mind, to give us a better idea of how intense, or labor-intensive it may be.

Ms. COLVIN. I do not think I can do that sitting here. That is a very technical process. As I mentioned earlier, it takes well over a year for a disability examiner to become proficient. Can I give you that for the record?

Ms. DELAURO. Yes. I would appreciate that. I think it would be useful for us to have a better basic understanding of what you are faced with.

[The information follows:]

Most Social Security disability claims are initially processed through a network of local Social Security Administration (SSA) field offices and State agencies (usually called Disability Determination Services or DDSs).

Individuals may file applications for disability benefits in person, by telephone, by mail, or online. The application and related forms ask for a description of the claimant's impairment(s), treatment sources, and other information that relates to the alleged disability. (The "claimant" is the person who is requesting disability benefits.)

The field office is responsible for verifying non-medical eligibility requirements, which may include age, employment, marital status, or Social Security coverage information. The field office then sends the case to a DDS for evaluation of disability.

Fully funded by the Federal Government, the DDSs are responsible for developing medical evidence and making the initial determination on whether or not a claimant is disabled or blind under the law. They consult with medical/psychological consultants (MCs/PCs) and other staff to resolve problems in obtaining evidence from various medical sources.

The DDS first identifies sources of evidence from the claim folder information. The DDS then requests medical evidence of record (MER) from the claimant's medical sources and follows up on letter requests, telephone requests, and other forms of communication to obtain needed medical evidence.

If the evidence is unavailable or insufficient to make a determination, the DDS will arrange for a consultative examination (CE) to obtain the additional information needed. The claimant's treating source is the preferred source for the CE; however, the DDS may obtain the CE from an independent source. We evaluate adult claimants under a standardized five-step evaluation process (sequential evaluation). At step one; we determine whether the claimant is engaging in substantial gainful activity (SGA). SGA is significant work normally done for pay or profit. If the claimant is engaging in SGA, we deny the claim without considering medical factors.

If the claimant is not engaging in SGA, at step two we assess the existence, severity, and duration of the claimant's medically determinable impairment (or combination of impairments). We consider the combined effect of all the claimant's impairments, regardless of whether any one impairment is severe. Through sequential evaluation, we consider all of the claimant's physical and mental impairments singly and in combination.

If we determine that the claimant does not have a medically determinable impairment, or the impairment or combined impairments are “not severe,” we deny the claim at the second step. If the impairment is “severe,” we proceed to the third step.

At the third step, we determine whether the impairment “meets” or “equals” the criteria of one of the medical Listings of Impairments (Listings) in our regulations. The Listings describe for each major body system the impairments considered so debilitating that they would reasonably prevent an adult from doing any gainful activity. The listed impairments are permanent, expected to result in death, or last for a specific period of at least 12 months. If the claimant has an impairment that meets or equals the criteria in the Listings, we allow the disability claim.

As part of our process at step three, we have developed an important initiative – our Compassionate Allowances (CAL) initiative – that allows us to identify claimants who are highly likely to be disabled because the nature of their disease or condition clearly meets the statutory standard for disability. With the help of sophisticated new information technology that flags these cases, we can quickly identify potential CALs and then swiftly make decisions. We currently recognize 200 CAL conditions and continue to review our CAL policy to ensure it is based on the most up-to-date medical science.

A claimant whose impairment does not meet or equal a listing may still be disabled.

At step four, we consider how a claimant’s condition affects his or her ability to perform previous work, and at step five, we consider the claimant’s age, education, and work experience, to determine whether he or she can perform other work that exists in significant numbers in the national economy. Before we go to these steps, however, we assess what the claimant can still do despite his or her physical or mental limitations – that is, we assess his or her physical and mental residual functional capacity (RFC). We use that RFC assessment in the last two steps of sequential evaluation. We assess the claimant’s RFC based on all of the evidence in the record, such as treatment history, objective medical evidence, and activities of daily living.

We must also consider the credibility of a claimant’s subjective complaints, such as pain. Such decisions are inherently extremely difficult. Under our regulations, we use a two-step process to evaluate credibility. First, we must determine whether medical signs and laboratory findings show that the claimant has a medically determinable impairment that could reasonably be expected to produce the pain or other symptoms alleged. If the claimant has such an impairment, we must then consider all of the medical and non-medical evidence to determine the credibility of the claimant’s statements about the intensity, persistence, and limiting effects of symptoms. We cannot disregard the claimant’s statements about his or her symptoms solely because

the available objective medical evidence does not substantiate the claimant's statements.

After we complete the development of evidence and the RFC assessment, we determine whether the claimant can perform his or her past relevant work. If the claimant can perform his or her past work, we deny the disability claim.

If the claimant cannot perform past relevant work (or if the claimant did not have any past relevant work), we move to the fifth step of sequential evaluation. At step five, we determine whether the claimant, given his or her RFC, age, education, and work experience, can do other work that exists in the national economy. If the claimant cannot perform other work, we will find that the claimant is disabled.

We use detailed vocational rules to minimize subjectivity and promote national consistency in determining whether a claimant can perform other work that exists in the national economy. The medical-vocational rules, set out in a series of "grids," relate age, education, and past work experience to the claimant's RFC to perform work-related physical and mental activities. Depending on those factors, the rules may direct us to allow or deny a disability claim. For cases that do not fall squarely within a vocational rule, we use the rules as a framework for decision-making. In addition, an adjudicator may rely on a vocational specialist to identify other work that a claimant could perform.

After making the disability determination, the DDS returns the case to the field office for appropriate action. If the DDS found that the claimant is disabled, SSA completes any outstanding non-disability development, computes the benefit amount, notifies the claimant, and begins paying benefits. If the DDS found that the claimant is not disabled, the field office notifies the claimant and provides information about appeal rights. DDS staff or Administrative Law Judge in SSA's Office of Disability Adjudication and Review decide on subsequent appeals of unfavorable determinations.

Ms. DELAURO. I will go back to where I left off. What can be done with technology and what cannot be done with technology?

Ms. COLVIN. In the disability process?

Mr. KINGSTON. I promise the majority had nothing to do with your microphones.

Ms. DELAURO. I will give you the benefit of the doubt, Jack.

Because sometimes we over-think the technology side and there is a lack of understanding of the person-to-person interview, the kind of effort required because this is not cookie cutter. This is based on individuals.

Tell us a little bit about the 1-800 number, what is happening with that, what is the backlog, response time. And obviously, given the nature of our current budget situation and the sequestration, what will happen with that? That has got to be one of the most frustrating things, when you put in a call and it goes nowhere. It is like a hole. So tell me a little bit about what is happening there.

Ms. COLVIN. As I mentioned earlier, we have seen a deterioration in all of our metrics. The numbers are going in the wrong direction. But just now we are looking at 15 percent or 3,300,000 of our calls where when people dial, they get a busy signal. That is 15 percent, or 3,300,000 of the calls that we get a year. Those individuals get a busy signal.

Ms. DELAURO. 3,300,000 calls?

Ms. COLVIN. Yes. 15 percent of our calls.

And then once they get through, we have what we call average speed of answer, how quickly we answer once you get through. We are now at 7.5 minutes, which means it is doubled since fiscal year 2010. So not only do you have trouble getting in, once you get in, you still wait another 7.5 minutes before you get a live operator. So our metrics are going in the wrong direction, and that is because, again, we have not hired since 2010. More people are calling because of the waiting. They would prefer not to stand in line for 2 hours. So they go home and they try to call, and they cannot get through.

Ms. DELAURO. I cannot see the clock, so I do not know if I have any time left.

Mr. KINGSTON. You are good.

Ms. DELAURO. You may have answered this, and if that is the case, I apologize.

The reasons disability claims are going up?

Ms. COLVIN. Well, I answered that question. I think Mr. Chairman and I sort of had different views, but I indicated that our actuary has indicated that those increases are due to demographic changes, the result of the baby boomers aging out, the individuals reaching the disability-prone years, and some of it to unemployment, individuals who meet our listings, tried to work but have not been able to sustain work and now with the job market have just decided that they are eligible, they think, and they apply. Now, in some instances when people are unemployed, they apply. So our application rates go up, but they are denied. So we still believe that we have a high accuracy rate relative to approving people who are, in fact, disabled.

Ms. DELAURO. And then just finally, I would love to see if you have the data on gender breakdown, on what is happening to women.

Ms. COLVIN. I am glad you brought that up because I missed that important variable. The actuary also indicates that because more women have entered the labor force, they are on parity now, and they also contribute to the incident rate of allowances. So that is a variable. Yes. Thank you for mentioning that.

Ms. DELAURO. Thank you, Mr. Chairman.

Mr. KINGSTON. Mr. Alexander.

Mr. ALEXANDER. Thank you, Mr. Chairman.

Ms. COLVIN. Good morning, sir.

Mr. ALEXANDER. Good morning. I believe in your testimony you mentioned closing of some of the field offices, 41. One was in Louisiana in my congressional district. Look, I commend you for taking the often difficult step of reducing cost, savings, but my concern is that there is a lack of a long-term strategic plan. So can you outline how field offices are closed and how you decide on which ones and tell us how they fit into the administration's long-term plan for dealing with—

Ms. COLVIN. Let me answer that in two ways. We are in the process of developing a long-term plan. I know this committee has been concerned that a plan did not exist. There is a plan that is coming in that was developed under the previous Commissioner. We are going to let that move forward. But I am also going to be starting a planning process during the interim period that I am there as Acting Commissioner.

With the closing of offices, I have asked to look at the criteria that we use. A lot of it is based on the viability of an office as we lose staff, whether or not there are other offices that are in close proximity. So there is a whole host of criteria that goes into making a decision about whether or not it is going to close. I think it would be better if I provided you with something for the record that indicates the existing criteria, but I am looking at that again also.

[The information follows:]

I am currently reviewing our process for consolidating field offices. Historically, many factors influenced our decision to consolidate an office. Examples of those factors are:

Proximity and accessibility of other SSA offices: We consider the distance between an office and its surrounding offices. For example, we may have two offices that are within 3 miles of each other and fully accessible via public transportation. In these cases, maintaining two separate offices may not be cost effective or necessary.

Staffing losses: Our staff losses occur disproportionately across the country, making it difficult to sustain acceptable service levels in some locations. By consolidating offices, we gain some economy of scale, which allows us to maintain quality service.

Demographic shifts and demand for service: We evaluate changing demographics and population shifts that affect the number of individuals seeking service from each office. We measure changes in the number of daily walk-in visitors, phone calls, and related workloads. We examine the special needs of the local population, including the age of visitors (average visitor age is currently 46 nationwide).

Use of online and telephone service: We consider the use of our online services and telephone services. We continue to expand our online services, and usage has grown dramatically. Many people prefer to do business without face-to-face contact.

Safety and security considerations: The number of serious violent threats to our staff has increased in the past couple of years. We have taken measures in response to these threats, including millions of dollars spent on barrier walls, magnetometers, and guards. Nonetheless, some locations present significant risks to our staff and the public we serve.

Expiration of lease: SSA generally enters into five-year firm term leases with five option years. Most of these leases have cancellation rights that can be exercised over the course of the lease as needed. However, it makes particularly good business sense to evaluate the current office location whenever a lease is expiring to determine if the current location remains desirable for the future.

Mr. ALEXANDER. Okay. Thank you.

Mr. KINGSTON. I wanted to ask. You are in a position to see up close what works and what does not work. And you might not want to answer this, but just to venture into policy a little bit, do you have some suggestions that could be helpful for us as we discuss Social Security?

For example, yesterday the President met with the Republican Conference and said that he does support changing CPI. And his point to us was that is not necessarily a comfortable position for a Democrat. What he was saying to us is you have to move from comfortable positions too, and if we are going to save these universally popular programs, we have to do something.

He did not say this statistic, but I think this is generally accurate. My dad retired at age 65 in 1980, and all the money he put in Social Security he received back in 3 years. He lived 25 years. So it was a great deal for him. Today if you retire, I believe it takes 17 years to recoup what you put in it. But for our children, they will probably get 70 cents on the dollar. I think those are roughly correct, don't you think?

And so as we sit here, we know we have to change things. I do not know changing CPI does the trick. I do not know that means testing does. I do not know that raising the age. And by the way, what is the age today? Because I know it is moving up?

Ms. COLVIN. It is around 67.

Mr. KINGSTON. It is not quite to 67, though, is it? It is 66?

Ms. COLVIN. It is between 66 and 67.

Mr. KINGSTON. It is going up 3 months a year.

Ms. COLVIN. It is going up depending upon date of birth.

Mr. KINGSTON. And you know, when that decision was made in 1982, I think 40 Members of Congress got an invitation back to the private sector showing how difficult it was even then.

I mean, do you want to say anything about policy? You certainly do not need to.

Ms. COLVIN. Well, I think, you know, Mr. Kingston, that the Treasury Department is really the agency that deals with the solvency debate. Our role at Social Security is to provide data, to provide analysis, to indicate what the impacts will be of various proposals that go forth. We provide technical assistance to the committees here, the congressional committees, and we provide technical assistance to the White House, to the Office of Management and Budget. My role is to implement the law as you have passed it and to run the agency. So fortunately or unfortunately, I do not have to—

Mr. KINGSTON. I am not trying to debate you in a policy discussion. Trust me. I just was wondering.

Ms. DeLauro.

Ms. DELAURO. Just in terms of notifying offices on closure, how much advance warning do they get?

Ms. COLVIN. 60 days.

[CLERK'S NOTE. Later corrected to "90 days"]

Ms. DELAURO. The coordination of workloads between offices. You know, what we have heard—the impacts of erosion of funding due to inflation, that it is creating a problem to work between agencies. Is that accurate?

Ms. COLVIN. Between agencies?

Ms. DELAURO. Field offices and coordinating workloads. I am sorry. Field offices.

Ms. COLVIN. What we do is we have our field offices that are stressed, and they are not able to get to the workload. We have the ability to transfer work among offices because we have virtual offices, and a lot of our work now is electronic. What we are trying to do is ensure that you are not disadvantaged because you live in a particular geographic area of the country and trying to provide the same level of services as we can. So we do constantly look at what is happening and see where we can share work across offices where it is electronic.

Ms. DELAURO. And what will be your continued ability to do that with further cuts?

Ms. COLVIN. I do not know the answer to that. It depends upon my level of funding. As I said, we continue to lose staff. So I really do not know the answer to that.

Ms. DELAURO. I think it is important—and I know Mr. Alexander asked about the facility in his district. I really do believe it is going to be important for Members to know where notices are going out, if that occurs, if we proceed forward here with this, and it appears that sequestration is moving forward. And I know you said you do advise them and so forth.

Ms. COLVIN. We do.

Ms. DELAURO. But I think it does not hurt to let people know that whether it is your contact station or your field offices or even where offices have shortened hours—that always generates complaints to our district offices, the lack of service. So I just think that Members have to continually be aware of what is at stake in these efforts.

I think it is also interesting that your budget is almost entirely staff or support for staff, unlike some of the agencies that come before us. At the Social Security Administration you do not administer grants or loans or do any of that. What is a unique challenge because of the nature of your agency with regard to a flat budget or sequestration?

Ms. COLVIN. Well, you know, we have fixed costs that go up, rental facilities and other costs that are fixed, and they go up each year. So we do not have a lot of flexibility.

Unlike other agencies, none of our work is discretionary. It is all required by statute. And we do not control the number of applicants that come in the door. And so if we do not have a sufficient budget, which means we do not have sufficient staff and we are not able to invest technology, that means we are going to continue to see a deterioration of services. And the American public has to accept the fact that they are not going to get the kind of service that they got in past years.

We do not have other places to cut. All of our budget supports our staff. Training. We are going to see some quality issues because if you do not train people, they are not going to know how to do the job correctly, and once they learn incorrectly, they continue to do it incorrectly. Or if they are trying to serve too many people in a span of time, they are going to make mistakes. And so every time

you have to redo a case because it is not correct, the information is older, and it is more expensive.

Ms. DELAURO. That leads me to my last comment, if you will. If SSA saves money with program integrity work, those funds are simply kept in the trust fund for future years. These are not funds—

Ms. COLVIN. It does not help us with our administrative needs.

Ms. DELAURO. With your administrative needs.

Ms. COLVIN. No, it does not.

Ms. DELAURO. So I would just say once again, as I said earlier, that I think that we should not be penny wise and pound foolish when it comes to program integrity, that we should allow you to deal with those redeterminations and other efforts in order to be able to safeguard overall the program and the beneficiaries.

Ms. COLVIN. I would really just urge the committee to look at giving us adequate, sustained, and predictable funding. I think if you look at how we spend the dollars, you can see them easily accounted for. Our metrics are very clear. The number of benefits we give out, the number of program integrity initiatives that we handle are spelled out so there is no lack of clarity relative to how we use the money and where it goes. But we need sustained funding. We need predictable funding, and of course, we need adequate funding. Our funding for the last 2 years has been \$1,000,000,000 less than the President's request. It is just not going to allow us to do the work. It is not going to allow us to serve the public.

Ms. DELAURO. Thank you.

Thank you, Mr. Chairman.

Mr. KINGSTON. I just have three closing comments.

Number one, I want to join—and I want to speak on behalf of all the members of this committee. We do feel that your field employees, who are a very important part of our field offices as well are doing a great job.

Ms. COLVIN. Thank you.

Mr. KINGSTON. They are responsive to us. And I believe that they have the customer's best interest in mind.

Ms. COLVIN. They do.

Mr. KINGSTON. And they are sympathetic and empathetic.

Number two, I do want to pledge to work with you on this SSI issue.

Ms. COLVIN. Thank you.

Mr. KINGSTON. If I am wrong, I am going to be the first to admit it. If I am right, though, let's join together and find out.

Ms. COLVIN. Absolutely.

Mr. KINGSTON. And then number three and something very important, I wanted to have the pleasure of ending a hearing on Social Security with my good friend, Rosa DeLauro, on the far right of me. [Laughter.]

Ms. DELAURO. Touché.

Mr. KINGSTON. Thank you very much.

[The following questions were submitted for the record.]

**Department of Labor, Health and Human Services and Education
and Related Agencies**

**Social Security Administration Oversight Hearing
March 14, 2013**

**QUESTIONS FOR ACTING COMMISSIONER COLVIN
TO BE SUBMITTED FOR THE PUBLIC HEARING RECORD**

Chairman Kingston

INFORMATION TECHNOLOGY UPGRADES

SSA's current mode of serving the public is not functioning well. The strains on local offices have reached the point where they are seriously hampering SSA's ability to function. It is evident that both the public as well as the SSA workforce would benefit from a number of services being automated. Please address in detail the agency's plans to exploit technological advances to make service automation possible. Include a list of functions and services that you plan to automate as well as an estimate of the costs and period of time required to perform the necessary development, testing and deployment work.

We have made great strides in recent years to become a highly automated, mostly paperless agency; our enterprise systems are available to end-users, with good response times, over 99.9 percent of the time. Our Internet applications for the public and businesses are thoughtfully designed, highly rated (by the independent American Customer Satisfaction Index and our own surveys), and have allowed us to maintain high and improving service levels even with rising workloads. Just to name a few other recent information technology initiatives, we are piloting a new case processing system for State disability determination services ([DDS] i.e., the State agencies that process initial disability claims); building a national visitor intake system for our field offices; adding more advanced systems capabilities in our hearing offices; converting our master-files to DB2 databases; increasing the use of video for appeals and operational workloads; modernizing our earnings record software; building more agile data exchange programs; and building more online services for our "My Social Security" portal.

With workloads at an all-time high, we must continue to capitalize on new technologies to cut costs, operate more efficiently, and provide the services Americans deserve. We must continue to respond to the fiscal realities, which means that we cannot do business as we always have.

In answer to your question, I discuss below our vision for developing a long-term strategic plan. A crucial part of that plan includes plotting a course of information technology (IT) development that will allow us to continue to automate work, increase efficiency, and offer more online services. In our current IT planning process, we define and prioritize the IT initiatives to accomplish the strategic goals and objectives in our Agency Strategic Plan (ASP). Our May 2012 Information Resources Management (IRM) Strategic Plan describes our IT

guiding principles and plans for systematically modernizing our infrastructure using sound and viable technologies. We are currently updating the fiscal year (FY) 2013 IRM Strategic Plan according to the guidance and timelines prescribed by the Federal Chief Information Officer. Our FY 2012 IRM Strategic Plan is available at <http://www.ssa.gov/irm/index.htm>.

We are now developing a number of projects that are critical for improving our efficiency and the quality of our service. For example, we expect to introduce the following self-service online applications soon:

- Internet Medicare Replacement Cards – Individuals will have the ability to request a replacement Medicare card online at their convenience and in a more secure environment. We anticipate releasing this application to the public in October 2013. The estimated cost for development is \$1.5 million.
- Internet Replacement 1099 – Individuals will have the ability to request a replacement Social Security Benefit Statement (SSA-1099) online, at their convenience and in a more secure environment. We anticipate releasing this application in October 2013. The estimated cost for development is \$2.5 million.
- Marriage of the iClaim Disability application with the Disability Report – We are streamlining the online process for applying for disability by providing a single point to access both the benefit application (iClaim) and the Revised Adult Disability Report (i3368). This enhancement should result in a faster disability decision for the claimant and time savings for us, because it will reduce our need to recontact individuals for additional information. Currently, individuals often provide either the iClaim or the i3668, and we must recontact them to get the missing document. We anticipate completing this application process in January 2014. The estimated cost for development is \$4.6 million.
- Mobile wage reporting – We are currently piloting a mobile application which permits Supplemental Security Income (SSI) beneficiaries to report their wages. They will no longer need to call or visit a Social Security office to report wages. We are currently piloting the mobile application in 263 offices across the country and expect to expand it to the rest of the country in late summer 2013. The estimated cost is \$5 million.

Additionally, it is my understanding that a number of information technology upgrades are underway. Please provide a comprehensive list of all the work underway and the upgrades under consideration as well as an estimate of both the amount of time required to complete those projects underway and the time required to complete the projects under consideration.

You can access a list of all of our current IT projects by going to the Federal IT Portfolio website at <http://www.itdashboard.gov/portfolios/agency=016> and clicking the “investments” tab. The site also provides the status of and the estimated time to complete every project.

Finally, please provide the current balance available within the no-year IT account and explain what the agency intends to devote these funds to over the course of the current fiscal year and FY 14.

The total in the no-year IT account available for fiscal year (FY) 2013 is \$161 million. Below is a list of major initiatives included in the IT budget funded by the Limitation on Administrative Expenses account and no-year IT. We are in the process of planning for FY 2014.

- **IT Infrastructure:** The IT Infrastructure initiatives assure the sustained operation of current IT systems and provide an environment to support the growth of our agency's new systems and technical infrastructure. The following are major IT Infrastructure initiatives:
 - Data Center Support
 - Office Automation
 - Telecommunications
 - Telephone Systems Replacement Project
 - National Support Center
- **Core Services:** Core Services develop seamless, integrated, customer-centric automation tools that support all service delivery channels and several of our agency's major business processes. The following are major Core Services initiatives:
 - Citizen Access Routing Enterprise Through 2020 (CARE Through 2020)
 - Medicare Modernization Act Project
 - eServices (formerly Online Claims)
 - Earnings Redesign
 - Title II Redesign
 - SSI Modernization
- **Disability Process:** Disability Process investments support the administration of SSA's disability programs and allow our employees to provide quality service that is responsive to the needs of persons with disabilities. The following are major Disability Process initiatives:
 - Disability Case Processing System (DCPS)
 - Disability Determination Services (DDS) Automation
 - Intelligent Disability
- **Security and Business Recovery:** Security and Business Recovery investments implement security policies and procedures within our IT environment. These investments will ensure that we protect our IT resources from internal and external user threats, such as unauthorized access, misuse, damage, or loss.
- **High Performing Workforce:** High Performing Workforce initiatives improve the productivity, efficiency, and quality of our human resource systems and services. Interactive Video Teletraining is an example of a major High Performing Workforce initiative.

- Program Integrity: Program Integrity investments support our goal of preserving the public's trust in our programs. Our Program Integrity goals are to: minimize improper payments; automate the collection of death information; increase the electronic filing of wage reports and improve earnings record accuracy; strengthen our ability to protect program dollars from fraud, waste, and abuse; ensure that internal control deficiencies affecting our financial statements are corrected; and ensure the safety of SSA's resources during emergencies.
- Enterprise Architecture and Planning: Enterprise Architecture and Planning investments provide support services, hardware, and software needed to design, develop, and document enhancements to our Enterprise Architecture and explore promising technologies.
- Financial Management Systems: Financial Management Systems investments support our compliance with applicable accounting principles, standards, and related requirements; management control standards; and Federally-prescribed policies. Our financial accounting system is the only major investment in the Financial Management Systems area.
- Hearings Process: Hearings Process investments promote and manage IT projects that directly advance efforts to eliminate the hearings backlog and prevent its recurrence.

STRATEGIC PLAN

In light of all the management challenges and budgetary uncertainty SSA is facing, we directed SSA in the FY12 Omnibus to work with the National Academy of Public Administration (NAPA) to produce a long-range strategic plan. The Subcommittee believed it was crucial that this strategic plan include the input of an external body competent in addressing complex management challenges within the public sphere. In spite of claiming that SSA cannot work with NAPA unless they were selected through a fair and open competition, you all have not taken any steps to compete a contract for this work. While there may be value in establishing a shorter term service delivery plan, such a plan cannot take the place of a true long-range strategic plan.

Acting Commissioner Colvin indicated at our recent hearing that she was prepared to review the decision to not move forward on producing a strategic plan in partnership with NAPA. Please explain the steps the Acting Commissioner intends to take to fulfill this commitment over the course of the current fiscal year. We expect to be informed in the response to this question: a) whether the Commissioner intends to produce a true long-range strategic plan and the timeframe for doing so, and, b) whether the Commissioner intends to include NAPA in the effort to produce such a plan. If not, please address whether SSA intends to open up a competition to contract with an outside group for this work.

I am pleased to announce that I recently designated Ruby Burrell as our Chief Strategic Officer and Performance Improvement Officer. Ms. Burrell is an innovative, strategic thinker who has

envisioned and led some of the most transformational initiatives at SSA. She led our effort to move from paper to electronic disability claims processing and developed the vision and strategic plan for our Disability Case Processing System (DCPS), which I mentioned in a response to a previous question. DCPS will replace the five legacy systems used by our State DDS partners.

Ms. Burrell will lead the agency-wide effort to develop a long-range strategic plan with a three-to-five-year time horizon that will integrate IT, service delivery, and human capital plans. Ms. Burrell reports directly to the Office of the Commissioner. Together and with the support of our talented leaders at our agency, we plan to build a culture that encourages and fosters strategic thinking. We expect to complete the long-range plan by February 2015 and to release it with the President's Budget for Fiscal Year 2016. We will engage with employees, advocates, Congress, and other stakeholders in the process.

In addition to embarking on a new long-range planning initiative, we are currently updating our existing Agency Strategic Plan, which spans 2013-2016. As required by the GPRA Modernization Act of 2010, our updated plan will cover the period 2014-2018. I established an Executive Steering Committee to oversee the process, and we have a dedicated group of skilled employees working to gather input from the public and build engagement within our agency and with our external stakeholders. We also look forward to getting input from Members of Congress. We have asked for suggestions for innovative and efficient ways to accomplish our core mission in this environment of constrained budgets and increasing service demands. We expect to update this plan by February 2014 and to release it with the President's Budget for Fiscal Year 2015.

I believe that strategic planning expertise would be valuable in defining a forward-looking plan. We would welcome the participation of an entity like NAPA in the development of our long-range plan. We currently are considering our options for accomplishing this.

Congressman Mike Simpson

1. I am aware that SSA has been employing data analytics and predictive analysis with positive results in the Quick Disability Determination program and the Compassionate Allowance program. Can you please provide me with information on the reductions in processing times overall, the average per case, and the QDD success rate.

The success of our Quick Disability Determination (QDD) and Compassionate Allowance (CAL) processes is reflected in several ways, including faster processing time and highly accurate decisions. In FY 2012, we selected approximately 5.8 percent of our initial disability cases for the QDD and CAL processes. The DDSs processed these cases in an average of 10.8 days, which is significantly faster than the DDS average time of 82.9 days for all initial disability claims.¹ The accuracy of our QDD and CAL cases is in line with the DDS decisional accuracy of 97 percent for all initial disability decisions. Approving clearly eligible claimants early in the

¹ These processing times reflect the DDS work performed at both State and SSA agency offices. We have very rare situations where locations other than a DDS (such as a Program Service Center) act as a DDS and process CAL and QDD cases as well as other disability claims.

process helps persons with severe disabilities and, at the same time, allows us to focus our attention on the more ambiguous cases. While we can provide processing times for our disability cases, we are not able to isolate or quantify the effect that the QDD and CAL processes have on reducing the processing times for other disability cases.

2. Do you plan to incorporate similar tools in the newly developing Disability Case Processing System?

Yes, the DCPS currently receives the QDD indicators and CAL flags, which identify the cases for expedited processing. We will continue to utilize confidence scoring and predictive modeling throughout our case development. In addition, our Electronic Claims Analysis Tool (eCAT) contains “intelligent pathing” and quality checks to assist the user in addressing critical policy issues relevant to the disability claim. We plan to continue enhancing eCAT and will incorporate additional functionality into DCPS.

3. Please provide me information on the status and future plans for greater use of predictive analytics for the: Ticket to Work program, Office of Disability Adjudication and Review, and SSI redetermination reviews

Ticket to Work Program

Predictive analysis helps us find ways to more effectively utilize our Ticket to Work (TTW) program resources and still target beneficiaries who are most likely to return work. By analyzing our data, we determined we could effectively target Ticket mailings to the beneficiaries who are most likely to use them, instead of automatically mailing Tickets to all beneficiaries. Our model showed we could contact fewer than half of new beneficiaries and still reach most of the beneficiaries who would eventually use a Ticket. Beneficiaries not automatically mailed a Ticket would still be eligible to participate in the TTW program.

In January 2012, we initiated a targeted auto-dialing project. Each month, we make about 20,000 automated calls to beneficiaries selected by the predictive model. Since the project started, about 22 to 25 percent of those called every month stay on the line to speak to a representative or call back to obtain more information about the TTW program.

Office of Disability Adjudication and Review

In our Office of Disability Adjudication and Review (ODAR), we use predictive analysis in a variety of ways to improve efficiency and offer improved public service. For example, we are using predictive analysis to identify hearing requests that can be decided by senior attorney adjudicators or informally remanded to the DDS, thereby saving scarce administrative law judge time for more complex cases. We also developed a model that predicts the time required to process cases in each hearing office and identifies transfers we can make between hearing offices to balance our workloads across the nation. The Office of Appellate Operations (OAO) also used predictive analysis to develop productivity standards for employees, and we are using the same model to create similar standards at the hearing level. These standards allow us to predict production more accurately.

Our additional efforts to employ analytic tools to improve ODAR's business processes include:

- Using structured data to create “heat maps” that identify patterns in how we process cases at the hearing and appeals levels. We then use these patterns to improve consistency in adjudication, highlight areas for more training, and identify policies that need revision;
- Developing the “Case Context Tool” to find patterns and anomalies in processing and dispositions among similar claims;
- Developing the “Case Status Change Model” to estimate the time a claim spends in each step of the hearing process in a hearing office. This information will be useful in designing predictive models of case flow through ODAR; and
- Exploring whether we can use “clustering analysis” in OAO to improve efficiency and quality by assigning cases involving similar issues to the same employee.

SSI Redeterminations

We are in the beginning stages of exploring the use of third-party data to enhance the efficiency and effectiveness of the predictive model we use to identify SSI beneficiaries who have likely received too much in SSI benefits. We use this information to schedule and prioritize redeterminations for SSI beneficiaries with the greatest likelihood of overpayment. We will soon publish a Request for Information to learn more about what useful third-party data may be available.

4. I am aware that other agencies are using these tools to identify improper payments and patterns of fraud to alert investigators. Do you have plans to incorporate similar efforts?

Improper Payments

Yes. We plan to explore the use of data analytics offered by the Do Not Pay “Business Center” to prevent and detect improper payments, which would complement our current improper payment efforts. On April 12, 2012, the President issued a memorandum, *Reducing Improper Payments Through the “Do Not Pay List,”* which directed Executive Agencies to take immediate steps to use the centralized solutions in place for pre-payment eligibility review. The Improper Payments Elimination and Reduction Improvement Act of 2012 further directs agencies to use Do Not Pay for pre-payment verification. We are evaluating the following potential uses, contingent upon available resources, of Do Not Pay's data analytics:

- Investigating situations in which unusually high numbers of payments are going to the same address or the same depositor account number;
- Identifying frequent or suspicious patterns of direct deposit account changes; and

- Verifying the suitability of organizational representative payees.

Additionally, we developed a statistical model that predicts the likelihood of beneficiaries being at risk of receiving large overpayments due to work. This model prioritizes Continuing Disability Review Enforcement Operation (CDREO) alerts according to the likelihood of a “critical” overpayment (\$20,000 or more). The model factors historical earnings, prior CDREO alerts, previous benefit increases due to earnings, overpayments, amount of monthly benefits, time on the rolls, and impairment codes. We are seeing early success in testing this model in two pilots.

Fraud

The Office of the Inspector General (OIG), Office of Audit (OA) is using data analytics to identify improper payments in the Social Security and SSI programs. The OA employs a team of IT Specialists who extract data from SSA’s various systems—including the master beneficiary records as well as enumeration, earnings, and death data—in search of errors, problems, and trends. OIG auditors conduct audits using the results of the data analysis to quantify improper payments, identify the root causes of the errors, and make recommendations to our agency to prevent future payment errors.

In addition, the OIG, Office of Investigations (OI) is in the developmental stages of creating an Electronic Intelligence Center within its Forensic Intelligence and Analysis Division. One of the functions of this Center will be to perform predictive analytics. Initially, the Center will develop its predictive analytics algorithms based upon the successful outcomes of the cases contained within its National Investigative Case Management System. These algorithms will then be applied to new, incoming allegations with the goal of focusing the OI’s efforts on those allegations that show the most promise. Ultimately, those predictive analytics algorithms will be developed to the point where they can be applied to SSA’s new, incoming claims for benefits with the goal of alerting potential fraud before it starts.

Congresswoman Barbara Lee

Constrained Budget

In your testimony you spoke about the challenges SSA is facing due budgetary constraints, the challenges you are facing due to sequestration, and the fact that the funds appropriated have been lower than the funds requested by the Commissioner and the President.

Question 1: What more would you have been able to accomplish had you received the funding requested in the President’s FY 2013 Budget?

Our funding level for FY 2013 (post-sequestration) is \$11.046 billion. Our President’s Budget request for FY 2013 was \$11.760 billion. If we had received the FY 2013 President’s Budget we would have been able to mitigate much of the degradation of service described in my testimony and work towards improving service and stewardship. Under the President’s Budget, we estimated that we would complete over 650,000 full medical continuing disability reviews

(CDR) in FY 2013. Instead, with the reduced funding that we received, we estimate that we will complete only 422,000 full medical CDRs. In FY 2013, we estimate that every dollar spent on CDRs will yield about \$9 in program savings over ten years, including Medicare and Medicaid program effects. We would have been able to replace our losses through one-for-one hiring which would have allowed us to relieve the burden on critically understaffed field offices, the State DDSs, and our teleservice centers. We also would have been able to provide a considerable amount of overtime, comparable to the last two years, to help reduce backlogs of initial claims and hearings. We would have looked at resuming the full mailing of the Social Security Statement.

We are experiencing significant challenges stemming from three consecutive years of funding levels that were nearly a billion dollars below the President's Budget Requests. Tighter budgets, including cuts due to sequestration, have exacerbated our ability to serve members of the public who need our services, resulting in growing backlogs and longer wait times. Due to reduced staff and overtime, we estimate that:

- Callers to our 800-number will wait almost 45 percent longer in FY 2013 than in FY 2012;
- The average busy rate will rise from approximately five percent in FY 2012 to 16 percent by the end of FY 2013;
- The pending levels of initial disability claims will rise from 708,000 in FY 2012 to 804,000 at the end of FY 2013, an increase of nearly 100,000 claims; and
- On average, applicants will have to wait a week longer for a decision on an initial disability claim and nearly a month longer for a disability hearing decision compared to last year.

Question 2: Please explain to me what happens if funding for your program integrity activities are reduced?

Our program integrity funding has already been reduced. We currently expect to handle 422,000 CDRs, more than 200,000 below the amount authorized under the Budget Control Act and our FY 2013 President's Budget request, which is less than we accomplished in FY 2012. We plan to complete the same level of SSI non-disability redeterminations as we did last year, 2.622 million. For the FY 2013 President's Budget, we estimated that every dollar spent on CDRs will yield about \$9 in program savings over ten years, including savings accruing to Medicare and Medicaid. For the FY 2013 President's Budget, we estimated that every dollar spent on SSI redeterminations will yield about \$6 in program savings over ten years, including savings for the Medicaid program.

Despite enactment of multi-year discretionary cap adjustments, the annual appropriations process has not provided the full amount of program integrity funding authorized in the Balanced Budget and Emergency Deficit Control Act of 1985, as amended. Tens of billions of dollars in deficit savings over the next ten years from curtailing improper payments will not be realized if sufficient funding for the administrative expenses for our program integrity activities is not

provided. To ensure these important program integrity investments are made, the FY 2014 President's Budget includes a legislative proposal that would create a new Program Integrity Administrative Expenses Account in order to provide a reliable stream of mandatory program integrity funding. In FY 2013, the request is for an additional \$266 million in mandatory funding, which would allow us to handle significantly more CDRs.

Staffing Shortfalls and Cuts in Service Hours

Thousands of skilled, experienced SSA employees have been lost through attrition and have not been replaced, resulting in an increased workload for the remaining employees.

Question 1: How many people visiting the field offices – whether claimants or those who simply need to replace a lost Medicare card – are denied service daily due to insufficient staffing?

SSA has been forced to reduce hours. You close an hour early every day, and on Wednesdays your offices are open for only 3 hours (from 9 to noon). In addition to this overtime has been largely eliminated, so employees are being asked to do more with less.

I want to be clear that we do not turn people away; we serve every person who comes through our doors during office hours. But years of funding below the President's Budget request level, combined with the sequester have made it increasingly difficult to provide service of the quality we pride ourselves on and the American public expects. Visitors have had to wait longer for us to see them. This fiscal year, the percentage of visitors who leave our offices without receiving any service from us increased from five to six percent per month. We do not know the exact reasons why these visitors left, but certainly many did so in frustration at the length of time they would have waited.

Question 2: How has this affected service, and what appropriation would be sufficient to restore the ability of the field offices to operate at full capacity?

As you noted above, we cut our office hours. We are now operating with nearly a billion dollars less than we had in FY 2010, the last fiscal year in which we operated with unreduced office hours. As early as FY 2011, we began to experience the adverse effect of attrition in our offices. Because of the recent reduced appropriations, we have been unable to replace lost staff or offer enough overtime to catch up. We started closing our offices early in order to better keep up with existing workloads.

This fiscal year, visitors without an appointment have had to wait, on average, nearly 26 minutes for us to see them, about 40 percent longer than in FY 2011. Not only has the average national wait time increased, but the number of visitors without an appointment who must wait a long time—30 minutes or more—for us to see them has increased from approximately 20 percent in FY 2011 to 36 percent this fiscal year. In some of our busiest offices with the most staff losses, the typical visitor without an appointment waits for longer than two hours for service. The American public deserves better.

Question 3: How many fewer appointments are being scheduled, and how does it impact walk-ins?

Comparing FY 2011 to this fiscal year, we are scheduling an average of 1,000 fewer appointments per day. However, this decrease alone does not adequately capture the fallout we experience in other service areas when there are fewer people in our office to secure appointments. We have a harder time scheduling people in a timely manner. We have historically scheduled approximately 90 percent of appointments within three weeks of receiving a request. However, since January of this year, we have scheduled only about 70 percent of appointments within three weeks of receiving a request.

Another consequence of people not being able to schedule a timely appointment is the increase in people choosing to walk in rather than wait so long for an appointment. While we cannot quantify how many do not make appointments, we know it affects our ability to serve walk-ins. I have described in my responses above the increase in the average wait time for walk-in service and the percentage of people who leave our offices without being seen. Additionally, to date in FY 2013, an average of 7,600 visitors coming to our field offices each week have to wait over two hours for service, a figure that increased 176 percent since FY 2011.

Impact of Sequestration

You mentioned the sequester in your testimony, and after hearing the budgetary constraints you are already operating under, it is very hard for me to imagine where further cuts could be made.

Please describe the actions that you anticipate taking as a result of sequestration.

Question 1: How many employees do you anticipate furloughing?

We do not expect to furlough any employees this year. As I noted in my written statement, we have been painfully frugal. We severely restricted overtime and we have postponed all hiring with the exception of a small number of staff hired to fill critical, front-line service positions. By the end of this year, we expect to lose an additional 3,300 employees through attrition on top of the 9,200 we have already lost since the beginning of FY 2011—a total loss of nearly 15 percent of our workforce.

As I answered to a previous question, our service to the public has suffered because of these losses. We expect that callers to our 800-number will wait almost nine minutes for us to answer, nearly twice as long as in 2012. The average busy rate will more than triple to 16 percent by the end of FY 2013. Pending initial disability claims will rise from 708,000 to 804,000 from the beginning to the end of FY 2013, an increase of nearly 100,000 claims. On average, applicants will have to wait a week longer for a decision on an initial disability claim and nearly a month longer for a disability hearing decision compared to last year.

We also must reduce the number of CDRs we complete to 422,000, more than 200,000 fewer than the FY 2013 President's Budget request and fewer than we completed in FY 2012. This

reduction is particularly worrisome because CDRs are so cost effective; for every \$1 we spend doing a CDR, the taxpayer saves \$9 over 10 years. These and other cuts to our program integrity efforts achieve short-term savings at the price of long-term costs.

Question 2: How many fewer claims will be processed?

We expect to handle 2,962,000 initial disability claims this year, 245,000 fewer than we handled in FY 2012.

Question 3: How will the backlog be affected?

We expect that the pending level of initial disability claims will grow from 708,000 in FY 2012 to 804,000 by the end of FY 2013, an increase of nearly 100,000 claims. On average, applicants will have to wait a week longer for a decision on an initial disability claim and nearly a month longer for a disability hearing decision compared to last year.

Question 4: How much longer will people have to wait for their initial appointment?

As I answered to a previous question, we now schedule about 30 percent of all appointments more than three weeks from the date of the request. Historically, we have scheduled less than ten percent of all appointments more than three weeks from the request. We do not project how many more people will have to wait for longer than three weeks for the next available appointment, but we do not expect the length of the delays to improve under our current budget constraints.

WEDNESDAY, MARCH 20, 2013.

CHILDREN'S MENTAL HEALTH

WITNESSES

PAMELA HYDE, ADMINISTRATOR, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEB DELISLE, ASSISTANT SECRETARY, OFFICE OF ELEMENTARY AND SECONDARY EDUCATION, DEPARTMENT OF EDUCATION

INTRODUCTIONS

Mr. ALEXANDER. Good morning. The chairman will be here in a few minutes, we understand. But he wants to go ahead and get started so we won't mess up everybody's day.

Good morning. Today, we will hear from the Department of Education and the Substance Abuse and Mental Health Services Administration of the Department of Health and Human Services about the state of the mental health system for children in the U.S.

The tragic massacre of 20 children and 6 adults at Sandy Hook Elementary School on December the 14th of last year has led to a national discussion about whether the mental health care system in the U.S. is designed to effectively identify and treat youth with mental health diseases and disorders before they lead to, in the most extreme cases, tragedies like the one I just mentioned.

The administration is already talking about creating new programs. But today, we are going to take a step back and look at the current system as it exists today. We will hear about what has and hasn't been effective at improving the mental health of children and reducing violent and disruptive behavior in schools, focusing on the role of Federal programs.

I am interested in learning how we can better target current resources to address this issue. On an issue as important as this, we can't afford to waste a single dollar on programs that are duplicative or ineffective.

And I will yield now to Ms. Lee for an opening statement.

Ms. LEE. Thank you very much.

First, let me thank both of you for being here today and take a moment to just mention that our subcommittee ranking member, Congresswoman Rosa DeLauro, was asked to join the official House delegation to the inauguration of Pope Francis. So she won't be with us today.

But I am very pleased to take the lead for the Democratic side today, as she requested me to do. My background, of course, is in clinical social work and mental health, community mental health, and I am really pleased to be here today with you.

The recent mass shootings, including those in Connecticut, Colorado, and Arizona, have launched a real national discussion about

mental health issues, especially as they affect our youth. This is certainly a discussion we should be having, one that really should have started a long time ago. These horrific events really serve as a reminder of the possible consequences of untreated mental illness.

But we should also remember that the vast majority of people living with mental illness are not violent and also that the vast majority of violence is not caused by people with mental illness. The fact is that those suffering from a mental illness are far more likely to become victims of violence than the perpetrators.

Also, the reality is that for far too long, too many of our young people, their experience with violence is not the devastating mass shootings, but the everyday violence that is all too common in communities like Chicago and my district in Oakland and right here in Washington, D.C. So when we fail to address mental illness, when people cannot access services and there is nowhere for them to go, the outcomes are not positive.

Children with undiagnosed, untreated mental illness become adults who often end up in prison, experience homelessness, and are victims of violence and have many health concerns that are harder to treat due to their mental state. As a clinical social worker, I opened a community mental health center in Berkeley, California, that served low-income clients, and I saw firsthand the effects of the lack of services on the mental health of individuals, on their families, and on their communities.

There was an overwhelming need then, and that was in the '70s. And there is an overwhelming need now. It is the resources that, inexcusably, are lacking.

In recent years, we have seen a dramatic decrease in resources for mental health at all levels. SAMHSA mental health programs were cut by 5 percent between 2010 and 2012, and sequestration has almost doubled that cut. Adjusted for inflation and population, 2013 now is about one-fifth lower than 2002 level.

As for the States, the Association of State Mental Health Directors estimates that in the last 4 years, States have cut \$4,350,000,000 in mental health services while, at the same time, an additional 1 million people sought help at public mental health facilities.

So I hope that today we can hear more about the consequences of these cuts. I hope that we are able to discuss what can be done to reach more children with undiagnosed and untreated mental health challenges. Since we know that in most cases treatment does work, and early treatment and prevention is absolutely necessary.

Finally, I hope to discuss how to make our schools a safer learning environment without turning them into armed camps, the impact of mental health treatments on the pipeline to prison, which is really devastating low-income communities and communities of color. So I thank our witnesses for being here and look forward to today's discussion.

Thank you, Mr. Chairman.

Mr. KINGSTON [presiding]. Well, thank you very much, Ms. Lee and Mr. Alexander.

Ms. Hyde, we will go ahead and start with you, and then Ms. Delisle, you will do the same.

OPENING STATEMENT OF PAMELA HYDE

Ms. HYDE. Thank you, Chairman Kingston and Vice Chairman Alexander and Ranking Member DeLauro and Congresswoman Lee, for your holding this hearing.

And I do want to acknowledge Assistant Secretary Deb Delisle, whom you are going to hear from in a moment. Our agency works very closely with the Department of Education. You will see that as we talk through today.

I think you are aware that SAMHSA's mission is, in fact, to reduce the impact of mental illness and substance abuse on America's communities, and we do that in a number of ways. We do it by being a voice for behavioral health, but also by substance abuse and mental health surveillance and data, by setting standards and regulating programs, by doing practice improvement efforts, by funding States, tribes, territories, and communities, and by providing information to the public.

I wanted to start with just some of that public information that we try to get people to be aware of, and that is that three-quarters of adult mental health issues start before the age of 24, about half before the age of 14. So investing in the mental health of our children and youth is critical not only to them, but to adults.

Less than half of adults and less than one in five children and adolescents receive treatment for diagnosable mental health and substance use disorders. And even less, about 11 percent of adults with substance use disorders, receive treatment.

The reasons for this lack of treatment include cost, not knowing whether and where to get help, and not knowing whether treatment will work. Generally, people wait much longer to get treatment for a mental health or substance abuse disorder than for physical symptoms for themselves or their children.

And science tells us that we can prevent mental and behavioral health disorders among young people, and the sooner we intervene, the better the outcome. So the longer we can keep a young person from drinking or taking drugs such as marijuana or abusing prescription drugs, the more likely we can keep that young person from developing a serious problem in adulthood.

Persons with behavioral health problems have higher rates of heart disease, hypertension, disease, and smoking than those without those conditions. And people with mental and substance use disorders are nearly two times as likely as the general population to die prematurely. About half the deaths from tobacco use in our country are among people with mental and substance use disorders.

Today, suicide is, unfortunately, the third-leading cause of death among young people. However, it doesn't have to be this way. We know that behavioral health, mental illness, and substance abuse prevention, treatment, and recovery is, in fact, a public health issue, and it can be tackled and solved in that way. Positive emotional, mental, and behavioral health increases a young person's chance of social, academic, and developmental success, and that benefits us all.

As you know, in January, the President announced some initiatives to ensure that students and young adults receive treatment for mental health issues. To ensure adequate coverage of mental health and addiction services, the administration issued a letter to State health officials about Medicaid plans being subject to MHPAEA, or Mental Health Parity and Addiction Equity Act. And in addition, the administration will issue final regs about MHPAEA this year.

The President also proposed initiatives to increase mental health access for the Nation's young people. And SAMHSA has a specific role in three of those.

The first is Project AWARE, Advancing Wellness and Resilience in Education. This project would provide States with resources to help schools and communities address mental health issues, identify mental illness early, and refer young people to treatment. Project AWARE would also provide Mental Health First Aid training.

Second program is Healthy Transitions. It is a proposed new grant program for innovative State-based strategies supporting young people ages 16 to 25.

And a third program is a workforce program to be operated jointly with HRSA that would train more than 5,000 additional mental health professionals to serve students and young adults.

And finally, HHS and Education, along with the White House, will soon launch a national dialogue on mental health.

So we have come a long way in the prevention, treatment, and recovery supports for mental and addictive disorders, but we have a long way to go. And we can do better, which is why the administration is taking steps to increase awareness of the importance of mental health to our Nation's health and increase access to mental health services, especially for young people.

Thank you again for this opportunity to discuss SAMHSA's role in this, and I would be pleased to answer any questions you may have.

[The prepared statement of Administrator Pamela Hyde follows:]



Testimony Before the

**Committee on Appropriations Subcommittee on Labor, Health and Human
Services, Education and Related Agencies
Hearing on Children's Mental Health**

March 20, 2013

Statement of Pamela S. Hyde, J.D.

Administrator

Substance Abuse and Mental Health Services Administration

U.S. Department of Health and Human Services

Good morning Chairman Kingston, Ranking Member DeLauro and members of the Committee. Thank you for inviting me to testify today on the role of the federal government in addressing America's mental health needs. I also am happy to be joined by my colleague, Deb Delisle from the Department of Education (ED). In addition to discussing SAMHSA's role in addressing this country's mental health needs, I am pleased to share some of the initiatives related to mental health included in the President's plan, *Now is the Time*, which emphasizes early intervention and treatment for young people struggling with mental health problems.

The Substance Abuse and Mental Health Services Administration (SAMHSA)

As you are aware, the Substance Abuse and Mental Health Services Administration's (SAMHSA) mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA envisions a Nation that acts on the knowledge that:

- Behavioral health is essential for health;
- Prevention works;
- Treatment is effective; and
- People recover from mental and substance use disorders.

In order to achieve this mission, SAMHSA has identified eight Strategic Initiatives to focus the Agency's work on improving lives and capitalizing on emerging opportunities. SAMHSA's top Strategic Initiatives are: Prevention; Trauma and Justice; Health Reform; Military Families; Recovery Supports; Health Information Technology; Data, Outcomes and Quality; and Public Awareness and Support.

SAMHSA acts on its mission and vision by: providing leadership and voice for and about behavioral health; conducting surveillance and reporting data; improving practice; setting standards and regulating programs; providing information to the public and the field; and providing funding to states, tribes, territories and communities.

Prevalence of Behavioral Health Conditions and Treatment

It is estimated that almost half of all Americans will experience symptoms of a mental health condition – mental illness or addiction – at some point in their lives. Yet, today, less than one in five children and adolescents with diagnosable mental health problems receive the treatment they need.¹ And according to data from SAMHSA’s National Survey on Drug Use and Health (NSDUH), only 38% of adults with diagnosable mental health problems – and only 11% of those with diagnosable substance use disorders - receive needed treatment.²

With respect to the onset of behavioral health conditions, half of all lifetime cases of mental and substance use disorders begin by age 14 and three-fourths by age 24.³ Cost, access, and recognition of the problems are the primary reasons this treatment is not received.

Behavioral health – mental illness and substance abuse prevention, treatment, and recovery – is a public health problem, and it can be tackled and solved in that way. Today, persons with mental illness and substance use disorders have higher rates of heart disease, hypertension, diabetes, and smoking than those without such conditions. The cost of treating these co-morbid health conditions is much greater when the underlying behavioral health issue is inadequately addressed or untreated. However, it doesn’t have to be this way. For most of these conditions, prevention works, treatment is effective, and people do recover.

When persons with mental health conditions or substance use disorders do not receive the proper treatment and supportive services they need, crisis situations can arise affecting individuals, families, schools, and communities. We need to do more to identify mental health and substance abuse issues early and help individuals get the treatment they need before these crisis situations develop. And we need to help communities understand and implement the prevention approaches we know can be effective in stopping issues from developing in the first place.

¹ Unmet Need for Mental Health Care Among U.S. Children: Variation by Ethnicity and Insurance Status
Sheryl H. Kataoka, M.D., M.S.H.S.; Lily Zhang, M.S.; Kenneth B. Wells, M.D., M.P.H., *Am J Psychiatry* 2002;159:1548-1555. 10.1176/appi.ajp.159.9.1548

² Substance Abuse and Mental Health Services Administration, *Results from the 2011 National Survey on Drug Use and Health: Mental Health Findings*, NSDUH Series H-45, HHS Publication No. (SMA) 12-4725. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.

³ Kessler, R. C., Berglund, P., Demler, O., Jin, R., Merikangas, K. R., & Walters, E. E. (2005). Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. *Archives of General Psychiatry*, 62(6), 593–602.

Mental Health Financing

According to the *National Expenditures for Mental Health Services & Substance Abuse Treatment 1986 – 2009*, the most up-to-date data shows that at \$147 billion, mental health spending accounted for 6.3 percent of all health spending in 2009. Medicaid (27 percent of mental health spending) and private insurance (26 percent of mental health spending) accounted for more than half of mental health spending in 2009.

A key source of funding for services for adults with serious mental illness and children with severe emotional disturbances is the Community Mental Health Services Block Grant (MHBG), which is a flexible funding source that is used by States to provide a range of mental health services described in their plans for comprehensive community-based mental health services for children with serious emotional disturbance and adults with serious mental illness. These funds are used to support service delivery through planning, administration, evaluation, educational activities, and services. Services include rehabilitation services, crisis stabilization and case management, peer specialist and consumer-directed services, wrap around services for children and families, supported employment and housing, jail diversion programs, and services for special populations. The State plan is developed in collaboration with the State mental health planning councils. Planning Councils' membership is statutorily mandated to include consumers, family members of adult and child consumers, providers, and representatives of other principal State agencies. The FY 2013 President's Budget proposed \$460 million to continue the MHBG.

President's Policies

Reaching Youth and Young Adults

In January, the President announced initiatives to ensure that students and young adults receive treatment for mental health issues, including:

1. **Reach 750,000 young people through programs to identify mental illness early and refer them to treatment:** We need to train teachers and other adults who regularly interact with students to recognize young people who need help and ensure they are referred to mental health services. The Administration is calling for a new initiative, Project AWARE (Advancing Wellness and Resilience

in Education), to provide this training and set up school-community partnerships to promote mental health, and facilitate referrals when needed. This initiative has two parts:

- a. **Provide “Mental Health First Aid” training for teachers:** Project AWARE proposes \$15 million for training for teachers and other adults who interact with youth to detect and respond to mental illness in children and young adults, including how to encourage adolescents and families experiencing these problems to seek treatment.
 - b. **Make sure students with signs of mental illness get referred to treatment:** Project AWARE also proposes \$40 million to help states and school districts work with community leaders, law enforcement, mental health agencies, families and youth, and other local organizations to assure students with mental health issues or other behavioral issues are referred to and receive the services they need. This initiative builds on strategies that, for over a decade, have proven to improve mental health.
2. **Support individuals ages 16 to 25 at high risk for mental illness:** Efforts to help youth and young adults cannot end when a student leaves high school. Individuals ages 16 to 25 are at high risk for mental illness, substance abuse, and suicide, but they are among the least likely to seek help. Even those who received services as a child may fall through the cracks when they turn 18. The Administration is proposing \$25 million for innovative state-based strategies supporting young people ages 16 to 25 with mental health or substance abuse issues.
 3. **Train more than 5,000 additional mental health professionals to serve students and young adults:** Experts often cite the shortage of mental health service providers as one reason it can be hard to access treatment. To help fill this gap, the Administration is proposing \$50 million to train social workers, counselors, psychologists, and other mental health professionals. This would allow SAMHSA and the Health Resources and Services Administration to provide stipends and tuition

reimbursement to train more than 5,000 mental health professionals serving young people in our schools and communities.

These SAMHSA proposals will be included in the FY2014 President's Budget and are designed to compliment the ED proposals also included in the President's Budget.

Coverage

In addition to identifying early signs of mental health problems, doing a better job referring individuals who need help to treatment, and training a stronger mental health workforce, we also need to make sure that people have access to affordable coverage for mental health services.

The Affordable Care Act expands access to affordable mental health services by requiring all new small group and individual plans to cover ten essential health benefit categories, including mental health and substance abuse services, and these behavioral health services must be covered at parity with medical and surgical benefits. This past February, the Administration issued the final essential health benefits rule to extend mental health parity protections to 62 million Americans. And later this year, the Administration will issue final regulations governing how existing group health plans that offer mental health services must cover them at parity under the Mental Health Parity and Addiction Equity Act of 2008.

National Dialogue on Mental Health

In order to change the conversation about mental illness and mental health in America, the President has directed the Secretaries of HHS and ED to launch a National Dialogue on Mental Health. The National Dialogue will be a nationwide conversation seeking to increase awareness of early warning signs of mental health issues, to promote conversations about mental and emotional health, and to help individuals in need access treatment. The goal of the campaign is to provide youth and adults accurate information about the prevention and treatment of mental health conditions and opportunities to

tell their stories, ask for help, share their successes, and support one another. The Administration will launch this Dialogue in the next several weeks.

Conclusion

We have come a long way in the prevention, treatment, and recovery supports for mental and addictive disorders. But we have a long way to go, and we can do better, which is why the Administration is taking steps to increase access to mental health services and calling on Congress to do the same. Thank you again for this opportunity to discuss SAMHSA's role in addressing this country's mental health needs. I would be pleased to answer any questions that you may have.

OPENING STATEMENT OF DEB DELISLE

Ms. DELISLE. Thank you very much.

Chairman Kingston, Congresswoman Lee, and members of the subcommittee, thank you so much for holding this very important hearing on children's mental health.

I appreciate the opportunity to share the Department's efforts, as well as the President's plan for improving mental health supports for students. And obviously, I am very pleased to be here with my colleague Pam Hyde because we have done a lot of work together, and our partnership is deepening every single day.

As you are very well aware and has been expressed earlier, our students today face a whole host of challenges to their mental, behavioral, and emotional well-being in their schools, in their homes, and in their communities. There are many complexities of life that impact children's overall well-being and, in turn, influence their academic achievement and their feelings of inclusiveness and safety in school settings.

There is a growing awareness among Federal policymakers of the linkages between children's exposure to violence and mental and emotional wellness. The groundbreaking National Survey of Children Exposed to Violence found that 10 percent of children in this country have been exposed to multiple forms of violence, such as community violence, sexual abuse, and domestic violence. And secondly, the risk and severity of health and mental disorders increases for children who have been victimized multiple times by up to tenfold.

To ensure that our students can focus on learning, our educators must have both school-based resources and effective partnerships with community health professionals to identify risk factors, recognize students displaying signs of emotional and mental distress, and connect students and their families to a continuum of supports to help them cope, to recover, and to continue successfully in their academic careers as well as in life.

Further, under applicable Federal law, schools have an obligation to identify, evaluate, and provide special education and related services to students with disabilities, including mental health-related disabilities. School-based mental health supports are particularly critical to helping educators respond effectively to the myriad of incidents affecting students on campus and in school buildings, from teen dating violence to the emotional distress that students bring to school and to tragic events, such as that which occurred in Newtown, Connecticut.

Last December, I testified before the Senate Judiciary Committee about our efforts to stem the use of suspensions and expulsions, which disproportionately impact students with disabilities and students of color. Schools must recognize behavioral incidents as opportunities to help students cope with trauma and to support, rather than to exclude, students with emotional and behavioral difficulties.

In recent years, the Department has worked to improve educator and student access to mental health resources and supports through financial support to school districts, technical assistance, and interagency partnerships with Federal partners, such as

SAMHSA. For example, since 1999, the Department has partnered with DOJ and SAMHSA to address youth violence prevention and support the social, emotional, and behavioral needs of students through the Safe Schools/Healthy Students initiative.

Far too often, the resources directly available within a school building are limited. For example, while the American School Counselors Association recommends a ratio of 250 students to every counselor, the national student-to-counselor ratio is approximately 450 to 1, as of 2010. One counselor to attend to the needs of 450 students, is an overwhelming ratio for sure.

Our Office of Safe and Healthy Students administers a grant program to establish or expand school counseling in elementary and secondary schools. In 2012, we awarded \$21,200,000 to 60 recipients in 24 States to hire and train qualified mental health professionals, with the goal of expanding the range, availability, quantity, and quality of counseling services.

The Department's Office of Special Education and Rehabilitative Services has invested in behavioral research, demonstration, and technical assistance activities for more than 20 years, including through the positive behavioral interventions and support centers, which provide States, schools, and communities with a clear, evidence-based roadmap to safer school climates that support students through evidence-based behavioral frameworks.

Further, we are working closely with DOJ and HHS to strengthen the use of behavioral frameworks in the 10 cities that comprise the National Forum for Youth Violence Prevention, which have all pledged to strengthen local capacity to prevent youth violence and gang violence.

On January 16th, as Pam mentioned, the President announced a comprehensive plan "Now is the Time," which outlines a multifaceted approach to reducing gun violence and is based on the recommendations of the Vice President's task force that was established in the wake of the school shooting in Newtown, Connecticut.

Mr. KINGSTON. Your time has expired.

Ms. DELISLE. Okay.

Mr. KINGSTON. But Members have looked at your testimony, and it is very good, very meaty, and so don't think we haven't—

Ms. DELISLE. Thank you. I appreciate that. Thank you for the opportunity to be here.

[The prepared statement of Assistant Secretary Deb Delisle follows:]

DEPARTMENT OF EDUCATION
Statement by
Deborah Delisle
Assistant Secretary
Office of Elementary and Secondary Education
on
Children's Mental Health

March 20, 2013

Chairman Kingston, Ranking Member DeLauro, and Members of the Subcommittee - thank you for holding this hearing on children's mental health. I appreciate the opportunity to share the Department of Education's (Department) efforts and the Obama Administration's plan for improving mental health supports for students. I am very pleased to be here with my colleague, Pam Hyde, from the Substance Abuse and Mental Health Services Administration.

Introduction

Our students today face a myriad of challenges impacting their mental, behavioral, and emotional wellbeing – in their schools, in their homes, and in their communities. There are many complexities of life impacting children's overall wellbeing and, in turn, affecting their academic achievement and their feelings of inclusiveness and safety in school settings.

There is a growing awareness among policymakers of the linkages between children's exposure to violence and their mental and emotional wellness. The Department of Justice's (DOJ) and Centers for Disease Control and Prevention's (CDC) groundbreaking National Survey of Children Exposed to Violence has demonstrated the impact of violence on the wellbeing of students. As many as ten percent of children in this country are polyvictims – that is, they have been exposed to multiple forms of violence, such as community violence, sexual abuse, domestic violence, and others. Repeat victimization, by multiple forms of violence, increases the risk and severity of health and mental health disorders for exposed children by at least twofold and up to tenfold.¹ Children who have been experienced victimization and trauma often have cognitive, physical, social, and emotional needs that may or may not meet the diagnostic criteria for a mental health disorder but still must be addressed in order for them to be successful in school, at home and in the community.

More than ten percent of girls will have been physically forced to have sexual intercourse by the time they graduate from high school.² Victims of sexual assault are

¹ Report of the Attorney General's National Task Force on Children Exposed to Violence, 2012.

² Centers for Disease Control and Prevention. Youth Risk Behavior Surveillance survey – United States, 2011. MMWR 2012; 61(No.SS-4):[10].

more likely to suffer academically and from depression, post-traumatic stress disorder, to abuse alcohol and drugs, and to contemplate suicide.³

Further, the data clearly shows that more progress is needed in the area of youth suicide. According to the CDC's Youth Risk Behavior Surveillance Survey, almost 16 percent of students seriously considered attempting suicide in 2011, and almost 8 percent actually attempted suicide.⁴

To ensure that our students are able to focus on learning, our schools must equip staff with effective tools and strengthen partnerships with community mental health professionals to help identify risk factors, identify students displaying signs of emotional and mental distress, and offer strategies to connect students to a continuum of supports to help them cope, recover, and continue in their academic careers. School-based mental health services are one important tool to help ensure that our students obtain the care they need. School-based mental health services have many benefits, including easy access for all students and a positive effect on the learning environment and educational outcomes.

Under applicable federal laws, schools have an obligation to identify, evaluate, and provide special education and related aids and services to students who are known or suspected to have disabilities, including mental-health-related disabilities.⁵ Providing school-based mental health services offers the convenience of location for busy families who need care, which can mean less time away from work and the classroom. The capacity to provide individually tailored mental health supports and counseling services helps schools keep students with social and emotional challenges engaged and successful in school.

However, addressing the mental health needs of all children requires a broad array of approaches and techniques – some of which are beyond the resources of a school. For example, while the American School Counselors Association recommends a ratio of 250 students to every counselor, the national student to counselor ratio is approximately 450 to 1, as of 2010. Only five states maintain ratios under 300 to 1.⁶ Additionally, it is not common to have adequate numbers of social workers and psychologists working in schools to train staff and meet the needs of our students, especially those who are most vulnerable.

Therefore, we need to not only improve and increase access to school-based mental health supports but also foster close partnerships between schools and mental health organizations within the broader community. These community resources can

³ Centers for Disease Control and Prevention, Understanding Sexual Violence Fact Sheet (2011).

⁴ Trends in Prevalence of Suicide-Related Behaviors. National YRBS: 1991- 2011.

⁵ Under the Individuals with Disabilities Education Act (IDEA), school districts have a "child find" obligation, which requires districts to identify, locate, and evaluate all children with disabilities in a State from birth through age 21, regardless of the severity of disabilities. 34 CFR 300.111. Likewise, under Section 504 of the Rehabilitation Act of 1973, school districts must conduct an evaluation before placement or change in placement for any student who, because of disability, needs or is believed to need regular or special education or related aids and services. 34 CFR 104.35(a).

⁶ The College Completion Agenda: 2012 Progress Report. College Board Advocacy and Policy Center.

provide information and resources about mental health, and high-quality treatment options, to help our educators provide high-quality instruction to all students, especially those most at risk.

Further, this capacity to provide school-based mental health services and referral to community resources is critical to ensuring that educators are able to prevent and respond effectively to the myriad of incidents that can impact students – from emotional distress that students bring with them to school, to bullying, harassment and teen dating violence. Last December, I testified before the Senate Judiciary Committee about the epidemic of school suspensions, expulsions, and referrals to law enforcement that are pushing our students into the juvenile justice system, and are creating obstacles to high school completion. Schools' staff must be trained to recognize that some misbehavior may be symptomatic of mental illness or substance use disorder and should not automatically lead to detention or suspension which contributes to the school to prison pipeline for this population of students. Behavioral incidents can be an opportunity to help a student who is dealing with trauma and to support the needs of students with emotional and behavioral difficulties. In 2011, 18.2 percent of youths aged 12 to 17 who had a major depressive episode (MDE) also had a substance use disorder.⁷ Yet, only 21.5 percent of children 12-17 with a diagnosis of depression, 10.5 percent of youth with drug use who reported a need for treatment and 6.4 percent of youth with alcohol use disorders⁸ reported receiving treatment at a specialty facility. Without this understanding, many schools turn to suspension or expulsion, attempting to remove a disruptive "problem child" from the classroom and school. Too many of our schools are, unfortunately, operating in a reactive mode rather than a proactive one. Such a deficit model is not conducive to the emotional wellbeing of our students.

Recent Department Efforts

In recent years, the Department has worked to improve educator and student access to mental health resources and supports through financial support to school districts, technical assistance, and interagency partnerships with federal partners such as the Department of Health and Human Services' (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA).

Safe Schools/Healthy Students (SS/HS). Since 1999, the Department has partnered with DOJ and SAMHSA to address youth violence prevention and supporting the social-emotional and behavioral needs of students and communities through the SS/HS initiative. Through the Supportive School Discipline Initiative and the National Forum on Youth Violence Prevention (described below), the SS/HS initiative has

⁷ Substance Abuse and Mental Health Services Administration, *Results from the 2011 National Survey on Drug Use and Health: Mental Health Findings*, NSDUH Series H-45, HHS Publication No. (SMA) 12-4725. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.

⁸ Substance Abuse and Mental Health Services Administration, *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-44, HHS Publication No. (SMA) 12-4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.

partnered with other federal initiatives to share the important teachings from SS/HS grantee communities.

Elementary and Secondary School Counseling Grants. Our Office of Safe and Healthy Students also administers a grant program to establish or expand school counseling in elementary and secondary schools. In 2012, we awarded \$21.2 million to 60 recipients in 24 states to hire and train qualified mental-health professionals with the goal of expanding the range, availability, quantity, and quality of counseling services.

National Center for Safe Supportive Learning Environments. In 2012, the Office of Elementary and Secondary Education worked closely with SAMHSA to jointly establish a new technical assistance center focused on helping elementary, secondary, and postsecondary schools to improve school climate and strengthen mental health supports for students and to prevent bullying in schools. This collaboration aims to help schools better access SAMHSA's wealth of information and resources on mental and behavioral health promotion.

Positive Behavioral Interventions and Supports (PBIS). The Office of Special Education and Rehabilitative Services (OSERS), which has invested in behavioral research, demonstration, and technical assistance activities for more than 20 years, including through the Positive Behavioral Interventions and Supports Center, provides states, schools, and communities with a clear, evidence-based roadmap to safer school climates that support students through evidence-based behavioral frameworks.

National Forum for Youth Violence Prevention. The Department is one of multiple federal partners supporting the National Forum on Youth Violence Prevention – an interagency initiative to help 10 cities across the Nation elevate youth and gang violence as an issue of significance; enhance the capacity of participating localities, along with others across the country, to more effectively prevent youth and gang violence; and sustain progress and systems change through engagement, alignment, and assessment. We are working closely with DOJ and HHS to strengthen the use of behavioral frameworks in these cities' schools. The ten cities⁹ that comprise the National Forum have pledged to strengthen local capacity to prevent youth violence and gang violence. We see behavioral frameworks as a key strategy for their schools to boost capacity in delivering mental health and social and emotional supports, and creating safer and more productive environments for their students and staff.

Supportive School Discipline Initiative (SSDI). As I noted earlier, the Department sees a relationship between schools' ability to support students' mental health and their ability to manage and respond to student misbehavior. We have partnered with DOJ to reduce school reliance on suspensions, expulsions, and referrals to law enforcement, and, at the same time, help educators identify effective alternatives to exclusionary discipline. At the core of the SSDI is an effort to develop a broad consensus on the steps that the

⁹ The 10 cities that currently compose the National Forum for Youth Violence Prevention as of December 2012: New Orleans, LA; Philadelphia, PA; Minneapolis, MN; Camden, NJ; Boston, MA; Chicago, IL; Detroit, MI; Memphis, TN; Salinas, CA; and San Jose, CA.

education, judicial, and health communities must take to realize essential changes. As part of this effort, the Department and DOJ have supported the efforts of the Council of State Governments Justice Center, in concert with members of the philanthropic community, to lead the development of consensus-based recommendations on how to keep school environments safe and students productively engaged in school. Over the course of the next year, this national consensus-building project will convene groups from multiple disciplines – including education, behavioral health, juvenile justice, social services, law enforcement, and child welfare—to first identify key issues related to academic success, juvenile justice concerns, and safe and engaging learning environments, and then recommend solutions that keep students engaged in school and out of the justice system. The strength of this work lies in its ability to bring together adults from different sectors, including mental health professionals, who care deeply about our most vulnerable children and support collective action on behalf of these youth.

Now is the Time

On January 16th, the President announced a comprehensive plan, *Now is the Time*, to protect our children and communities by reducing gun violence. This plan outlines a multi-faceted approach that reflects the complexity of the problem and is based on the recommendations of the Vice President's Task Force established in the wake of the school shooting in Newtown. No educator, child, parent, family, or community should experience the horrific events such as those of Newtown, Virginia Tech, and Columbine. In communities all across America, young lives are lost due to senseless gun violence at a rate that is absolutely staggering. It is essential that our schools and communities are made safer by identifying and taking common-sense approaches to help prevent future tragedies.

The education-related proposals in *Now is the Time* are organized around improving mental health services for young people and school safety. In designing those proposals, we worked with our partners at HHS to develop a number of policy proposals to ensure students and young adults have access to and receive appropriate mental health treatment when needed. HHS is spearheading initiatives designed to reach 750,000 young people through programs that train teachers and other adults to identify mental health issues early and refer young people to treatment, to support state-based strategies to help individuals ages 16-25 at high risk for mental illness, and to train more than 5,000 additional mental health professionals to serve students and young adults.

Additionally, Secretary Duncan is working with Secretary Sebelius to launch a national dialogue about mental health. This dialogue aims to reduce the social barriers that prevent individuals from seeking the mental health help they need, and to reduce negative attitudes toward individuals with mental illness. The dialogue also will bring to light efforts to diminish the fear or shame associated with having a mental illness, and to correct the misinformation or lack of information about mental health services. The national dialogue, which will begin this spring, will help decrease these barriers so more individuals in need of help will reach out for mental health services and more

communities across the country will be better equipped to discuss mental health issues and help those who need services to access them.

While many of the mental-health focused proposals will be led by our partners at HHS, one school-based initiative with a strong mental health component that the Department is leading is a program to address pervasive violence in communities, which can have significant mental health consequences. Exposure to violence affects approximately two out of every three children.¹⁰ In order to help break the cycle of violence and help schools address the effects of pervasive violence that affects many students, *Now is the Time* includes a proposal for a \$25 million initiative that will support school-based violence prevention strategies, conflict resolution programs, and mental health services for trauma or anxiety. This important initiative would help address the effects of violence, reinforce positive learning environments in schools, and help prevent future violence.

A nurturing and supportive school climate is essential to helping students feel safe and we recognize that it significantly impacts student achievement. *Now is the Time* also includes a \$50 million proposal for a new initiative to help schools create safer and more nurturing school climates. These grants would assist schools in the use of evidence-based strategies to address problem behaviors such as bullying and harassment and intervene positively in the redirection of students' behaviors and responses. Our proposal draws heavily from what the Department has learned through OSERS' PBIS work which research shows, when implemented well, improves students' social skills, leading to an improved self concept and a reduction in problem behavior, bullying, peer victimization, and harmful suspensions that disrupt a child's educational opportunities through unnecessary removal from the classroom.

The plan also includes \$30 million to provide one-time grants to states to help schools develop and implement high quality emergency management plans. This investment would help schools review their emergency management plans to make sure they are high quality and are actually practiced and used. The Department also is working with DOJ, HHS, and the Department of Homeland Security (DHS) to release a set of model high-quality emergency management plans. The President's plan will also provide resources to school districts that will be designed to meet local needs, including improving access to mental health professionals, as appropriate. The Comprehensive School Safety program would provide \$150 million to develop school safety plans, improve equipment and systems, and train crisis intervention teams. School districts and law enforcement agencies would hire staff such as school psychologists, social workers, counselors and school resource officers and make other critical investments in school safety based on the needs of the local community and school system. We are working very closely with DOJ on successfully implementing proposals for this program, which DOJ would administer.

Providing essential services to improve the mental health of children is a critical component of our goal of empowering all children to find success in their daily lives and

¹⁰ <http://www.justice.gov/defendingchildhood/cev-rpt-full.pdf>.

to feel great hope for their futures. By providing support systems for our children, and by offering essential tools and resources to our educators, we demonstrate that children's health and emotional well-being are important and we tell educators that we care about their success.

Again, thank you for this opportunity to testify, and I am happy to answer your questions.

Mr. KINGSTON [continuing]. Time because I think you will find a lot of bipartisan support for the direction we all want to move on this committee, and I want to give Members plenty of time for questions.

So, not being rude, but want to move on to the dialogue.

Ms. DELISLE. Thank you.

Mr. KINGSTON. Sorry, my mike wasn't on. I hope you heard what I said.

IDENTIFYING CHILDREN WHO NEED MENTAL HEALTH SERVICES

Ms. Hyde, and I want to say one of just the most heartbreaking statistic that I have just heard is that the number-three cause of death in teenagers is suicide. I don't know that America knows that statistic, but I think all of us, as parents and family members, are just heartbroken to ponder what that means. And we have all seen it, and so certainly, we want to do everything we can.

A friend of mine, Dr. Chris Tillitski in Macon, Georgia, told me that—and he is a child psychologist—said after Columbine, there was just a tremendous growth in his industry because, he said, any time a child drew a weird picture, the mom would bring him in and say, “Is he the next Dylan Klebold?” the perpetrator of—and he said, you know, for some of his colleagues, it was a great opportunity for successions.

And he said, but there is also, if you know what you are doing, you could say, “No, this is a kid being a kid.” It is so difficult to identify when there is a mental illness, and one of the things that your testimony has said is that schools would identify. But I don't think schools or school counselors, whether it is 1 to 5 or 1 to 500 have that ability to truly identify the kids.

So can you comment on that? Because you sure don't want to misdiagnose it and plant some seed that, well, you drew a weird picture. Therefore, you have got a problem.

Ms. HYDE. Thank you, Mr. Chairman.

That is true. We don't want to identify children that don't need help. What we know, though, is that there are a number of children who do need help who don't get identified.

And I think part of what these proposals would do is help people have more information—school officials, families, community intervention folks, other sort of folks who are interfacing with young people—know what the signs and symptoms are, what they should be looking for, what is appropriate to look for. And then the referral process is to refer to an individual who is capable of doing the appropriate assessments to determine what is going on.

So we know that sometimes behaviors are part of young people's growing up. But we also know that sometimes those behaviors do identify young people with needs that are not getting attended to.

Mr. KINGSTON. Well, who would have the power—you know, coming at it for a minute from a Libertarian standpoint, how would the State be given that power that you don't like a child. The child is belligerent or whatever. And so, you say you need testing and counseling.

Because I know that teachers aren't perfect, and teachers often may have their own ax to grind on a child. And it would appear

to me to have some concerns about the State having the power to be able to send somebody off.

Ms. HYDE. I don't think the State would take that power. I think Assistant Secretary Delisle may want to comment about how the schools would do this. We're not asking anyone who is not—or not suggesting that anyone who is not trained, licensed, and able to make those assessments do that.

What we are trying to do is raise awareness. For example, suicidality and other kinds of things that may indicate a need for professional help rather than trying to get teachers to be diagnosticians. That is not what we are trying to accomplish.

Mr. KINGSTON. But the teacher would be closest to the child, observe the behavior, refer the child to somebody, and that could lead to mandatory assessment. And that is empowering the State. Is that not the case?

Ms. HYDE. I don't know—

Mr. KINGSTON. I am just saying there is a real fine line there.

Ms. HYDE. I don't think we are looking at mandatory assessments. Parents and others are involved in these decisions. It is not the State that makes those decisions. It is rather a teacher or a parent who is identifying behavior—

Mr. KINGSTON. Well, the teacher is the State, though. I mean, the teacher is a State employee. So if the teacher is empowered to do it. I am just saying a little concern on that.

Let me ask you this, in terms of the exposure to violence, and you had mentioned exposure to violence very close to being a victim of violence. But what about the cultural exposure to violence, whether it is from violent lyrics in a song or Hollywood movies or whatever? Do you feel like there is any influence on behavior because of the barrage that children are exposed to?

Ms. HYDE. We have done a lot of work about child exposure to violence. CDC has also done a significant amount of work. But frankly, we don't have good evidence about what those impacts are. We do know that witnessing violent behavior or witnessing violence in the community can have a traumatic impact on a child.

For some children, they have the resilience and capacity to take that in and deal with it and bounce back. For others, it has a profound and lasting impact on their health and mental health.

So it depends, and we don't have the complete data that we need to make those decisions at this point.

Mr. KINGSTON. Is that something that we should study?

Ms. HYDE. I would commend you to the CDC to talk about those issues. They and others are looking at whether or not those issues can be studied.

Mr. KINGSTON. You look very, very young. However, I would have to ask you this. Do you think children are exposed to more violence today than they were when, say, you were 10 years old?

Ms. HYDE. Mr. Chairman, I am not as young as you seem to think I am. I wish I were. [Laughter.]

Ms. HYDE. I don't know that I can answer that. My children are in their 30s. I know what they did and what they saw when they were young people. I don't have grandchildren. So I don't know what children so much are exposed to today.

There is no question that there is a culture in our communities about violent behavior, and the issue is how do we make sure, from SAMHSA's point of view, that anything that is a traumatic event, what is the impact on that child's behavioral health. And again, we have a number of years, about 10 years' worth of work in child trauma issues and identifying what kinds of things will have an impact on a child's behavioral health.

Mr. KINGSTON. I am just wondering if gratuitous violence and blood splattering in Hollywood is more than it used to be, which I think it would be, and if that has any influence? And would you think that would be something we should examine, or should that not be examined?

Ms. HYDE. Mr. Chairman, again, this is not my area. So we could probably try to get back to you with some information about that.

Mr. KINGSTON. Okay. Ms. Lee.

Ms. LEE. Thank you very much, Mr. Chairman.

Before you arrived, I mentioned that I am a trained clinical social worker by profession. My background is mental health. And I wanted to follow up with regard to your question in terms of the signs and symptoms and just say a couple of things, why it is important, I think, to follow up with that.

Because you are absolutely correct. There is a fine line. But trained mental health professionals really know how to make those diagnoses, and they know what the signs and symptoms are. And that is why it is so important to—and you mentioned the ratio of 1 to 450.

In my own State of California, when I was in the California legislature, we had one mental health counselor to about 1,200 students. And of course, I have legislation that would really authorize a full mental health school counselor national program. But I think it is extremely important that we know that we have to have trained mental health counselors, whether it is psychiatrists, psychologists, clinical social workers, on campuses to really begin to address that in a big way.

I don't know what the ratio is now in some States, but I know California is even more than 1 to 1,200 counselors. And on the other hand, when you look at what is happening with students of color, young African-American and Latino boys, they are being suspended and kicked out of school for a variety of reasons. Where a mental health counselor could identify what some of the behavioral issues are and really help reduce the drop-out rate tremendously if we had a larger number of mental health counselors on campus.

So let me just ask you, in terms of the violence that the chairman referred to, because I think there is—since I was a teenager, there is an increase in violence throughout the country. I am concerned about the impact of this trauma on a child's mental health, whether they are a direct victim of violence or witnessing or living in areas.

Because in my community, some of these young people I would diagnose as having post traumatic stress syndrome. They live in war zones, and that is how they function, as if they are living in a war zone because of the trauma around the violence.

Could you comment on that and how you see, how this administration sees the results of violence in terms of the trauma to the mental health of young people throughout the country?

Ms. DELISLE. If I could comment—

Mr. KINGSTON. If the gentlewoman would yield a second? You know one thing that I don't know if you can touch on it now, but among the young men of color that you referred to, they have not been the perpetrators of these slayings. Is that correct?

Ms. LEE. That is correct. You look at the statistic—

Mr. KINGSTON. And that is interesting. You know, I don't know if—

Ms. LEE. But what you would see, though, with young men of color, this becomes a pipeline from the cradle to the prison because majority of them never come back to school, and they end up in behavior that sends them into juvenile hall and then into prison.

Mr. KINGSTON. Yes, and there are other losses.

Ms. LEE. That is right.

Mr. KINGSTON. Yes, thanks.

Ms. HYDE. Mr. Chairman and Congresswoman Lee, the issue about young men of color, if I could just touch on that? I think that we tend to galvanize and get our interest up when a mass casualty shooting occurs. But as you said, Congresswoman Lee, there are young people who die every day on the streets of our cities who are disproportionately, in many cases, people of color because of the everyday violence that we experience.

And I think that is part of what your question is about this trauma that we deal with. As I said earlier, we have a long history of working in the trauma arena in SAMHSA. We have a National Child Traumatic Stress Network and program, and they have done significant work in coming up with appropriate evidence-based practices to address those issues and to be able to identify those young people who have mental health problems because of it.

There is a whole set of issues about risk and resilience factors, but there is some point at which resilience is not enough if you are exposed to violence constantly. And there is pretty good evidence that that exposure to violence, especially cumulative, has implications for both health and behavioral health issues.

Ms. LEE. What are the implications, though?

Ms. HYDE. The implications are more substance use, more suicidality, more mental health issues, more depression, anxiety, more issues in school in performance, and just the developmental growing up process.

Mr. KINGSTON. Thank you.

STUDENT SAFETY TO AND FROM AND AT SCHOOL

Ms. DELISLE. Chairman Kingston and Congresswoman Lee, I just want to add one piece to that. That is one of the difficulties we have, particularly on the way to school and on the way home from school, as you indicated, with neighborhoods. So we still know that schools are still one of the safest places to be.

However, having been in education for 38 years, I have seen the numbers of students who have passed through my own career who have been afraid to come to school. And we know that they are walking through gang-infested neighborhoods. They have experi-

ence—so even as young as 5 years old, student absenteeism becomes very high when they are living in neighborhoods, when we keep kids out of school for whatever reason, through suspensions, expulsions, or when they are self-selecting out because of walking to and from school in unsafe neighborhoods. They are missing school.

DISPROPORTIONATE IMPACT OF STUDENT DISCIPLINARY ACTIONS

Your emphasis on the school-to-prison pipeline is very real. Obviously, we have a lot of reports out about the range of students who—especially students of color and students with disabilities—who are disproportionately impacted by suspensions and expulsions.

So, at the Department, we are working really hard to put out guidance and to be sure that people are very familiar with the data, particularly with some recent data that has been released. We have been supportive of schools having a response to intervention and restorative justice programs. And we need counselors and mental health workers who are able to work with students as well as with teachers to ensure that there are behavioral supports, that they know what are the strategies to use with certain students to be sure that they are focused on learning.

Ms. LEE. Thank you very much.

Thank you, Mr. Chairman.

Mr. KINGSTON. Mr. Alexander.

STIGMA OF MENTAL ILLNESS

Mr. ALEXANDER. I used to be on the Health and Welfare Committee in the State legislature, and it was always a puzzle to me, as I made visits to sites around the State of Louisiana that took care of the mentally ill, it was always a puzzle why everyone was reluctant to talk about the problem.

Parents, every day, today we will hear somebody say, “Well, my brother has got cancer,” or “My sister has got cancer. You all pray for them,” or whatever. But we never hear anybody ask someone to be concerned about a family member that has a mental problem.

Do we find it easier today for individuals to talk about the massive problem that we have in mental health? Is it easier to talk about it today than 20 years ago?

Ms. HYDE. Mr. Vice Chairman, it is a great question, and I think short answer is, yes, it is easier today than it was years ago, but we are a long way from where we need to be. There are still a number of negative attitudes about mental health. There are misperceptions, misinformation.

There is an assumption that addiction is just a matter of will. There is an assumption that these things are moral issues and social issues rather than public health issues.

There was a time, and I am sure you recall, when cancer was not something we wanted to talk about, and we are much more willing to do that today. I think one of the positive outcomes of things like this hearing and our opportunities to talk about it is people are more willing, I think, than ever, as it is discussed, to come out, if you will, about being in recovery, having a family member who has a mental health or addiction issue and being willing to address it.

So to the extent that those concerns about how people will be treated, either in school or for adults their employment or other kinds of social relationships, if you look at the public attitudes, they do suggest that people have misperceptions about not wanting to have such individuals live in their community.

There is a public attitude that doesn't really match reality about people thinking people with mental health issues are dangerous to each other or to other people in the community. So there is a lot of misinformation still out there and a lot of concerns about having those disorders. And therefore, it makes it difficult for people to be willing to talk about it.

It is part of the reason we are going to announce a national dialogue on mental health soon is to try to be able to get the volume up on talking about mental health and addiction disorders.

Mr. ALEXANDER [presiding]. Okay. Thank you.

Ms. Roybal-Allard.

Ms. ROYBAL-ALLARD. Good morning.

Ms. HYDE. Good morning.

Ms. ROYBAL-ALLARD. Administrator Hyde, I have been very concerned about the use of psychotropic drugs to treat children with behavioral problems. And I, along with Representative DeLauro and Senator Tom Harkin, asked GAO to look into this issue. And what GAO found was that children on Medicaid are prescribed these medications at twice the rate of privately insured children and that an alarming 18 percent of foster children were taking psychotropic medications.

GAO also reported that these drugs represent the single largest expenditure in Medicaid. It was over \$2,800,000,000 in 2007. Given your mission to reduce the impact of substance abuse, what is your agency doing to address this pervasive and costly substance abuse problem? And are you building partnerships with Medicaid, the foster care program, medical specialty societies, and treatment centers to work on ways to better treat these children and avoid turning them into drug-addicted individuals?

Ms. HYDE. Thank you, Congresswoman. Thank you for the question because we are doing a lot.

We have a strong relationship with the Administration on Children and Families. They have taken this issue on very strongly, looking at psychotropic drug use among foster children.

And I am sure you know that foster children are sort of disproportionately on Medicaid. So sometimes those numbers coincide to make it also look that way for Medicaid-eligible children.

SAMHSA focuses on the right treatment at the right time. We are focusing heavily on psychosocial interventions, wraparound interventions, where ACF is very much interested in having foster parents aware of how they can get those kinds of interventions.

We are trying to monitor with them more the use of medications to see what is happening with that and trying to make sure that medication is only one part of a treatment plan. And frankly, if psychosocial interventions can happen first, that is the preference.

So we also have been sponsoring a child and adolescent psychiatric fellow from Johns Hopkins. He comes to SAMHSA once a week, and he is currently working on an issue brief regarding en-

gaging Asian-American youth in psychiatric treatment and trying to look at ways to do this without starting with medication.

So we also have a lot of work with State systems in our NCTSI, or National Child Traumatic Stress Initiative. Also looks at ways to intervene with young people who have traumatic experiences, and frankly, most foster children come to the system with some sort of traumatic experience.

So we are doing a lot, and it is our goal jointly with both the private sector professional groups as well as with our Federal partners. CMS has also been very heavily involved in this effort to try to look at both the trauma aspects, how to get more funding into Medicaid for services that are not starting with medication for children.

Ms. ROYBAL-ALLARD. Okay. One of the concerns is that there is no consistent Federal policy guidance on prescribing these drugs to children in the Medicaid and CHIP programs. So as the lead mental health agency for our country, what can SAMHSA do to encourage that alternative treatment options, such as counseling and psychotherapy, find their way into practice for these children that are in Medicaid and CHIP?

Ms. HYDE. Congresswoman, one of the things that we are doing with the association for adolescent—child and adolescent psychiatry professionals is try to develop guidance on the use of psychotropic medications. So it is frequently the professional groups that will set this guidance. We are trying to provide support in doing that, and we are also supporting a youth advisory group working with the AACAP is the acronym.

That group is providing feedback about Web site resources for youth, including the creation of youth videos. So youth by youth. Youth listen to other youth, and trying to get them more educated about psychotropic medication issues as well.

Ms. ROYBAL-ALLARD. Do I have time for another question, or is it—

Mr. ALEXANDER. I believe you have 36 seconds.

Ms. ROYBAL-ALLARD. Okay. I will just wait.

Mr. ALEXANDER. I won't be quite as strict as the chairman. But thank you.

And Members will ask questions in the order in which they came into the room. So, Mr. Joyce, Dr. Harris beat you over here. So, Dr. Harris.

Mr. JOYCE. I am leaving then. [Laughter.]

Mr. HARRIS. You chased him out. No, thank you very much.

And Ms. Hyde, I have a question for you, and I am glad we are going to open a dialogue on mental health because it is important. But part of my concerns are that as we discuss serious mental health issues in youth that could lead to problems and then link that to solutions to gun violence issues.

And for instance, in our State, they are attempting to link this by requiring that anyone who is involuntarily committed loses their right to obtain a firearm for the rest of their life. I mean, this is not—and the reason why this is significant is because part of your testimony was we have to dispel this perception that people with mental health issues are dangerous. But in Maryland, they are

about to pass a law that says someone with a mental health issue is dangerous.

We are going to add stigma instead of removing stigma. We are going to add—I think we add impediments to obtaining help rather than removing them.

Interestingly, one of the Vice President's recommendations was is that we address unnecessary barriers, including HIPAA, that prevent sharing of data. But HIPAA, the purpose of HIPAA is actually to prevent sharing of data, the—some of the most private data you have, which is your medical data.

So the quandary is how do we—and one of the reasons why we need a dialogue and haven't it because this is a tough issue. I mean, how do we address and how is your administration thinking about addressing the issue of identifying people who need help, who may be dangerous to themselves and others, but not stigmatizing those people? Because I think that is a key to getting people into the system in many circumstances.

So my first question would be how do you—how do you do that? And specifically because, again in your testimony, I will read word-for-word your testimony. "For most of these conditions," you are talking about mental health conditions, "prevention works, treatment is effective, and people do recover."

So how do we avoid a lifelong stigma attached to treatment of some of these serious issues?

Ms. HYDE. Mr. Chairman, Congressman Harris, thank you for the question. It is a great question because we share your concern.

And part of the reason we want to launch a national dialogue, and we are going to do that with Education, is to try to get at these tough issues, as you said. There is already in the Brady bill language about prohibition of individuals who have experienced involuntary commitment being prohibited from getting a gun. It is left to the States to determine whether or not there is a way out of that for the individual, and only part of the States have passed those laws to allow that.

Part of what we want to do with the national dialogue is, in fact, have fact-based conversations and make sure that we don't tie mental illness and dangerousness or violence. There is no evidence that people with mental illness who do commit acts of violence do it with guns any more than anybody else who commit acts of violence.

So people with mental health problems are not that different in that sense. What they have is a public health issue and a diagnosable illness that can be treated, in many cases prevented, and people do recover.

So that is the kind of conversation we want to have and foster. And then we want to have in each community who takes on this kind of a dialogue an opportunity to have facts to support that and also to have an opportunity to think about in their local community how will they address this issue and how will they take that on?

We want to make sure that local residents who are ordinary citizens have that part of that conversation because a lot of times, people come to that with media views of what people with mental health are, and those are not always accurate. We are also working

on some media guidelines and trying to help people get accurate facts in order to begin the conversation.

Mr. HARRIS. Thank you very much.

I appreciate that because these are—again, these are very difficult issues that we are going to have to work our way through, always being mindful that individual rights and liberties are—that is a cornerstone of America. And I share some of the chairman, before he had to leave, some of his comments that as we—in our zeal to identify people who need treatment, we have to be careful because we are empowering people to be agents of I will say agents of the State, really.

As he suggested, a teacher who refers someone for mental health is the government doing it, and we have to be sensitive to that, that that kind of perception will—I think in my mind will actually impair access at some point. Some people will be reticent to have the government involved, and we should be thinking of ways to guide some of this more into—more into mainstream medical treatment. Because most medical treatment in the United States is not delivered by the Government, and that is why I think people seek it.

Ms. HYDE. Congressman, we agree. And one of the reasons that we want to do things like Mental Health First Aid is we don't want to have someone like me treat cardiac problems, but we may want somebody like me to know when a person has the signs and symptoms of a heart attack so that we can get the right help at the right time.

So Mental Health First Aid and that whole approach to awareness and raising consciousness about this is not at all meant to have agents of the State or even the public treat people. It is to help them know when to help someone seek help and get the help they need.

Mr. HARRIS. Great. That is an important distinction.

Thank you very much, Mr. Chairman.

Mr. ALEXANDER. Ms. Lee.

Ms. LEE. Thank you, Mr. Chairman.

And I think, following up on that question, I think that is part of the reason why I am so pleased to see in the President's initiative funding to train mental health professionals. I mean, that is extremely important. And I hope this committee would support that effort because early identification of possible mental health issues is extremely important.

And teachers are hired to teach. They are not hired to be mental health counselors or psychotherapists. But teachers can know the signs and learn the signs. And if we had the mental health counselors right there on campus, the early assessment could be made, and determinations with the family could be made in terms of the course of action.

BULLYING PREVENTION

Let me ask you, Congressman Honda is chair of our bullying caucus, and I wanted to ask you about bullying because we know that there has been an increased rate of suicide as a result of bullying. And how are you—I mean, what is going on now in the country?

Are there strategies and programs to address bullying? Because this is a very serious problem that young people are faced with in all of our districts.

Ms. DELISLE. Sure. I will start there. Congresswoman Lee, I think that this is an issue which is certainly a priority for the Department as well as for schools across the country because of the issues of bullying, as you mentioned, that result in some pretty horrific events for students and for children in their lifetime.

We have a number of initiatives, including through proposals in Now is the Time, to increase programs, evidence-based programs in schools for teachers and for students and for families to engage in around the issues of bullying and school climate. And I want to emphasize school climate is so critical because when many of us have walked into school districts or schools, when we have had an opportunity to kind of just walk in the school, within 5 minutes you know whether or not you want your own child in that school.

And if the school climate is such that there is an answer of no to that question, "Do I want my own child in this school," we should not wish it for any other child in any other family.

Part of the culture of that school is creating a safe haven for students, is creating a climate in which students and teachers feel respected, and they also learn the art, if you will, of communicating with one another. And they also provide opportunities for students to learn behaviors other than bullying, and they respond to that.

So programs such as Positive Behavior Intervention Support, which is included in the proposal in Now is the Time, is one such example of increasing funds and technical support to schools to do that.

We also have been working closely with SAMHSA throughout the proposals through Now is the Time, in addition, in other kinds of ways in making sure that our kids feel safe and secure in schools emotionally as well as physically.

Ms. HYDE. And Congresswoman Lee, I would add to that that one of the things that this administration has done, from the President and First Lady, is to call on all of us to collaborate around the issue of bullying because it is such a pervasive issue. We have created a common Web site, stopbullying.gov. We had multiple Web sites and multiple places for people to get information, schools to get information, kids to get information about bullying.

We have created some cyber-bullying prevention efforts, and that common Web site is actually jointly funded and managed between HHS and Education. And within HHS, there is three operating divisions and offices that are collaborating on the editorial board about making sure that we all contribute, and then Education is providing a lot of the guidance and leadership on that.

So we are working a lot on that, and CDC and others have been doing research around what happens to kids when they are bullied and what kinds of impacts that has. You see kids with increased behaviors that are like inappropriate sexual behaviors, inappropriate eating behaviors, inappropriate substance use behaviors, in many cases tied back to bullying behavior.

So we are doing research. We are doing public information. We are doing information for teachers and parents and for youth themselves, and calling on youth also to get engaged to just say this is

not okay. It is not an okay behavior that we, as youth, want to put up with in our schools.

Ms. LEE. I will hold my next question until the next go-around, Mr. Chairman.

DUPLICATIVE VS. COLLABORATIVE PROGRAMS

Mr. ALEXANDER. Thank you.

I guess I offended Mr. Joyce.

You both mentioned and the President has mentioned new initiatives to deal with mental health. The Government Accountability Office tells us that today we have 82 teacher training programs, and it is hard for us to believe that within the programs that exist today that there is not a program that would adequately deal with the problem that lies before us.

So my question is if these new programs are authorized and financed, what current programs would they likely take the place of?

Ms. HYDE. Vice Chairman Alexander, we carefully crafted these proposals with the White House, OMB, and each other to make sure they were not duplicative and were actually collaborative. They, in many cases, build on successes that we have done at a pilot level, and we are now proposing to try to take some things statewide, to move things into a statewide approach.

In other cases, like Healthy Transitions, for example, it is a pilot to try to see if we can specifically address that very difficult transition age or what is now being called the emerging adults population because they have very specific and difficult issues. And some of them are in schools, and some of them are not.

So bringing communities and schools, parents, law enforcement, and others together is really critical. So we want to support the in-school programs, and we also want to support the community-based mental health and first responders and parents programs. So we are working very carefully to collaborate, rather than to duplicate.

Ms. DELISLE. Yes, I would just add to that, I think the strength of the proposals are really deepening our partnership, which is already existing and working really hard for schools to see that they have an ability to really deepen their partnerships in the local community.

So as I mentioned previously, I have been in education for a long time, and it has been more common practice to have schools sort of isolate themselves around the community services that are available. So part of our partnering and the proposals in Now is the Time really lift that up and cause communities to think about how do they strategize across the support structures that are needed for students in the Pre-K through 12 setting.

And in mentioning the teacher training programs, we also have to be very aware that in the teacher training programs, as Congresswoman Lee mentioned, teachers are learning to teach our youth. They are not learning all the trades and the tools that mental health workers have available to them. That is a specialty area in and of itself.

So our proposals are also linking those so that while teachers may have access to resources or to become better, I guess, identifiers of students who may potentially have issues, the real crux

here is—in the proposals—is the partnership and those community relationships. And some of them are a little bit new and deeper.

So, for example, in *Now is the Time*, we also are going to be providing \$25,000,000 to address the post traumatic stress disorders that Congresswoman Lee actually mentioned. That is a deeper program than has been issued before.

We are very careful that our programs are not just replicating themselves just in quantity, but also in quality.

Mr. ALEXANDER. Okay. Ms. Roybal-Allard.

PREVENTING UNDERAGE DRINKING AND VIOLENCE

Ms. ROYBAL-ALLARD. While we have had some success, underage drinking remains a serious public health and safety concern. Just yesterday, an article in the L.A. Times highlighted the severity of the problem, telling the heartbreak story of a young woman who was raped while she was intoxicated.

For years, members of this committee, including Rosa DeLauro, Frank Wolf, and myself, have worked to provide SAMHSA with resources to prevent underage drinking through the STOP Act, and we have watched with disappointment and with a great deal of concern as much of the school substance abuse prevention money has been reduced or eliminated.

Administrator Hyde, can you speak more to the relationship between youth alcohol abuse and violence, where you have seen the most success in preventing youth alcohol abuse and why, and what else needs to be done?

Ms. HYDE. Thank you, Congresswoman Roybal-Allard, and thank you for your support of the STOP Act and for these issues.

As you know, we have reinstated this year, or last year, the ICCPUD. It is sort of the worst acronym in the Federal Government. But it is the Interagency Coordinating Committee on the Prevention of Underage Drinking. It comes out of the STOP Act, and we reinstated it at the principal level. It had been working at the staff level, but really to try to raise these issues.

The connection between youth and students who are drinking and causing violent behavior, it is usually one-on-one or individual violence, but nevertheless, about 696,000 students between the ages of 18 and 24 are assaulted by another student who has been drinking each year. These are 2009 data. About 97,000 students between the ages of 18 and 24 are victims of alcohol-related sexual assault or date rape.

So this is a huge issue. We have seen major gains about the reduction of underage drinking in certain age groups. So the 12- to 17-year-old age group, binge drinking is actually quite—is down quite a bit, about 30 percent over the last few years. The 18- to 24-year-old age group, not so much. We haven't seen those kinds of reductions. We also see continuing deaths from alcohol-related injuries by car, by vehicle or by accident when a young person is intoxicated.

So the STOP Act is an important part of our portfolio. Part of it is this interagency working effort we have. We have launched this year a webinar series that has gotten incredible reaction to try to get information out about underage drinking and how the data that we put into the congressional report, which is funded by the

STOP Act, has become a really important tool to the field and to communities and to organizations like our drug-free communities, prevention programs that are focusing on substance abuse among young people, including alcohol.

So the STOP Act itself has funded about 180 communities, and last year, we did an additional 81 grants, and we expect about 15 new ones this year. You can see that the numbers are lower in part because of the reduction in dollars that have occurred over the last couple of years. I think Congresswoman Lee read those numbers.

So we provide as much funding and as much support, and the webinar series is a way to try to get word and information out short of calling people together in conferences and other ways that we might have done that in the past, but to try to continue to get our efforts around underage drinking dealt with.

We also know, frankly, that young people who don't drink until they are older, until they are 21 or older, are much less likely to have problem drinking as an adult. So it is a critical issue not only for our young people, but for adults as well.

SCHOOL-BASED ALCOHOL PREVENTION STRATEGIES

Ms. ROYBAL-ALLARD. Okay. Assistant Secretary Delisle, can you talk about what is being done in the schools to address underage drinking with I understand your limited resources as well? And what more could be done if you did have adequate resources?

Ms. DELISLE. Thank you, Congresswoman, for that question.

I think one of the issues in schools is always providing information to students and to their families. Not just about the data around the inappropriateness and the legal ramifications of underage drinking, but certainly the health-related risks as well.

In my experience in viewing schools across the country, they rely heavily on school counselors to help with that information gathering, providing support structures for teens. We have seen some examples of schools that actually have created student support groups and also have created community events so that students have a place to go that are non-alcohol related.

So even in the high school years, they may have a prom or after prom activities that are totally devoted and are ensuring that the students who come there are committed to an alcohol-free life.

So the proposals that we put forth to increase counselors in the schools would certainly help to provide that information, as well as to help bridge the gap with communities that are facing the 18 and up group to which Ms. Hyde referred.

BUDGET REQUEST FOR HEALTHY TRANSITION GRANTS

Mr. ALEXANDER. Mr. Joyce.

Mr. JOYCE. Thank you.

Administrator Hyde, I would like to thank you for coming today and ask you about when you were speaking about individuals 16 to 25 being at high risk for mental illness, substance abuse, and suicide, at the same time, these are the least likely group to actually go out and seek help.

I see that the administration arrived at a \$25,000,000 funding level for State-based strategies to support these young people. How did you arrive at that number?

Ms. HYDE. What we were trying to recognize is that this age group has special issues—system issues, legal issues, and just coming of age issues. We have other programs in about that age or about that cost range that will allow us to pilot and do a pretty good demonstration to determine what is the best way to approach those kinds of issues.

We have some programs here and there that do transition age youth, but it's not been a focus. So what we are trying to do is use these dollars to pilot in a few States what would be the best approaches. So anytime we start a new program like this, we do an extensive evaluation and then try to make sure that we have got the best programs and the best practices before we try to take it to scale.

Mr. JOYCE. With the other things that you have been doing, do you have any idea what your success rate is as far as getting kids to attend and be involved in these type of things?

Ms. HYDE. Our programs, whether it is our Drug-Free communities program or whether it is the Safe Schools/Healthy Students program or any of them, show incredible success. When you engage young people, you can reduce the perceptions of violence as well as the actual violent behaviors. You can reduce the drug use, and you can reduce the violence associated with that drug use or that alcohol use.

So, on any particular program that we have in place now, we do have data, and we can share that with you if you have a particular interest in a particular program. Or if you would like some information just in general about what we are seeing in those programs, we can let you know.

Mr. JOYCE. Thank you.

IDENTIFYING STUDENTS WHO HAVE MENTAL HEALTH ISSUES

Assistant Secretary Delisle, thank you also for being here today. It is easy for teachers to be able to tell when somebody has a fever. What are we doing to assist teachers in trying to pick out those who might be having mental issues?

Ms. DELISLE. Congressman Joyce, it is actually nice to become reacquainted with you. I actually worked in the West Geauga local school districts, and we had some interactions with your office. So it is nice to become reacquainted with you.

Mr. JOYCE. I recall.

Ms. DELISLE. Yes. [Laughter.]

I was going to say it wasn't always under the best of circumstances. Not on your condition, it was because of some of our folks.

Anyway, I think one of the things we discussed a little bit earlier and was provided in my testimony is that it isn't easy for a teacher to do because they are not naturally trained in that. And as Congresswoman Lee has mentioned, that is not their area of expertise.

So the more that we can provide knowledge and resources to teachers, the better. So what are these indicators? And then have them be able to connect with a mental health provider who can follow up on that and just suggest whether or not that is something that we ought to look at a little bit closer, or it is developmentally appropriate for that student to be behaving in that kind of way.

What is even more important, though, is not just that diagnosis or that recognition of that mental health disorder, but also how the strategies that a teacher may use within the classroom to more certainly engage that child in a productive kind of way. That is what is really necessary.

So we look to mental health providers to provide that information, that knowledge, and resources to students as well as to their families because sometimes families don't know how to cope with a child who may have a mental health disorder.

Mr. JOYCE. And you know why this is of special interest to me after what took place in Chardon?

Ms. DELISLE. Yes.

EFFECTS OF VIOLENCE IN VIDEO GAMES

Mr. JOYCE. And that is why I want to know what—also you had, Ms. Hyde, you had talked before with the chairman about violence in programming. What about has there been any studies done on violence in video games and its effect on teenage?

Ms. HYDE. Congressman Joyce, that was the question the Chairman asked me, and it is not my area of expertise. So I actually don't have the information here about that. I know that there are other parts of the department that are looking at those issues. So I would—we can get back to you about who might be the right individual to have talk to you about that.

Mr. JOYCE. Do you have any input on that, Ms. Delisle?

Ms. DELISLE. I would say the same. [Laughter.]

Mr. JOYCE. Well, it is of special interest to me, obviously, because there is a combination. Obviously, there are some mental health issues, and there is also some issues with the violence that you will notice that between the video games, the fact that—and Hollywood. But in video games, the fact that they re-spawn, and all of a sudden, 60 seconds later, 30 seconds later, I don't know what that is, but then all of a sudden, these kids come back.

And in that case particularly where this young man shot the people in the high school, the first thing he asked was "Why did you do it?" "I don't know why." And wanted to have that moment back in time.

Well, because I really think that it is on top of having some mental issues that there is also a play of how much violence these kids are getting used to, and it is not right. So any help you could give us in that area, I would really appreciate it because it is something I am very interested in.

Thank you.

Mr. ALEXANDER. Thank you.

AMOUNT OF FEDERAL FUNDING ON MENTAL HEALTH IN EDUCATION

What percent or what is the total amount spent by the Federal Government on mental health in education? Do we know?

Ms. DELISLE. Congressman, I do not have that number. We could certainly get that back to you and combine all of our programs out of Ed, but a starting estimate would be \$50 million.

Mr. ALEXANDER. Thank you.

Ms. Lee.

Ms. LEE. Thank you very much.

MENTAL HEALTH TREATMENT MODALITIES USED IN SCHOOLS

There are a couple questions I would like to ask, and you probably would have to send this to the committee, the answer to this one. But I am interested in knowing what the treatment modalities now that are being used in schools in terms of mental health treatment.

I mean, I was trained way back in the day in psychoanalytic psychotherapy, play therapy, behavioral therapy. Is there any—and I know it depends on the diagnosis or the kind of plan, the treatment plan. But I am curious now to know what the primary mode of treatment is for young people.

Ms. DELISLE. Congresswoman Lee, actually, within schools, what we see is that the treatment occurs outside of schools with mental health professionals in a specific setting. What we see happening in schools is sort of what I would view as the secondary approach, and that is so everything from play therapy, et cetera, that is being used to support what occurs with that provider on the outside of the school.

Ms. LEE. I see.

Ms. DELISLE. So that interaction and that information sharing is really critical.

Ms. HYDE. Congresswoman Lee, there is a program that was initially researched by NIMH, the National Institute of Mental Health, with very good results, and we have with Education implemented it in many school settings. And that is something called the “Good Behavior Game.” It is a program that is a preventive program. It trains teachers how to deal with behaviors in the classroom.

And there are incredible results for both the teachers and the young people. That is more of a preventive intervention, but it is—and it is child specific. So that is an example of something—

Ms. LEE. I would like to learn more about this.

Ms. HYDE. Okay.

IMPACT OF FUNDING CUTS ON PROGRAMS

Ms. LEE. Let me ask you about going to the funding. I mentioned in my opening statement funds have been cut between 2010 to 2012 for SAMHSA, what, 5 percent? Now, on top of that, we have got sequestration. Funding now is about a fifth lower than 2002.

Tell me what is going on with regard to funding, and how you are going to—what the impact of sequestration is on children’s mental health programs and services? Knowing that we are nowhere near where we need to be, does this mean we go backwards again, or what do we do at this point?

Ms. HYDE. Congresswoman Lee, obviously, all of our programs are programs that are showing good results in what they do. And if they don’t show good results, we don’t continue them. So any program that sees a reduction means it is less that we can do for the communities in America.

In some cases, sequester will result in fewer new grants. I gave you an example of that with the STOP Act grants that we anticipate this year. In other cases, it is literally fewer people who will

be able to get substance abuse treatment or other kinds of services that support people getting those treatments.

For the last 3 years, we have taken the responsibility to consolidate, make sure that programs that are able to be more efficient and more effective can be done in a different way. So we have done everything we can to reduce expenditures without reducing impact on programs.

We are at the point where that is no longer possible. So additional reductions are going to mean reductions in grants and programs and our public efforts, our public education efforts, and our efforts at outreach and our efforts at data collection, et cetera.

Ms. DELISLE. So, Congresswoman Lee, I would add to that that in the President's 2013 budget, it actually included \$196,000,000 for a Successful, Safe, and Healthy Students program that was part of the ESEA reauthorization proposal. And much of that was really focused in on supporting students in schools both with mental health issues as well as creating these positive support structures that I place.

So, like SAMHSA, we are very concerned with sequestration about the possibilities of grants being reduced and funding available to schools. So, for example, in our Project SERV program, we actually provide dollars to the local school district. So when there is an incident that occurs, a shooting such as in Chardon, Ohio, when learning is interrupted, we provide dollars for mental health workers to support the students and the educators.

But the other concern that I have is almost a secondary one, which is, for example, in Title I, which serves our poorest children, particularly in the areas of reading and mathematics, while that is focused on an academic venue, what my concern is that with that lowered, lessened services to students in the academic field may, in fact, yield more behavioral incidents in schools when students become frustrated because they can't read or they can't catch up with their academics.

So there is also a secondary component that is really critical.

Ms. LEE. Thank you very much.

Mr. ALEXANDER. Dr. Harris.

Mr. HARRIS. Thank you very much.

ALARMING TREND IN YOUTH SUICIDE STATISTICS

Ms. Hyde, let me just talk about another topic that people don't like to talk about. We need to talk about it because a lot of people are concerned, and that is teenage suicide.

It is of concern to me that the CDC report last year indicated that if you look at children who either attempt or complete suicide, that the incidence over the past few years from they looked at data from 2009 to 2011, actually increased about 20 percent, where just under 8 percent of teenagers say they either considered or attempted suicide.

And interestingly enough, the highest incidence are Hispanic girls, which is interesting, and I am not sure what the explanation is. But it actually gets to the point, two points and two questions.

One is whatever we are doing, it is not working because the incidence is going up. As we continue to spend billions of dollars, I mean, the incidence is going up. And I guess the questions are re-

lated. In your opinion, what is the cause of the increased incidence, and why haven't our strategies worked for that particular topic, teenage suicide?

Ms. HYDE. Congressman Harris, thanks again for that question.

You may be aware that over the last couple of years, there has been a public-private partnership called the National Action Alliance for Suicide Prevention that was kicked off a couple of years ago by Secretary Sebelius and Secretary Gates because we are also concerned about this issue, obviously, among military personnel and veterans and their families.

That effort has spent 2 years with the Surgeon General updating something the Surgeon General just released last fall called the "National Strategy for Suicide Prevention." And in that strategy, we looked at young people. We looked specifically at Native Americans. We looked specifically at military personnel, and we looked a number of other groups.

We also brought together the different players in the Federal Government who do the data about this. So CDC tends to do the mortality data, and SAMHSA, frankly, does a lot of the data around thoughts, plans, and acts to commit suicide, but may not result in actual death.

So we have been able now to combine those data to get a better picture of young people who have higher rates of attempts and thoughts of suicide. Frankly, older people, older men have attempts that result in death.

So we are sort of looking at the whole range. There is a different approach when you are looking at the distress of young people that results in the kinds of attempts and acts and thoughts versus the actual result in death.

We also have done an increasing amount of work, at least in SAMHSA, to address the Latina, young women of Hispanic background. About 25 percent of our Garrett Lee Smith grantees are specifically focused on this community. So I think there is looking at the data, that is a community that has a higher incidence of those kinds of thoughts and actions, and we are trying to look at it from young people before college, but also on college campuses and that age group that is specifically addressed appropriate there.

Why has it not worked? I think that is part of what we have learned through the interagency and public-private partnership from the Strategy and the Alliance. And I think what we know is intervening early. I think we know that there are a lot of individuals who don't know the signs and symptoms. So right in front of you can be a young person who is exhibiting signs and symptoms, but either a parent or teacher or a faith leader doesn't know what kind of outreach to do.

There are youth who don't know how to reach to other youth, and they are some of our best early interveners to get help for young people. And then, frankly, young people as well as older people who attempt and enter hospitals or enter emergency rooms after an attempt are at high, high risk of repeat attempts and death from suicide.

So we are also looking at hospital emergency rooms, readmission rates, connections, and care coordination once they leave there. Those are the kinds of issues we are also trying to look at.

The National Action Alliance set a goal of a reduction in over 5 years of a specific set of numbers, which is not in my head at the moment. But so we are really trying to look at the metric and trying to get those numbers down.

Mr. HARRIS. And what—are there any proposals—has this alliance actually come forth with their proposals yet? I mean, because this trend is not a new trend. My understanding is this trend started around the middle of the last decade, and after gradually dropping off, it started to increase.

And you know, the CDC data is not just mortality. CDC data is attempt or complete. So this is not new data. I mean, how long is it going to take for us to actually be able to do something?

We spend a lot of money on this. We spend millions and millions of dollars on some of the grants you suggest. Is there a realistic possibility that we can actually reverse this trend?

Ms. HYDE. Congressman Harris, again, we collaborate with CDC and use each other's data. So they do use some of our data on the acts and completions—I mean the acts and the thoughts. And what we are trying to look at there is what is the trend compared to what is going on in the environment?

So, frankly, as the economic issues have been more dire, we have seen some of the rates go up. We are also trying to look at what that data, the mortality data comes a little later than the data about thoughts and actions. So, yes, the Action Alliance has actually put out some recommendations and the strategy has very explicit things.

It just came out last fall, and we are now in the process of implementing. And as I said, there is a commitment at the public-private level as a metric to reduce those numbers in a certain period of time. We can get you that metric. I just can't pull it out of my head.

Mr. HARRIS. I would appreciate that. Again, and the report, any reports you have from the alliance. I would appreciate that.

Ms. HYDE. Okay.

Mr. HARRIS. Thank you very much, Mr. Chairman.

Mr. ALEXANDER. Fiscal year 2012, \$117,000,000 was devoted to mental health. The fiscal year 2013 request from the President was \$88,000,000. That is quite a bit less, and the President now is proposing after a response or in response to the Sandy Hook tragedy to train an additional 5,000 mental health providers.

And another aspect of the President's proposal includes devoting \$25,000,000 to State-based strategies on young people between the ages of 18 and 25. So the question is for those 17 or 18 to 25 that are no longer in school, how do we propose reaching them?

Ms. HYDE. Congressman Alexander, there are actually two parts to your question. The first part, I think, refers to our program, which is called the Children's Mental Health Initiative. It is a program that has been in existence for a number of years. We have done a lot of evaluation, and it is a great program. We have developed models that help us know now that we need to push those out across the country.

So in the same President's budget, there was actually a proposed increase in the Mental Health Block Grant, and what we were trying to do was say, okay, we have proved the process and let us

begin to move it to scale by moving it throughout all the States, not just in the communities that we could fund. So there was a rationale to the way that set of proposals was proposed.

You asked a second question, and I have just lost it. Was the second part of your question was?

Mr. ALEXANDER. How do we reach those that are no longer in school?

Ms. HYDE. Ah, okay. The Healthy Transitions project then is proposed as what we call our "theory of change," actually. It is once we prove a program works for a specific set of kids, and the Children's Mental Health Initiative was for young people with serious emotional disturbances. We now see a set of young people who are moving from the child-serving system to the adult-serving system, moving out of school, sometimes into community colleges or colleges, but not always, and have a very different set of structures to deal with.

So what we want to do now is do some pilot work to see what is the best approach for serving those young people and do the evaluation that we have done on some of the other programs that have been in place for a while.

Mr. ALEXANDER. Ms. Lee.

Ms. LEE. Let me ask you, going back to the funding and the impacts, your response in terms of the sequester really is very scary because we are talking about what we need to do in the future. So I don't know what is going to happen to these kids. I just don't know.

So I want to hear from you what you think could happen and what we need to be prepared for in all of our communities. And then, secondly, the President's plan that he is putting forward, it has, of course, funding requirements. Is this going to be in his budget? I mean, he is going to request it in his budget, right, and this will come before this committee?

I mean, well, we are going to have to appropriate some funding for the President's plan, right? Okay. Now can you make the case for that?

Ms. HYDE. Congresswoman Lee, I can speak to the proposals on the mental health side, and Assistant Secretary Delisle can speak to the education programs.

The case for it I think we have been talking about in this hearing, and you have offered us an opportunity to do that, which is to try to take a program called Safe Schools and Healthy Students that we did a lot of good work on together over the last several years. We are taking that program, along with a new concept, the Mental Health First Aid, and packaging those together to try to take to scale in a few States a program called Project AWARE.

And what that will do is bring what we learned from the Safe Schools/Healthy Students program and put it together with Mental Health First Aid to get awareness up, to get communities and schools working together across a State, and to take it to scale in the State. See if we can do that. See if we can go from the projects to the scale.

The second project we just got through talking about is the Healthy Transitions Program, which is really trying to address that transition age youth. If you look at a number of the mass incidents

or mass casualty incidents, it is this age group that is involved. Not always, but some of them are.

We are not suggesting that we are trying to prevent those issues, but we do know that that age group has particular issues. It is when some of the first psychosis tends to happen. It is when, we have already talked about, there is more incidence of issues and less help seeking.

We know that parents are less involved as kids become adults. They are less able to influence children's behavior sometimes. So we are trying to look at all those issues and see what that can mean.

And then the third program is the workforce program, and we just produced a report that was requested by Congress, gave it to Congress last week, that sort of delineates the need for a health workforce of all sorts everywhere. It is not just in one place, but it is really a workforce that needs to be produced more.

Ms. LEE. Okay. So what happens, though, to the damage done by sequester? You know, I mean, I want to support and make sure all of the President's initiatives are fully funded.

But now we have a problem with the lack of funding for those who have been just sort of left outside of the service realm because the cuts have taken place. So what happens to them?

I mean, do you double down on the new programs? Do you increase it by 50 percent? Do we look at how to make up for lost time and lost services and lost children? I mean, how do we deal with it?

Ms. HYDE. Congresswoman Lee, we do the best we can with the dollars that Congress appropriates to us. And to the extent that the sequester has reduced programs, we are going to see fewer people treated. We are going to see fewer professionals trained. We are going to see fewer individuals informed about their ability to make a difference in this.

We are going to see less ability to train teachers. All of those things are going to happen across the board for the programs under the sequester reductions.

Ms. LEE. Yes, so it seems to me that the dollar amount that the President is requesting is not enough, quite frankly.

COLLABORATION BETWEEN SCHOOLS AND MENTAL HEALTH PROVIDERS

Mr. ALEXANDER. Mr. Joyce.

Mr. JOYCE. Thank you, Mr. Chairman.

Again, Assistant Secretary Delisle, if you would, could you explain what has been taking place, what outreach has been made in trying to encourage collaboration between school systems and local mental health facilities? And you may have answered that, and I may have been missing. And I apologize.

Ms. DELISLE. Thank you, Congressman Joyce.

I think we have had a lot of impact in modeling, first of all, at the Federal level about our own initiatives across not just with SAMHSA, but also with the Department of Justice. We have cosponsored some learning sessions. We have cosponsored some webinars. We have cosponsored some summits.

For example, we had a bullying summit last summer, which was highly effective in getting people to really discuss a very critical issue. So, first of all, we are modeling that at the Federal level.

At the local level, many of our grant programs actually have a requirement in them that communities and schools partner over a variety of issues, such as mental health issues, such as counseling, such as family support structure, such as family engagement.

So we have made that a priority in the Department for schools to actually reach out into the community to support the programs and to support the learning needs of all students.

Mr. JOYCE. That is fantastic. Is there any way to measure the outcomes of whether or not we are actually getting something accomplished?

Ms. DELISLE. Well, to the extent possible, Congressman, that we could measure the numbers of meetings and interactions, we will be looking at that. So even through our ESEA flexibility waiver packages, the States even had to arrive at ways in which they would reach out to schools, et cetera, and engage community members in those plans.

So we will be looking at that. I don't know if we will be able to actually collect data on the effectiveness of them because it is a pretty hard variable to isolate. But certainly, the numbers of interactions would be one that we could measure.

Mr. JOYCE. Great. Thank you.

I would yield back, Mr. Chairman.

HIGHER RATES OF ATTEMPTED SUICIDE BY LATINA YOUTH

Mr. ALEXANDER. Ms. Roybal-Allard.

Ms. ROYBAL-ALLARD. I want to go back to the previous issue that was raised by Dr. Harris with regards to adolescent suicides and add to the previous discussion with regards to Latina youth suicide. Because for the past 20 years, adolescent Latinas have had significantly higher rates of attempted suicide, and in 1995, it was reported that 1 in 5 reported a suicide attempt.

And recently, rates among adolescent girls have decreased. However, the Latina population has continued to have higher rates even than their African-American or white counterparts. More staggering is that for every 1 suicide death, there are reports of 8 to 15 attempts. And some of these cases are being seen in girls as young as 12 years of age.

So I just wanted to make the point that there is a real need for specific programming and extensive research focused on why Latinas are at a higher risk for attempted suicide. I really don't have—I have a question, but I just wanted to get that on the record.

Also, Administrator Hyde, for all of these issues that we have been discussing today, it is critical that we have a culturally and linguistically competent mental health workforce. In its Gun Violence Task Force recommendations, the administration has proposed \$50,000,000 to train more than 5,000 additional mental health professionals to serve students and adults.

And the proposal seems specifically designed to train more social workers, counselors, and psychologists. Can you give me a sense of how these resources will be allocated? For example, will money be

going to the National Health Service Corps? Is the administration proposing any new funding at all for the SAMHSA Minority Fellowship Program?

How is all this money going to be distributed and where?

Ms. HYDE. Congresswoman Roybal-Allard, yes. We are—a portion of the workforce proposal is specifically to double the Minority Fellowship Program that we do. It is currently a very small program, about \$5,000,000, but it gives us a lot of special efforts at increasing those professionals that are from those populations that are least well served.

We want to double it and focus the Minority Fellowship Program on a youth-serving population, not always under 18, but that young adult population. We want to try to get at that and encourage that. So that is another—that is a \$10,000,000 program.

Then \$35,000,000 of the program will be collaboration with HRSA, which is using its authority, it has a mental and behavioral health authority, to put specific grants out to develop new professionals in the groups that you said. We are focusing with them on those professionals that will be clinically trained. We can produce Ph.D.s as well, but sometimes the Ph.D.s are teachers or trainers.

And while we need those as well, this particular project is trying to focus on master's level individuals who will be clinically trained and work directly with young people and their families.

Then there is another part of the project that is for peers. So paraprofessionals and peers we know have a great capacity to engage, to do recovery supports, and to do some of the other really critical services that, frankly, especially for young people, a peer can do much better in many ways than the licensed professional, clinically trained folks.

So it is a combination, and we packaged this program with HRSA carefully to try to produce as many as we could with the dollars we had available in a 2-year period. So it is all of those things.

Ms. ROYBAL-ALLARD. Okay. I have just a few seconds left. So I didn't know if you wanted to comment on my previous comment on the Latina issue?

Ms. HYDE. On the Latina issue? Oh, yes, we have a very strong program that we call the National Network to Eliminate Disparities, and a couple of years ago, we also created an Office of Behavioral Health Equity. And the National Network to Eliminate Disparities in Behavioral Health, which we call NNED, has worked with the Human Interaction Research Institute and the Valley Nonprofit Resources to offer 20 of our NNED organizations, there are about 500 in the network. It is a learning community.

And we have specifically worked on coaching Latina multi-family group therapy and taken an organization or a program called a multi-family group program. It is based on a well-validated program and really tried to push it out. So we are trying to identify programs that work and then trying to help minority providers be able to push that out as well.

So we are trying to create more minority providers. We are trying to support them, train them, and then trying to take evidence-based practices and get it out as well.

Ms. ROYBAL-ALLARD. Okay. Thank you.

Mr. ALEXANDER. No more questions. We want to thank you all for being here today, and I would like to thank the committee members for engaging in a very productive committee hearing.

And I would remind the committee members that we have another meeting scheduled April the 10th. What time is it? At 10:00 a.m., April the 10th.

Okay. The committee stands adjourned.

Thank you.

[The following questions were submitted for the record.]

Department of Labor, Health and Human Services and Education and Related Agencies

Oversight Hearing FY 2014: Children's Mental Health

March 20, 2013

QUESTIONS TO BE SUBMITTED FOR THE PUBLIC HEARING RECORD

From SAMHSA

Chairman Jack Kingston

1. *Administrator Hyde, please describe the current plans for establishing a national dialogue on mental health. What will be the central themes of the messaging and how will it be disseminated?*

Response: On January 16, 2013, President Barack Obama directed Secretary Kathleen Sebelius of the U.S. Department of Health and Human Services and Secretary Arne Duncan of the U.S. Department of Education to launch a national conversation on mental health to reduce the shame and secrecy associated with mental illness, encourage people to seek help if they are experiencing mental health problems, and encourage individuals whose friends or family need help to connect them with help for mental health issues.

Mental health problems affect nearly every family. Yet as a nation, we have too often struggled to have an open and honest conversation about these issues. Misperceptions, fears of social consequences, discomfort associated with talking about these issues with others, and discrimination all can keep people silent. Meanwhile, if they get help, most people with mental illnesses can and do recover and lead happy, productive, and full lives.

The President, Vice-President – along with Secretaries Sebelius, Duncan, and Shinseki – began this conversation on Monday, June 3, 2013 with a White House National Conference on Mental Health. The conference brought together people from across the country, including mental health advocates, educators, health care providers, faith leaders, members of Congress, representatives from local governments and individuals who have struggled with mental health problems, to discuss how we can all work together to reduce negative attitudes and help the millions of Americans who have struggled with mental health problems recognize the importance of reaching out for assistance.

At the conference, the President announced that the Department of Veterans Affairs is directing 151 of its health care centers nationwide to conduct Mental Health Summits with community partners, including local government officials, community-based organizations, and Veteran Service Organizations starting July 1 through September 15. The Summits will identify and link community-based resources to support the mental health needs of Veterans and their families, as well as help increase awareness of available VA programs and services.

Increasing awareness of mental health issues and making it easier for people to seek help will take much more than the efforts of the federal government. So on June 3, the Administration

applauded the dozens of commitments made by organizations representing media, educators, health care providers, faith communities, and foundations to increase understanding and awareness of mental health. Some examples of these commitments are as follows: The National Association of Broadcasters, made up of local television and radio stations across the country and the broadcast networks, is developing a national public awareness campaign to reduce negative attitudes and perceptions about mental illness through television and radio ads, and social media. A number of organizations that work with young people are making new commitments – from secondary school principals across the country holding assemblies on mental health awareness to the YMCA teaching its staff and summer camp counselors to recognize the signs of depression and other mental health issues in kids. A diverse group of communities of faith have committed to launch new conversations about mental health in our houses of worship. This is just the tip of the iceberg. Medical professionals, foundations, technology companies and many others are launching new efforts that will make a difference. Communities across the country are organizing conversations to assess how mental health problems affect their communities and to discuss topics related to the mental health of young people.

In addition, HHS has launched www.mentalhealth.gov, an online resource for people looking for information about signs of mental illness, how individuals can seek help, and how communities can increase awareness around these important issues. The online resource will include videos (a mix of celebrities and every day citizens) who share their stories about mental illness and recovery. HHS will manage a social media campaign to continue to drive traffic to the site after the initial launch.

The goals for the online campaign include:

- 1) Help parents, young people and those who work with young people identify and talk about mental health challenges;
- 2) Find help when needed;
- 3) Provide people with information they can use in local conversations about mental health; and
- 4) Share stories and hope of recovery through videos from “real people”.

The ensuing national conversation will give Americans a chance to learn more, from research and from each other, about mental health issues. In addition, communities across the nation are organizing community conversations to assess how mental health problems affect their communities and to discuss topics related to the mental health of young people.

Ranking Member Rosa DeLauro

1. *What programs at SAMHSA’s Center for Mental Health Services are targeted to children and adolescents? What do these programs do, and what can you tell us about their performance and impact?*

Response: SAMHSA’s Center for Mental Health Services’ (CMHS) portfolio of programs to address mental health needs of children and adolescents reflects a continuum of services from prevention and promotion (e.g., Safe Schools/Healthy Students, Project LAUNCH,

Suicide Prevention) to intensive treatment (e.g., Children's Mental Health Initiative, National Child Traumatic Stress Initiative). All of the CMHS programs collect evaluation data and many produce specialized reports. These data and reports demonstrate significant effectiveness across process measures such as numbers served, collaborations across child serving agencies, improvements in policies, and use of evidence based practices, as well as outcome measures such as reductions in suicidal ideation and attempts, increased attendance and performance in school, stabilization of living situations, improvements in emotional and behavioral functioning, and reductions in contact with law enforcement.

Safe Schools/Healthy Students (SS/HS) has been an unprecedented collaboration between three federal departments: HHS/SAMHSA, ED, and the Department of Justice. Started in 1999 in response to a series of school shootings, SS/HS was created to identify problems early and intervene early and constructively to alter the course of children's lives. Since the program's inception, 365 local education agencies have received SS/HS grants with a cumulative federal investment of \$2.1 billion. The initiative is science-based and offers a comprehensive, multi-disciplinary approach. SS/HS grants support the creation of safe and violence-free schools by promoting early childhood social emotional learning and development; promoting mental, emotional and behavioral health; connecting families, schools and communities; and preventing and reducing alcohol, tobacco and other drug use. Extending early intervention services to children and youth prior to a formal diagnosis as a prerequisite for services has been especially important.

Results of the national evaluation show that more than 90 percent of school staff saw reduced violence on school grounds and nearly 80 percent reported that SS/HS had reduced violence in their communities. The program has seen significant increases in the number of students who received school-based mental health services, and community-based services. Nearly 90 percent of school staff stated that they were better able to detect mental health problems in their students and more than 90 percent of school staff reported that they saw reductions in alcohol and other substance use.

The Linking Actions for Unmet Needs in Children's Health (Project LAUNCH) initiative was developed in 2008 by SAMHSA to promote the physical, social, emotional, cognitive, and behavioral health of young children, birth to eight years of age. In order to facilitate effective collaboration among mental health and public health systems that can lead to a comprehensive range of services to children, families, and communities, the initiative has the dual focus of improved systems and services. Specifically, the Project LAUNCH framework encourages communities to 1) make infrastructure changes that improve coordination and collaboration across child-serving systems; and 2) implement evidence-based programs and practices that prevent mental, emotional and behavioral disorders and promote healthy development of all young children. Using a public health approach, Project LAUNCH seeks to improve outcomes at both community and individual levels by addressing risk factors that can lead to negative outcomes, as well as promoting protective factors that support resilience and healthy development which can protect individuals from later social, emotional, cognitive, physical and behavioral problems, including early substance and alcohol abuse.

Since inception, over 58,000 children have received screening and assessment, including developmental screenings with an emphasis on social/emotional development. Nearly 8,000 families have been served by voluntary participation in enhanced home visiting services including the expansion of evidence-based home visiting programs, and training and mental health consultation for home visitors to increase knowledge of mental health issues and capacity to work with families with complex behavioral health challenges. Approximately 4,000 child care providers and teachers, and over 2,500 primary care providers, have received mental health consultation to help assess, identify and address developmental and/or behavioral challenges experienced by a child or family in their care. And nearly 6,000 new partnerships have been developed at the community, tribal, and state levels in an effort to improve the systems serving young children and families and build prevention infrastructures.

The following are examples of preliminary child outcomes and indicators for some specific Project LAUNCH communities:

- 1) DC: During June 2010 – June 2012, mental health consultation was implemented in 25 community-based child development centers (CDCs) in all areas of the city. Out of the 1,300 young children served each year across the 25 CDCs, only 3 children were expelled per year, a rate which is less than half of the national average of 6.7 children per 1,000 served in pre-kindergarten (Gilliam, 2005)
- 2) Kansas: Incoming 4 year olds that participated in Project LAUNCH programs were compared to non-LAUNCH students in Finney County. School readiness scores from 2008 and 2010 on the Kansas Early Learning Inventory-4 (KELLI-4) for both sets of students were included in the analysis. The overall results indicated that there were statistically significant improvements in the developmental areas measured by the KELLI-4 between 2008 and 2010, specifically in the areas of general knowledge and physical development.
- 3) New Mexico: Parents participating in a 3 session parenting group showed statistically significant increases in positive parenting practices two months after their final meeting, including decreases in negative practices such as shouting/shaming and getting angry/annoyed. Mothers participating in a 6-week Maternal Depression group had a decrease in level of maternal depression and suicidal thoughts as measured by the Edinburgh Postnatal Depression Scale (EPDS). For example, the number of mothers reporting suicidal thoughts dropped from four mothers before the group to zero mothers after the group was completed.

Implementing Prevention Practices in Schools is a pilot program to implement a behavioral classroom management strategy with the short-term goal of reducing early aggressive and disruptive behavior in the classroom by socializing children in the role of students which helps children learn how to work together and with the teacher and create a positive learning environment. Thirty years of longitudinal research on programs similar to the Implementing Prevention Practices in Schools has shown long-term outcomes of reductions in illicit drug use, suicidal ideation, and the development of conduct disorder and antisocial personality disorder.

Now in the second year of the pilot program, 19,221 students are participating in this evidence-based program. In addition, 124 coaches and 889 teachers have been fully trained in implementation of the program.

The National Child Traumatic Stress Initiative (NCTSI) improves access to high-quality services throughout the United States for children, families, and communities who have been exposed to trauma. SAMHSA funds the National Child Traumatic Stress Network (NCTSN), a national network of centers specializing in trauma-focused treatments and trauma-informed service delivery. In 2012 alone, NCTSN trained 20,128 professionals and over 120,000 individuals. Since its inception in 2001, more than 17,000 children have received clinical services as reported in the NCTSN Core Data Set, and over 1.1 million people have been provided training or education in assessment and treatment of traumatic stress. Thousands of additional children have received NCTSN services. Today, the NCTSN is composed of 104 total centers (including affiliate members), 78 of which are currently funded centers.

NCTSN client-level data shows that the outcomes of children receiving evidence-based treatments, Trauma Focused – Cognitive Behavioral Therapy and Attachment (TF-CBT), and Self-Regulation and Competency (ARC) Clinical Service in NCTSN centers improved over time. For example, 2010 data shows that the percentage of children and adolescents who reported behavioral health problems at intake decreased by 26.6 percent at the end of the treatment follow-up. Post-traumatic stress and traumatic stress decreased by 18.2 percent and 13.3 percent, respectively.

Consultations with supervisors and colleagues, trainings hosted by NCTSN centers and information resources such as the NCTSN Web site are essential to clinicians learning about and implementing evidence-based treatments. Additionally, NCTSI's Learning Collaboratives are sustaining and spreading appropriate and trauma-informed services for children and families affected by traumatic stress, and they are supporting providers in both the initial implementation of an evidence-based practice as well as helping to sustain that practice over time. Network-affiliated respondents reported adopting specific evidence-based treatments at much higher rates than non-Network respondents.

The Network has developed resources for child/adolescent trauma on the NCTSN website, which receives more than 2,000 visits a day and houses over 150 NCTSN-developed resources downloaded more than 50,000 times a year. NCTSN resources are accessed by both mental health and non-mental health services sectors, including in responding to community tragedies such as the Newtown, CT shooting and the Boston bombing incidents. There was significant growth in the provision of specialized trauma services by non-mental health agencies between FY 2007 and FY 2009. One-third of agencies in both mental health and non-mental health service sectors attributed their specialized service provision efforts to information from, or collaboration with, the NCTSN during the second round of their surveys in FY 2008 and FY 2009. More than 80 percent of NCTSN collaborative group members reported developing relationships with agencies outside the Network and that the Network membership helped them to garner resources from agencies outside of the Network.

The Garrett Lee Smith State and Tribal Youth Suicide Prevention grant program focuses on children and youth age 10-24. The program supports youth suicide prevention efforts in a variety of settings including schools, foster care systems, juvenile justice (non-custodial) programs, emergency rooms, primary care clinics and others. Over 500,000 educators, health professionals, foster parents, family members and others have been trained to recognize the warning signs of suicide and actions to take in response. In addition, grantees have been able to demonstrate reductions in self-reported suicide attempts (Connecticut), as well as in suicidal ideation (Utah, White Mountain Apache tribe/Johns Hopkins Center for American Indian health).

The Children's Mental Health Initiative (CMHI) supports states, jurisdictions, the District of Columbia, territories, tribes and tribal organizations, in developing integrated home and community-based services and supports for children and youth with serious emotional disturbances and their families by encouraging the development and expansion of an effective and enduring system of care approach, which is defined as a coordinated network of community-based services and supports that creates partnerships with families and youth. Data from the CMHI national evaluation demonstrates school attendance and performance improves, behavioral and emotional strengths are increased, and children and youth have more stable living conditions. Within 6 months of service in CMHI, the number of youth reporting suicide attempts or thoughts of suicide as well as contacts with law enforcement decreased. For youth involved in the juvenile justice system, arrests decreased by nearly 50 percent from intake into the program after 12 months of service in CMHI.

2. *Do you consider the current appropriations level for these programs to be sufficient in meeting the need? If not, where would additional funds be most helpful and why? Please describe any cutbacks or reductions to services that have been made necessary in recent years due to budget constraints.*

Response: The implementation of the Affordable Care Act will help to address this need by expanding mental and substance use disorder services coverage opportunities and federal parity protections to 62 million Americans. Going forward, SAMHSA funding will focus increasingly infrastructure, prevention and mental health promotion, and new service delivery models that, once demonstrated, can be taken to scale or adopted by insurance mechanisms to provide evidence and value based purchasing of services to prevent, treat and support the recovery of individuals experiencing mental or substance use conditions.

For the Community Mental Health Services Block Grant, in FY13, there was approximately a 5 percent reduction, or -\$22 million, in funding due to sequestration. This reduction will result in the reduction of mental health related services and supports for approximately 373,000 adults with Serious Mental Illness (SMI) and children with Serious Emotional Disturbance (SED), which will likely lead to increased hospitalizations, involvement in criminal justice systems, and homelessness for these individuals. Another program that serves children with serious emotional disturbances is the Children's Mental Health Initiative. As a result of sequestration, the Children's Mental Health Initiative program funding – serving children with SED –was reduced by 5%, or \$6 million. The consequence

is that SAMHSA will fund fewer grants that provide treatment services for children with serious emotional disturbances.

In addition, the President's FY 2014 Budget includes a request for additional funding to support the President's *Now is the Time* initiatives. Specifically, the proposed initiatives would:

- 1) Reach 750,000 young people through programs to identify mental illness early and refer them to treatment: To support training for teachers and other adults who regularly interact with students to recognize young people who need help and ensure they are referred to mental health services, the Administration has proposed a new initiative, Project AWARE (Advancing Wellness and Resilience in Education), to provide this training and set up school-community partnerships to promote mental health, and facilitate referrals when needed. This initiative, which will be coordinated with related proposals at the Departments of Justice and Education, has two parts:
 - a. Provide Mental Health First Aid to train teachers: Project AWARE proposes \$15 million for training for teachers and other adults who interact with youth to detect and respond to mental illness, including how to encourage adolescents and families experiencing these problems to seek treatment.
 - b. Ensure students with signs of mental illness get referred to treatment: Project AWARE also proposes \$40 million to help states and school districts work with community leaders, law enforcement, mental health agencies, families and youth, and other local organizations to assure students with mental health issues or other behavioral issues are referred to and receive the services they need. This initiative builds on strategies that, for over a decade, have proven to decrease violence in schools and increase the number of students receiving mental health services.
- 2) Support individuals ages 16 to 25 at high risk for mental illness: The Administration is proposing \$25 million for a new initiative, Healthy Transitions, to support innovative state-based strategies to support young people ages 16 to 25 with mental health and/or co-occurring substance use disorders and their families navigate behavioral health treatment systems. Efforts to help youth and young adults cannot end when a student leaves high school especially because compared with their peers, young adults aged 18-25 with mental health conditions are more likely to experience homelessness, be arrested, drop out of school and be underemployed—in short to feel a greater burden of mental illness. Even those who received services as a child may fall through the cracks when they leave school or turn 18, resulting in missed opportunities.
- 3) Train more than 5,000 additional mental health professionals to serve students and young adults: The Administration is proposing \$50 million to train social workers, counselors, psychologists, behavioral health paraprofessionals, marriage and family therapists, nurses, and other mental health professionals. This would allow SAMHSA and HRSA to provide financial support to train more than 5,000 mental health

professionals to serve children, adolescents, young adults (including individuals aged 16-25 years old), and their families, in our schools and communities.

3. *The fragile and underdeveloped state of the system for children's mental health in the United States has been well documented. Despite a national picture of inadequacy, there do seem to be examples of positive strategies to improve services at the state level. For example, Minnesota is working to overcome shortages in rural areas through tele-psychiatry. Connecticut has demonstrated the value of making emergency psychiatric services available to schools.*

Response: SAMHSA agrees that there are many wonderful examples of states, tribes and territories creating and implementing strategies to improve services. In addition to those identified, SAMHSA would also note that the State of Maryland and other states have created a Children's Cabinet at the Governor's level to provide policy direction for children's mental health across state agencies. The state of New Jersey is using a statewide Administrative Services Organization and local care management organizations to provide wraparound services and help families access appropriate care. The state of Oklahoma, where the systems of care approach has been implemented in 55 of their 77 counties, has used Medicaid to expand services such as family support providers and behavioral health aides. The state of Rhode Island is requiring contracts to include language supporting a broad array of wraparound services across child serving agencies.

There are some additional exciting examples of tele-health utilization to better serve rural communities and the needs of children. For example, with support from SAMHSA's National Child Traumatic Stress Initiative, Dartmouth Trauma Interventions Research Center is engaging in children's tele-mental health treatment. The state of New Mexico has a significant investment in tele-psychiatry through the University of New Mexico and the state's telehealth council to assist rural areas and schools access the best treatment possible that is often available largely in urban areas.

SAMHSA has provided resources to ensure the dissemination of effective practices that are developed through its grant programs. Not only does SAMHSA provide peer-to-peer learning opportunities through program specific grantee meetings, but also disseminates these lessons through webinars, SAMHSA's National Registry of Evidence-based Programs and Practices (NREPP), and SAMHSA's technical assistance centers to other providers and state authorities.

4. *Please share your knowledge about further instances of innovation and effective practices that exist but are not sufficiently widespread. What can the federal government, and your agencies in particular, do to better spread best practices and support such efforts in communities where the resources are limited?*

Response: In an effort to support the Administration's response to the tragedy at Sandy Hook Elementary School, \$55 million is requested in FY 2014 to support Project AWARE, (Advancing Wellness and Resilience in Education) to increase awareness of mental health issues and connect young people with behavioral health issues and their families with needed services. SAMHSA will partner with the Departments of Education and Justice in the development, implementation and management of this initiative to maximize coordination and avoid duplication of efforts.

Project AWARE proposes two components: Project AWARE state grants (\$40.0 million) build on the Safe Schools/Healthy Students State Planning and Community Pilot Program intended to create safe and supportive schools and communities. For more than a decade, the Safe Schools/Healthy Students Initiative has successfully decreased violence and increased the number of students receiving mental health services. Project AWARE grants will be used in conjunction with funds from the Departments of Education and Justice to support 20 grants to State Education Agencies (SEAs) that will promote a comprehensive, coordinated and integrated program with the goal of making schools safer and increasing access to mental health services. The SEAs will be required to partner with the state mental health and law enforcement agencies to establish Interagency State Management Teams, conduct environmental needs assessments, develop a state plan with an evaluation mechanism, and develop the mechanisms to coordinate funding, service delivery, systems improvement, and data collection.

The second component, Mental Health First Aid (MHFA) (\$15.0 million) proposes widespread dissemination of the Mental Health First Aid curriculum and supports training to reach 750,000 students to identify mental illness early and refer them to treatment. It would prepare teachers and other individuals who work with youth to help schools and communities to understand, recognize, and respond to signs of mental illness or substance abuse in children and youth, including how to talk to adolescents and families experiencing these problems so they are more willing to seek treatment. The budget proposes that \$10 million of the Project AWARE – MHFA funds will be used in conjunction with Education and Justice funds to support competitive grants to LEAs with the goal of creating safer, more nurturing school climates by implementing an evidence-based behavioral framework and providing mental health literacy training. An Interagency Supervisory Team (IST) will work together to provide oversight and guidance to both the state and local initiatives. The additional \$5.0 million proposed for MHFA will be braided with the 20 SEA grants to support MHFA training in the SEAs and LEAs sub-grantees implementing Project AWARE.

Under section 565(b)(1), the Comprehensive Community-Based Mental Health Services for Children with Serious Emotional Disturbance [also known as the Children's Mental Health Initiative (CMHI)], the Secretary must provide technical assistance (TA) upon the request of a public entity receiving a grant under section 561(a). As a result, TA can only be provided to grantees of the program. However, due to the success of the Children's Mental Health Initiative and SAMHSA's role as the leader of public health efforts to advance the behavioral health of the nation, SAMHSA needs to be able to provide technical assistance to communities throughout the nation. SAMHSA's goal is the promotion of the use of the system of care model, and SAMHSA can help non-grantee communities pick up and

implement the evidence based model, thereby expanding the reach of the limited dollars available. As a result, the FY 2014 President's Budget requested legislative language be included in the FY 2014 LHHS appropriations bill that would permit technical assistance to communities that wish to establish systems of care programs even though the community may not have a grant.

Rep. Lucille Roybal-Allard

1. *How is SAMHSA working/partnering with CDC to prioritize mental health and addiction prevention in this grant program?*

Response: SAMHSA engages in regular, monthly information sharing meetings with CDC to discuss several areas, including the Community Transformation Grants (CTG) program. CTG is one of the high priority areas in which SAMHSA and CDC continue to focus ways to increase our partnership and coordination. CDC and SAMHSA partner together, at the staff level, to identify opportunities for collaboration and coordination concerning the CTG program, data and surveillance opportunities (e.g., children's mental health epidemiology and surveillance data), as well as program and disease impact areas such as suicide prevention, underage drinking, tobacco cessation issues, and reduction of cardiovascular disease, hypertension and diabetes among persons with serious mental illness.

2. *How is SAMHSA tracking the CTG grants and ensuring its partnering with CTG community recipients?*

Response: Although SAMHSA is not currently tracking the CTG recipients, CDC tracks these grantees since this is a CDC-funded program. SAMHSA does have monthly coordination meetings with CDC to focus on identifying Agency opportunities for collaboration.

Rep. Barbara Lee

In your testimony you both emphasize the portions of the President's Now is the Time document aimed at identifying children and young adults with mental health problems and referring them for treatment. I agree that this must be a priority.

1. *Could you each explain to us where this treatment would take place, whether it occurs in school-based health clinics, community health centers, etc.?*

Response: The approaches described in the President's initiatives outlined in *Now Is the Time* and the FY14 Budget are primarily outreach and engagement strategies to help connect people in need with treatment and services. They will take place in multiple settings and

will take advantage of the latest evidence. Some strategies are designed for schools and other community settings, while others are designed for outpatient settings.

2. *Do we have the systems and capacity in place to care for a significantly larger number of children and young adults, if we are successful in getting them referred for treatment? And if not, what will it take to build that capacity?*

Response:

To help address this issue, the Administration is proposing \$50 million to train additional social workers, counselors, psychologists, marriage and family therapists, and other mental health professionals including peer professionals. In addition, SAMHSA is working with the HRSA to begin to build the data necessary to track workforce shortages consistently and over time.

In addition, SAMHSA's highly successful Children's Mental Health Initiative (CMHI) has provided 30 System of Care Expansion Planning Grants (24 in FY 2011 and 6 in FY 2012) to help states, tribes and territories create blueprints to expand services and supports. For example, many grantees developed specific plans to expand "wraparound" services and increase the use child and family teams to create individualized service plans. Grantees also created financing strategies to expand services such as respite care, parent-to-parent support and trauma-focused interventions. In FY 2012 SAMHSA awarded 16 System of Care Expansion Implementation Grants. These four-year grants were designed as a follow-up to implement the plans that were developed. This year in FY 2013, additional Planning and Implementation Grants will be awarded.

SAMHSA is also working to address capacity and access by improving health information technology and through the use of tele-health and tele-psychiatry.

In addition, the numbers of mental health professionals serving in the areas that need them most has continued to grow thanks to the Administration's investments in the National Health Service Corps and Community Health Centers. Between 2008 and 2012, with funding from the Affordable Care Act and other sources, the size of the National Health Service Corps nearly tripled. The National Health Service Corps offers loans and scholarships to health care providers who commit to practicing in those areas of the country that need them most. The FY 2014 Budget includes \$305 million in Affordable Care Act funding to support primary care providers, and psychologists, clinical social workers, counselors and marriage and family therapists.

3. *How do the proposed initiatives differ from existing programs, such as the Elementary and Secondary School Counseling Program and the Safe Schools/Healthy Students Initiative?*

Response: Project AWARE builds on the success of the Safe Schools/Health Students (SS/HS) program and the evidence of its effectiveness and proposes to help take this program to scale and add a mental health literacy component. Project AWARE will be targeted to states because although over 1,200 communities have participated in the SS/HS program, no state has implemented the program at a state-wide level.

Project AWARE also expands the initial SS/HS program by now integrating Mental Health First Aid training into this new initiative to ensure youth, teachers, parents, and other adults who interact with youth are able to detect and respond to mental illness in children and young adults.

The Elementary and Secondary School Counseling (ESSC) Program at ED provides funding to school districts to establish or expand school counseling programs, including through the hiring of school counselors, social workers, psychologists and psychiatrists. The Administration's proposal to train 5,000 additional mental health professionals would create a pipeline of qualified and well-trained professionals who would be able to fill positions like those supported under ESSC.

4. *Please describe what steps, if any, SAMHSA is taking to address these mental health disparities?*

Response:

SAMHSA's Office of Behavioral Health Equity (OBHE) has several initiatives to address mental health disparities. SAMHSA has revised the standard language in its grant Request for Applications (RFAs) to require disparity impact statements from all services grant programs. Routinely collected grantee data will be analyzed for disparities in access to services, services utilized, and outcomes across diverse racial and ethnic populations served by the grant program. SAMHSA grant project officers will work with grantees - using the recently enhanced Culturally and Linguistically Appropriate Services (CLAS) standards and a quality improvement approach to eliminate these disparities.

OBHE operates the National Network to Eliminate Disparities in Behavioral Health (the NNED). The NNED is comprised of over 600 community-based organizations committed to serving diverse racial and ethnic communities across the U.S. The NNED provides capacity building efforts, training and coaching in evidence-based and culturally adapted evidence-based practices to assist these organizations in strengthening their quality of service provision to communities of color. For the past three years, OBHE has provided the NNEDLearn training conference which has brought together over 360 participants for in-depth training and six months of ongoing coaching in evidence-based practices for these communities.

For FY 2014, SAMHSA requests \$9.0 million for the Minority Fellowship Program to provide stipends to graduate students to increase the number of culturally competent behavioral health professionals who provide direct mental health and/or co-occurring substance abuse services to underserved minority populations. This includes an increase of \$5 million in the President's Now is the Time initiatives for a youth-specific expansion called Minority Fellowship Program – Youth (MFP-Y). MFP-Y would utilize the existing infrastructure of the MFP to expand the focus of the program to support master's level trained behavioral health providers in the fields of psychology, social work, professional counseling, marriage and family therapy, and nursing who are culturally and linguistically competent. This support would increase the number of providers who are available to provide clinical services to underserved, at-risk children, adolescents, and populations transitioning to adulthood (ages 16 – 25) in an effort to increase access to, and quality of, behavioral health services for this age group.

5. *What can you tell us about current shortages of mental health providers: how large are those shortages, are they increasing, and which professions are most affected?*

Response: In March 2013, SAMHSA – with help from HRSA – produced a report for Congress about the needs of the behavioral health workforce.¹ SAMHSA and HRSA are jointly working on data about the behavioral health workforce. HRSA reports data on officially designated Mental Health Professional Shortage Areas (HPSAs). As of March 31, 2013, there were 1,009 geographical areas, 159 population groups and 2,694 facilities designated as Mental Health HPSAs.

Data also show that racial and ethnic minority health providers are underrepresented in the behavioral health field when compared to diverse groups accessing care. For instance, racial and ethnic minorities as a whole comprise approximately 30 percent of the U.S. population (U.S. Census, 2010), and a similar percentage of those needing services (SAMHSA, 2012; 2008). However, for example, racial and ethnic minority providers of mental health and addictions services account for only² about 19 percent of all psychiatrists and 5 percent of psychologists.

This reinforces that cultural competence for all providers, as well as an increase in the numbers of diverse providers, continues to be important.

The Administration is proposing \$50 million in FY14 to train additional social workers, counselors, psychologists, marriage and family therapists, and other mental health professionals including peer professionals.

In FY12, HRSA supported a \$10 million initiative to train additional mental health providers serving underserved populations.

In addition, SAMHSA’s highly successful Children’s Mental Health Initiative (CMHI) has provided 30 System of Care Expansion Planning Grants (24 in FY 2011 and 6 in FY 2012) to help states, tribes and territories create blueprints to expand services and supports. For example, many grantees developed specific plans to expand “wraparound” services and increase the use child and family teams to create individualized service plans. Grantees also created financing strategies to expand services such as respite care, parent-to-parent support and trauma-focused interventions. In FY 2012 SAMHSA awarded 16 System of Care Expansion Implementation Grants. These four-year grants were designed as a follow-up to implement the plans that were developed. This year in FY 2013, additional Planning and Implementation Grants will be awarded.

SAMHSA is also working to address capacity and access by improving health information technology and through the use of tele-health and tele-psychiatry.

The numbers of mental health professionals serving in the areas that need them most has continued to grow thanks to the Administration’s investments in the National Health Service

¹ <http://store.samhsa.gov/product/PEP13-RTC-BHWORK>.

Corps. Between 2008 and 2012, with funding from the Affordable Care Act and other sources, the size of the National Health Service Corps nearly tripled. The National Health Service Corps offers loans and scholarships to health care providers who commit to practicing in those areas of the country that need them most. The FY 2014 Budget includes \$305 million for the National Health Services Corps to support primary care providers, including psychologists, clinical social workers, counselors and marriage and family therapists.

6. *What other strategies are available for increasing the number of mental health professionals?*

Response: In addition to the workforce expansion programs proposed in the President's FY 2014 Budget, SAMHSA administers the Minority Fellowship Program which is designed to increase the number of culturally competent providers available to provide quality mental health and substance abuse prevention and treatment to individuals from diverse and underrepresented communities. Behavioral health professions of focus for the Minority Fellowship Program include: psychiatrists, psychologists, social workers, counselors, marriage and family therapists and nurses. Specific goals of the Minority Fellowship Program are to:

- 1) Promote culturally competent mental health and substance abuse services provided to ethnic minority populations;
- 2) Increase the number of professionals delivering mental health and substance abuse services to ethnic minority populations;
- 3) Increase the general knowledge and relevant research related to the prevention, treatment and recovery of mental health and substance abuse disorders among racial and ethnic minority populations.

In addition, SAMHSA collaborates with HRSA in developing strategies to bring additional mental health professional into the National Health Service Corps (NHSC). The NHSC supports qualified health professionals, including psychologists, social workers, marriage and family therapists, psychiatric nurse specialists, and professional counselors, dedicated to working in areas of the United States where they are needed most.

Between 2008 and 2012, with funding from the Affordable Care Act and other sources, the size of the National Health Service Corps nearly tripled. The National Health Service Corps offers loans and scholarships to health care providers who commit to practicing in those areas of the country that need them most. The FY 2014 Budget includes \$305 million in Affordable Care Act funding to support primary care providers, and psychologists, clinical social workers, counselors and marriage and family therapists.

7. *What do you see as the role of the federal government—and particularly the role of the discretionary appropriations made in our bill—in improving the availability and quality of mental health care for children and young adults?*

Response: The role of SAMHSA and its Center for Mental Health Services, as the entity within SAMHSA to lead federal efforts to treat mental illnesses by promoting mental health and by preventing the development or worsening of mental illness when possible, is to serve as a national voice on mental health and mental illness and evidence-based behavioral health treatment and recovery support services. SAMHSA coordinates behavioral health surveillance to understand better the impact of mental illness on children, individuals, families and the costs associated with treatment. SAMHSA helps to ensure dollars are invested in evidence-based and data-driven programs and initiatives that result in improved health and resilience. SAMHSA's role provides a focused approach to increasing evidence-based mental health promotion practices on a national scale. To this end, SAMHSA supports innovation and practice improvement by disseminating key evidence-based behavioral health practices, such as Treatment Improvement Protocols (TIPs), Technical Assistance Publications (TAPS), The National Registry of Evidence-based Programs and Practices (NREPP), and evidence-based toolkits, to the mental health and substance abuse delivery system and facilitates practice improvement by engaging in activities that support mental health system transformation and reform. SAMHSA also provides resources and support for states and communities experiencing disasters and tragedies to help them connect individuals with the services they need as a result of trauma and in times of psychological distress resulting from tragedies and disasters such as the gulf oil spill, the Joplin and Oklahoma tornados, the Tucson, Aurora and Newtown shooting incidents, and the Boston bombing. Together, these actions provide ongoing support to improving the availability and quality of mental health services for children and young adults as well as for families and communities. As such, SAMHSA's responsive grant portfolio supports innovation by identifying solutions to emerging issues through the use of limited, short-term discretionary grants. Those evidence-based practice and policy results are then available to inform policy decisions on improvements to the Nation's behavioral health system through Block Grants to states, formula grants to states and tribes, on-going discretionary grants, Medicaid/Medicare, or private insurance.

8. *Why is that number so low? Can you tell us roughly how much is due to people not wanting to seek treatment and how much is due to people wanting treatment but being unable to obtain it—because of barriers like cost or availability?*

Response: According to the 2011 National Survey on Drug Use and Health (NSDUH), of the 19.3 million people identified as needing but who did not receive treatment for illicit drug or alcohol use, 95.3 percent of people didn't receive treatment because they didn't perceive a need. Another 3.3 percent felt they needed treatment but did not make any effort to get it; and 1.5 percent felt they needed treatment, made an effort to get it, but still didn't receive it.

Based on 2008-2011 combined NSDUH data, 37.3 percent of those who had a substance use disorder, felt a need for treatment, tried to get treatment, but did not receive treatment for substance use, did not receive it because they did not have any health coverage and could not afford the cost. Another 25.5 percent were not ready to stop using. Other barriers experienced by those seeking treatment but not receiving it were: fear that it might have a negative effect on their jobs (10.1 percent), health coverage did not cover treatment or did not cover costs associated with treatment (10.1 percent), did not have transportation or it was

inconvenient to get to treatment (9.5 percent), did not know where to go for treatment (7.3 percent), feared that it might cause neighbors/community to have negative opinion (7.2 percent), and did not have the time (7.1 percent).

9. *This problem getting better or worse—that is, is the percentage of people in need of substance abuse treatment but not obtaining it increasing or decreasing? What can we do to improve the situation?*

Response: The percentage receiving specialty substance abuse treatment among those who need treatment has remained relatively constant for the past decade. In 2002, the percentage was 10.3 percent, and in 2011 it was 10.8 percent. The Affordable Care Act and the Mental Health Parity and Addiction Equity Act, will expand coverage of mental health and substance use disorder benefits and federal parity protections in three distinct ways: (1) by including mental health and substance use disorder benefits in the Essential Health Benefits; (2) by applying federal parity protections to mental health and substance use disorder benefits in the individual and small group markets; and (3) by providing more Americans with access to quality health care that includes coverage for mental health and substance use disorder services. In addition, efforts such as SAMHSA sponsored and supported Recovery Month help to educate the public regarding substance abuse and mental health disorders and reduce fears about negative perceptions from family and community that serve as barriers for some.

10. *What are the benefits of providing services “upstream”?*

Response: Simply put, promoting positive mental health and preventing the onset of mental illness and/or its disabling effects saves lives and money. Providing services “upstream” is a critical component of a public health approach. It refers to the importance of identifying mental health challenges early and intervening early. Just as CDC works to prevent cardiovascular disease or diabetes rather than only serving those who have already experienced heart attacks or who already have end stage renal disease, SAMHSA works to prevent mental health issues in addition to providing or connecting to treatment services those individuals with the most serious mental illnesses. This is particularly important because, as indicated by the Institute of Medicine in its 2009 report on *Preventing Mental, Emotional, and Behavioral Disorders Among Young People*, 50 percent of mental health disorders in adulthood appear before the age of 14, and 75 percent appear before the age of 24. The IOM report also provides significant evidence that many evidence based practices to build resilience and protective factors as well as to address risk factors at individual, family and community levels can help to prevent or reduce the impacts of mental health, substance abuse and other behavioral health conditions in youth.

The National Institute of Mental Health (NIMH) is also supporting research showing evidence that early intervention in the lives of young people with first break psychosis can lead to prevention of disabling consequences of such mental health conditions, thereby saving lives and resources. Evidence clearly demonstrates the health benefits and economic value of providing services “upstream.” The benefit and value is greatest when prevention is implemented at the earliest opportunity. Early identification and early intervention are cost effective, and have been shown to improve outcomes.

The Adverse Childhood Experiences study shows that children who experience difficulties in childhood (such as abuse, neglect, parental divorce, etc.) have significantly higher rates of developing not only behavioral health problems such as substance abuse and suicidality, but also of developing medical problems such as cancer and heart disease. Upstream prevention works to create environments where children have a reduced risk of experiencing these health and behavioral health conditions as young people and as adults.

Preventing a child from becoming dependent on alcohol can save approximately \$700,000 and helping a child graduate from high school that would otherwise have dropped out, can save as much as \$388,000.³

11. *How much of the slightly over \$1 billion at CMHS is dedicated for children and adolescents?*

Response: In the President's FY 2014 budget approximately 44 percent of CMHS funding, including approximately 32% of Community Mental Health Services Block Grant state spending, is targeted to programs and services for children and adolescents and their families.

12. *What affect have these cuts had on SAMHSA's ability to serve the program's target population?*

Response: Due to sequestration, funding for the Community Mental Health Services Block Grant was reduced by approximately 5 percent, or -\$22 million, which will likely result in the reduction of mental health related services and supports for approximately 373,000 adults with Serious Mental Illness (SMI) and children with Serious Emotional Disturbance (SED). This will likely lead to increased hospitalizations, involvement in criminal justice systems, and homelessness for these individuals. Another program that serves children with serious emotional disturbances is the Children's Mental Health Initiative. As a result of sequestration, the program's funding was reduced by 5%, or \$6 million. The consequence is that SAMHSA will be able to fund fewer grants that provide treatment services for children with or at risk for serious emotional disturbances.

13. *How is SAMHSA working/partnering with CMS to enforce Early Periodic Screening Diagnosis and Treatment (EPSDT) in every state Medicaid program to improve the health of children?*

Response: SAMHSA partners with CMS by informing states of the EPSDT mandate, providing technical assistance on the integration of EPSDT into children's mental health system design, health home design, block grant coordination, and data collection and reporting. CMS recently released an informational bulletin for states to help them maximize the use of EPSDT to assess and provide behavioral health services for children and youth. SAMHSA worked with CMS on the development of the informational bulletin.⁴

³ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. (2012). Promoting Recovery and Resilience for Children and Youth Involved in the Juvenile Justice and Child Welfare Systems. Rockville, MD: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration.

⁴ <http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-03-27-2013.pdf>

Questions for the hearing record March 20, 2013**ED'S ROLE IN CHILDREN'S MENTAL HEALTH**

Mr. Kingston: Please describe the Department of Education's role in the overall mental health system for children in the U.S.

Ms. Delisle: In recent years, the Department has worked to improve educator and student access to mental health resources and supports through financial support to school districts, technical assistance, and interagency partnerships with federal partners such as the Department of Health and Human Services' (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA).

Safe Schools/Healthy Students (SS/HS). Since 1999, the Department has partnered with DOJ and SAMHSA to address youth violence prevention and supporting the social-emotional and behavioral needs of students and communities through the SS/HS initiative. Through the Supportive School Discipline Initiative and the National Forum on Youth Violence Prevention (described below), the SS/HS initiative has partnered with other federal initiatives to share the important teachings from SS/HS grantee communities.

Elementary and Secondary School Counseling Grants. Our Office of Safe and Healthy Students also administers a grant program to establish or expand school counseling in elementary and secondary schools. In 2013 we awarded \$12.3 million to 35 recipients in 17 states to hire and train qualified mental-health professionals with the goal of expanding the range, availability, quantity, and quality of counseling services.

National Center for Safe Supportive Learning Environments. In 2012, the Office of Elementary and Secondary Education worked closely with SAMHSA to jointly establish a new technical assistance center focused on helping elementary, secondary, and postsecondary schools to improve school climate and strengthen mental health supports for students and to prevent bullying in schools. This collaboration aims to help schools better access SAMHSA's wealth of information and resources on mental and behavioral health promotion.

Positive Behavioral Interventions and Supports (PBIS). The Office of Special Education and Rehabilitative Services (OSERS), which has invested in behavioral research, demonstration, and technical assistance activities for more than 20 years, including through the Positive Behavioral Interventions and Supports Center, provides states, schools, and communities with a clear, evidence-based roadmap to safer school climates that support students through evidence-based behavioral frameworks.

National Forum for Youth Violence Prevention. The Department is one of multiple federal partners supporting the National Forum on Youth Violence Prevention – an interagency initiative to help 10 cities across the Nation elevate youth and gang violence as an issue of significance; enhance the capacity of participating localities, along with others across the country, to more effectively prevent youth and gang violence; and sustain progress and systems change through engagement, alignment, and assessment.

We are working closely with DOJ and HHS to strengthen the use of behavioral frameworks in these cities' schools. The ten cities¹ that comprise the National Forum have pledged to strengthen local capacity to prevent youth violence and gang violence. We see behavioral frameworks as a key strategy for their schools to boost capacity in delivering mental health and social and emotional supports, and creating safer and more productive environments for their students and staff.

Supportive School Discipline Initiative (SSDI). As I noted earlier, the Department sees a relationship between schools' ability to support students' mental health and their ability to manage and respond to student misbehavior. We have partnered with DOJ to reduce school reliance on suspensions, expulsions, and referrals to law enforcement, and, at the same time, help educators identify effective alternatives to exclusionary discipline. At the core of the SSDI is an effort to develop a broad consensus on the steps that the education, judicial, and health communities must take to realize essential changes. As part of this effort, the Department and DOJ have supported the efforts of the Council of State Governments Justice Center, in concert with members of the philanthropic community, to lead the development of consensus-based recommendations on how to keep school environments safe and students productively engaged in school. Over the course of the next year, this national consensus-building project will convene groups from multiple disciplines – including education, behavioral health, juvenile justice, social services, law enforcement, and child welfare—to first identify key issues related to academic success, juvenile justice concerns, and safe and engaging learning environments, and then recommend solutions that keep students engaged in school and out of the justice system. The strength of this work lies in its ability to bring together adults from different sectors, including mental health professionals, who care deeply about our most vulnerable children and support collective action on behalf of these youth.

On January 16th, the President announced a comprehensive plan, *Now is the Time*, to protect our children and communities by reducing gun violence. This plan outlines a multi-faceted approach that reflects the complexity of the problem and is based on the recommendations of the Vice President's Task Force established in the wake of the school shooting in Newtown. No educator, child, parent, family, or community should experience the horrific events such as those of Newtown, Virginia Tech, and Columbine. In communities all across America, young lives are lost due to senseless gun violence at a rate that is absolutely staggering. It is essential that our schools and communities are made safer by identifying and taking common-sense approaches to help prevent future tragedies.

The education-related proposals in *Now is the Time* are organized around improving mental health services for young people and school safety. In designing those proposals, we worked with our partners at HHS to develop a number of policy proposals to ensure students and young adults have access to and receive appropriate mental health treatment when needed. HHS is spearheading initiatives designed to reach 750,000

¹ The 10 cities that currently compose the National Forum for Youth Violence Prevention as, as of December 2012: New Orleans, LA; Philadelphia, PA; Minneapolis, MN; Camden, NJ; Boston, MA; Chicago, IL; Detroit, MI; Memphis, TN; Salinas, CA; and San Jose, CA.

young people through programs that train teachers and other adults to identify mental health issues early and refer young people to treatment, to support state-based strategies to help individuals ages 16-25 at high risk for mental illness, and to train more than 5,000 additional mental health professionals to serve students and young adults.

Additionally, Secretary Duncan is working with Secretary Sebelius to launch a national dialogue about mental health. This dialogue aims to reduce the social barriers that prevent individuals from seeking the mental health help they need, and to reduce negative attitudes toward individuals with mental illness. The dialogue also will bring to light efforts to diminish the fear or shame associated with having a mental illness, and to correct the misinformation or lack of information about mental health services. The national dialogue began in June of this year at the National Conference on Mental Health held at the White House hosted by President Obama and Vice President Biden as part of the Administration's effort to launch a national conversation to increase understanding and awareness about mental health. Secretary Duncan and HHS Secretary Sibelius led discussions as part of the conference. The goal is to continue to explore ways to decrease these barriers so more individuals in need of help will reach out for mental health services and more communities across the country will be better equipped to discuss mental health issues and help those who need services to access them. A summary of the White House Conference may be found at: <http://www.whitehouse.gov/the-press-office/2013/06/03/background-national-conference-mental-health>

While many of the mental-health focused proposals will be led by our partners at HHS, one school-based initiative with a strong mental health component that the Department is leading is a program to address pervasive violence in communities, which can have significant mental health consequences. Exposure to violence affects approximately two out of every three children.² In order to help break the cycle of violence and help schools address the effects of pervasive violence that affects many students, *Now is the Time* includes a proposal for a \$25 million initiative that will support school-based violence prevention strategies, conflict resolution programs, and mental health services for trauma or anxiety. This important initiative would help address the effects of violence, reinforce positive learning environments in schools, and help prevent future violence.

A nurturing and supportive school climate is essential to helping students feel safe and we recognize that it significantly impacts student achievement. *Now is the Time* also includes a \$50 million proposal for a new initiative to help schools create safer and more nurturing school climates. These grants would assist schools in the use of evidence-based strategies to address problem behaviors such as bullying and harassment and intervene positively in the redirection of students' behaviors and responses. Our proposal draws heavily from what the Department has learned through OSERS' PBIS work which research shows, when implemented well, improves students' social skills, leading to an improved self concept and a reduction in problem behavior, bullying, peer victimization, and harmful suspensions that disrupt a child's educational opportunities through unnecessary removal from the classroom.

² <http://www.justice.gov/defendingchildhood/cev-rpt-full.pdf>.

The plan also includes \$30 million to provide one-time grants to states to help schools develop and implement high quality emergency management plans. This investment would help schools review their emergency management plans to make sure they are high quality and are actually practiced and used. The Department also joined with DOJ, HHS, and the Department of Homeland Security (DHS) to release a guide that includes model high-quality emergency management plans. The President's plan will also provide resources to school districts that will be designed to meet local needs, including improving access to mental health professionals, as appropriate. The Comprehensive School Safety program would provide \$150 million to develop school safety plans, improve equipment and systems, and train crisis intervention teams. School districts and law enforcement agencies would hire staff such as school psychologists, social workers, counselors and school resource officers and make other critical investments in school safety based on the needs of the local community and school system. We are working very closely with DOJ on successfully implementing proposals for this program, which DOJ would administer.

Providing essential services to improve the mental health of children is a critical component of our goal of empowering all children to find success in their daily lives and to feel great hope for their futures. By providing support systems for our children, and by offering essential tools and resources to our educators, we demonstrate that children's health and emotional well-being are important and we tell educators that we care about their success.

Mr. Kingston: How much does the Federal government spend on mental health services in schools?

Ms. Delisle: Unfortunately, this figure is difficult to estimate. While a few programs administered by the Department of Education, including the School Improvement Program and the Elementary and Secondary School Counseling Program, may provide support for additional school counselors, there are no programs the Department that provide direct services to students (e.g., treatment services). At the same time, there are a number of programs administered by other agencies within the Department of Health and Human Services that schools may utilize to support treatment for students. Many of these programs, both those in Education and Health and Human Services, include dollars not dedicated to mental health services; rather mental health services is one of several allowable uses. Given the number of programs across agencies that may contribute, and flexibility within programs that grant recipients have, the Department of Education does not have this information.

Mr. Kingston: What percentage of the total spending on mental health services in schools comes from Federal sources?

Ms. Delisle: Unfortunately, as mentioned in the previous question, these types of figures are difficult to estimate. Given the number of programs across agencies that may contribute, and flexibility within programs that grant recipients have, the Department of Education does not current have access to this information.

Mr. Kingston: What strategies have states and school districts used to successfully provide an adequate range of mental health services to students?

Ms. Delisle: One promising strategy is States and school districts have sought to foster better linkages between the school system and community-based mental health providers.

Fostering such system linkage was the focus of the Department's Integration of Schools and Mental Health Systems Grant program. To achieve this goal, grantees were required to enhance or develop collaborative efforts between school-based service systems, juvenile justice, and mental health service systems; enhance the availability of crisis intervention services; improve capacity to make appropriate referrals for students potentially in need of mental health services; and provide training for the school personnel and mental health professionals. They were required to put in place detailed linkage protocols outlining inter-agency agreements among partners. For the 2006, 2007, 2008, and 2009 grant cohorts, 89%, 95%, 99%, and 96% percentage of schools served by the grants in the respective cohorts had, at the end of their project period, comprehensive, detailed linkage protocols in place. For the 2006, 2007, 2008, and 2009 grant cohorts, 79%, 70%, 86%, and 84% percentage of school personnel served by the grant were trained to make appropriate referrals to mental health services, respectively

Other local education agencies have sought to bolster internal system capacity to provide in-school mental health services, while also creating community linkages for referral where such referrals are appropriate. As part of this effort some states have adopted the "Mental Health First Aid" model to systematically train teacher and school staff to identify, understand, and respond to signs of mental illnesses and substance use disorders, especially ensuring students are referred to treatment.

States and school and school districts have also taken concrete action at the universal intervention level to improve school climate and supports to all students.

CHILDREN'S MENTAL HEALTH WORKFORCE

Mr. Kingston: Some sources assert that there is not enough staff providing mental health services in schools. Do you agree with this assertion? If so, to what extent are the barriers: 1) an inadequate supply of trained professionals for schools to hire, versus 2) schools not hiring for these positions in the first place? In other words, is this primarily a supply problem or a demand problem?

Ms. Delisle: Currently, there are more trained school counselors than there are counselor positions to fill; counselors are not experiencing a personnel shortage – rather counselors are experiencing a position shortage. According to the American School Counseling Association, there has been a direct correlation between a reduction in the number of school counselors and a decline in the economy. Many times when schools need to trim the budget they eliminate not only school counselor positions but entire counseling departments. NCES reported that there were 105,079 school counselors in 2010-2011

(the most recent data available) down from 107,564 the previous school year and down again from 107,802 in 2008-2009. More graduate level counselors are graduating each year with few jobs available to them.

School Year	2008-2009	2009-2010	2010-2011
Total number of school counselors	107,802	107,564	105,079
School counselor:student ratio	457:1	459:1	471:1

Prior to 2008-2009, this number had steadily been climbing as far back as there is reporting data (1986-1987).

It is very difficult to “fill gaps” in terms of adequate staffing and personnel. We have found that schools are most successful when they are staffed with adequately trained personnel in terms of k-12 education and school leadership, working with students in a school setting and are knowledgeable about educational law and district policies. The most effective ways to provide a complement of services would be a partnership between school leadership and community resources that are effectively coordinated to best meet the needs of the individual students and their families. Best practices show that this is most successfully done when adequate school staff are in place first and are active in the coordination and facilitation of the ancillary services that stretch beyond the scope of the school.

Mr. Kingston: How many grantees of the Elementary and Secondary School Counseling Grant program are there? How many children receive mental health services solely because of this program?

Ms. Delisle: In the FY 2010 cohort there were 41 grantees, in the FY 2011 cohort there were 43 grantees, and in FY 2012 there were 60 grantees. These represent grant cohorts in which grant activities are currently underway. We made 35 new grant awards in FY 2013. As to the number of children receiving mental health services solely because of the program this is not information we collect from grantees. One of the performance measures for the program calls for grantees to close the gap between their student/mental professional ratios and ratios recommended by the statute, and applicants are called on to give careful consideration to this measure in conceptualizing their project design; we report on this performance measure in our “Department of Education Justifications of Appropriation Estimates to the Congress.”

Mr. Kingston: The Elementary and Secondary School Counseling Grant program has been in existence since 2000. Do the same grantees typically keep getting the awards?

Ms. Delisle: No. We have a few former grantees who apply and are awarded a grant after their projects have ended, but typically 95% of new awards are made to applicants who have never received a grant under the program. Furthermore, local education agencies that currently have an active grant under the program are ineligible to apply in new grant competitions.

Mr. Kingston: Have former grantees of this program been able to identify non-Federal resources to continue supporting these providers after their grant expires?

Ms. Delisle: We work closely with grantees to ensure sustainability of project activities after the federal funding period ends, especially maintaining school mental health professional positions added directly as a result of grant activities. Many of the local education agencies see the value in the enhanced system capacity to serve students and make an effort to find funding to maintain these positions. It is also important to note the grant does not focus solely on providing resources for new school mental health professional positions, but by statute requires grantees to improve their systems which continue after grant project periods end. Among the statutory requirements, grantees must be comprehensive in addressing the counseling and educational needs of all students; use innovative approaches to increase children's understanding of peer and family relationships, work and self, and decision making processes; include in-service training on mental health for teachers, instructional staff, and appropriate school personnel; involve community groups, social service agencies, or other public or private entities in collaborative efforts to enhance the school-based program and promote school-linked integration of services.

Mr. Kingston: At what level would the program need to be funded to ensure all children in the U.S. have access to a counselor, psychologist, or social worker when they need it?

Ms. Delisle: To our knowledge, there has been no economic analysis or needs assessment analysis of program level costs that would be required to ensure all children in the U.S. have access to a counselor, psychologist, or social worker when they need it. The statute for the program require grantees to "ensure a team approach to school counseling in the schools served by the local educational agency by working toward ratios recommended by the American School Health Association of one school counselor to 250 students, one school social worker to 800 students, and one school psychologist to 1,000 students." The Department, through the Common Core of Data (CCD) program of our National Center for Education Statistics, annually collects fiscal and non-fiscal data about all public schools, public school districts and state education agencies in the United States. Based on CCD data, the U.S. average (based on 2010-2011 school year data) of counselor to students was 471 to 1, with a range of 201 to 1 in Wyoming to 1016 to 1 in California. States and local education agencies may have a different "ideal" ratio,

depending on state and local priorities, student needs, and socio-economic conditions in the state or district and costs to increase staffing would vary by state and district..

Mr. Kingston: What specific policy lessons or new knowledge about the provision of counseling services has the Department learned from the experiences of grantees in this program? How does the Department work to apply lessons learned to other non-grantee districts and schools?

Ms. Delisle: There are numerous lessons we have learned. From our Safe Schools, Healthy Students Initiative we have learned about the importance of comprehensive and coordinated approaches that address multiple elements that affect the mental health of youth, including school climate, early childhood, and substance abuse and violence prevention, as well as enhancing school mental health capacity, and linkages to community providers.

From our Mental Health Integration grants we learned about the importance of robust linkage protocols between schools and community providers. Another lesson learned from this program is about the importance of ongoing evaluation as part of project design. In addition to the required GPRA program measures for this program, grantees developed, as part of the ongoing required local evaluation, project specific process measures to assist in ongoing assessment and continuous improvement. Grantees developed project specific outcome measures to focus on system change, and a plan for a long term outcomes-based evaluation that would extend past the grant period. One of the key lessons we learned from these evaluation efforts is grantees were much more intentional and strategic in setting specific goals and objectives that served the collective interests across agencies as well as thinking about long-term sustainability, in terms of ultimate outcomes, when they knew they would be measuring and reporting on progress. This resulted in closer alignment of their work with their strategic plan, leveraging of resources across agencies, and further reach in terms of the services within the community served.

The recently formed, and Department funded, National Center on Safe Supportive Learning Environments will help us share grantee lessons in the mental health in schools area. The new center provides information and technical assistance to states, districts, schools, institutions of higher education, communities, and other federal grantees programs on how to improve conditions for learning. To improve conditions for learning, the Center assists its clients in measuring school climate and conditions for learning and implementing appropriate programmatic interventions, so that all students have the opportunity to realize academic success in safe and supportive environments. The Center also specifically addresses related, emerging issues – bullying, violence and substance abuse prevention, school mental health – that are often identified in research as negatively impacting learning environments. Among, other activities, we use this center to provide lessons learned from grantee experiences with a wider audience.

Mr. Kingston: In recent budget requests, the Department has recommended eliminating the small school counselor program in favor of a broader, more systemic

approach to improving student safety and health. Can you elaborate on the thinking behind this proposal and explain how a more flexible, broader program might be better than the current structure? Do you believe this would be a more cost effective approach to reach more children?

Ms. Delisle: Consistent with our approach of proposing to consolidate a wide range of narrowly targeted programs into broader, more flexible authorities under a reauthorized Elementary and Secondary Education Act, we are not requesting separate funding for the Elementary and Secondary School Counseling program for fiscal year 2014. We believe that our proposal for a broader Successful, Safe, and Healthy Students program would increase the capacity of States, districts, and their partners to provide the resources and supports necessary for safe, healthy, and successful students, including through the use of program funds for school counseling programs that contribute to the reduction or prevention of drug use, alcohol use, bullying, harassment, or violence, and that promote and support the physical and mental well-being of students.

TITLE I

Mr. Kingston: How do schools use Title I funding to support mental health services and programs? What are the barriers, if any, for schools to use this funding for this purpose?

Ms. Delisle: Title I, Part A's (Title I) purpose is to ensure that all children have a fair, equal, and significant opportunity to obtain a high-quality education. To achieve this purpose the program is built on the concept of school-based programs designed to improve the teaching and learning of Title I students in each school.

The specific ways in which a Title I school may use Title I funds to carry out its Title I program depend on several factors that are often case specific. They include whether the school using the funds operates a schoolwide program, in which all students are eligible to receive services, or a targeted assistance program, in which only students who are identified as failing, or most at risk of failing, to meet State academic achievement standards are eligible to receive services. Other factors include ensuring that the Title I services are tailored to the specific needs in each school and that they supplement, and do not supplant, non-Federal funds.

In a schoolwide program, a school may use Title I funds to help upgrade the entire educational program in the school in order to improve the academic performance of all students, but particularly the lowest-achieving students. To operate a schoolwide program, a school must first conduct a comprehensive needs assessment of the entire school. Using data from the needs assessment, the school must develop a comprehensive schoolwide plan that describes how the school will address its identified needs to improve student achievement. Strategies for upgrading a school's educational program include instructional approaches that are based on scientifically based research that strengthen the core academic program, increase the amount and quality of learning time, and address the needs of the lowest-achieving children, as well as strategies to attract and retain highly qualified teachers, to provide high-quality professional development, and to increase parental involvement. As you know, Title I is not a funding

stream to support discrete projects or activities unless they support the broader goal of raising achievement of the lowest-achieving students. As such, Title I funds in a schoolwide program school must address the specific educational needs of students in the school identified by the needs assessment and articulated in the comprehensive plan. The use of those funds must also be reasonable and necessary for the proper and efficient performance of the schoolwide program. To help determine whether Title I funds may support mental health services as part of carrying out a schoolwide program, a school must analyze such use in the context of the schoolwide program by examining its needs to determine whether and how mental health services would address those needs. A school may also identify other needs—e.g., school climate, discipline, truancy, bullying, and dropout prevention—that contribute to the school's students' lack of academic achievement. In determining how best to use its Title I funds, the school should consider its particular educational needs to identify those that are most critical to raising student achievement—i.e., those that are reasonable and necessary to the performance of the schoolwide program. Because the use of Title I funds is tied to an individual school's needs, we fully expect that Title I funds would generally support different activities from school to school.

A school operating a targeted assistance program must use its Title I funds only to provide supplemental Title I services to eligible students selected for those services because they have the greatest need for assistance—that is, students who are failing, or most at risk of failing, to meet the State's academic achievement standards. Such students include at-risk children who are economically disadvantaged, children with disabilities, migrant children, English learners, and children experiencing homelessness (who are eligible without regard to the school they attend). A targeted assistance program must, among other things, use effective methods and instructional strategies that are based on scientifically based research, provide instruction by highly qualified teachers, provide opportunities for professional development, increase parent involvement, and minimize removing students from the regular classroom by, for example, extending learning time during the school day, week, or year. Targeted assistance schools may also use Title I funds to provide health, nutrition, and other social services to Title I students as a last resort if funds for these services are not reasonably available from other public or private sources. Thus, a targeted assistance school could only use Title I funds for mental health services to Title I students if the services are supplemental, fit with the design of the school's Title I program, which must be focused on helping Title I students meet the State's academic achievement standards, and resources for mental health services are not available from other public and private sources. Generally, we would expect that communities would have these resources and that it would be unlikely that a school would use Title I funds for this purpose. Instead, the school would use its Title I funds to provide supplemental instruction that is based on scientifically-based research to improve the academic achievement of its Title I students.

To summarize, schools and local educational agencies (LEAs) must design their Title I programs to tailor them to the unique needs of their students. As a result of these varying needs and other factors such as the extent of mental health services supported by non-Federal funds within an LEA, it may, in some circumstances, be appropriate for a

school to use Title I funds to support mental health activities. In many other cases, it would not be appropriate for a school to use Title I funds for this purpose, for example, if the particular educational needs of Title I students in the school would be more effectively met through other activities or these services are already provided through non-Federal funds. In planning Title I programs for the 2013-2014 school year schools and LEAs should work closely with their SEA to ensure that their Title I activities are allowable and designed to ensure maximum success in order for their Title I students to receive a high-quality education.

IDEA

Mr. Kingston: How do schools use IDEA funds to support mental health services and programs? To what extent are funds available for services and programs for non-IDEA eligible students? What are the barriers, if any, for schools to use this funding for this purpose?

Ms. Delisle: Under IDEA, the Secretary makes grants to States to assist them to provide special education and related services to children with disabilities. States can reserve funds at the State level to assist local educational agencies in providing positive behavioral interventions and supports and appropriate mental health services for children with disabilities. In schools, Part B funds are used primarily to pay the excess costs of providing special education and related services to children with disabilities, such as costs for special education teachers and administrators and related services providers. Related services providers supported with IDEA funds may provide mental health services to children with disabilities. In general, IDEA funds can only be used to support services to children with disabilities. Exceptions to these rules are when IDEA Part B funds are: (1) used to provide services to children with disabilities in accordance with their individualized educational programs but one or more nondisabled children benefit under 34 CFR §300.208(a)(1); (2) used for coordinated early intervening services under 34 CFR §300.226, or (3) consolidated in a Title I schoolwide school under the Elementary and Secondary Education Act pursuant to 34 CFR §300.206.

TEACHER TRAINING

Mr. Kingston: To what extent does the Department support training for teachers in identifying and referring students who may have mental health issues?

Ms. Delisle: The Office of Special Education Programs (OSEP) funds teacher training that focuses on the needs of students who have emotional disturbance, many of whom have mental health issues. In addition, OSEP funds grants to train teachers that focuses on the needs of students with other disabilities (e.g., autism) who may have a mental health component as part of their disability. Most of OSEP's training grants (OSEP funds currently support over 8,000 scholars) embed competencies on intrinsic and extrinsic behavior disorders. Special education teachers who have mastered these competencies may support the general education staff with the identification and referral of students who may have mental health issues.

HRSA-FUNDED SCHOOL MENTAL HEALTH RESOURCE CENTERS

Mr. Kingston: To what extent does the Department coordinate with or use information provided by the two HRSA-funded school mental health resource centers (the University of Maryland's Center for Schools and Mental Health and UCLA's Center for Mental Health in Schools)?

Ms. Delisle: Through our Office of Safe and Healthy Students newsletter we routinely share federal resources with those interested in mental health in schools, as well as other topics related to maintaining safe and healthy learning environments. We also share information on federal technical assistance resources with our grantees that focus on mental health.

SUPPORT FOR CHILDREN'S MENTAL HEALTH SYSTEMS

Ms. DeLauro: The fragile and underdeveloped state of the system for children's mental health in the United States has been well documented. Despite a national picture of inadequacy, there do seem to be examples of positive strategies to improve services at the state level. For example, Minnesota is working to overcome shortages in rural areas through tele-psychiatry. Connecticut has demonstrated the value of making emergency psychiatric services available to schools. Please share your knowledge about further instances of innovation and effective practices that exist but are not sufficiently widespread. What can the federal government, and your agencies in particular, do to better spread best practices and support such efforts in communities where the resources are limited?

Ms. Delisle: States and school districts have sought to foster better linkages between the school systems and community-based mental health providers. This was the focus of the Department's Integration of Schools and Mental Health Systems Grant program. To achieve this goal, grantees were required to enhance or develop collaborative efforts between school-based service systems, juvenile justice, and mental health service systems; enhance the availability of crisis intervention services; improve capacity to make appropriate referrals for students potentially in need of mental health services; and provide training for the school personnel and mental health professionals. They were required to put in place detailed linkage protocols outlining inter-agency agreements among partners.

Other local education agencies have sought to bolster internal system capacity to provide in school mental health services, while also creating community linkages for referral where such referral are appropriate. As part of this effort some states have adopted the "Mental Health First Aid" model to systematically train teacher and school staff to identify, understand, and respond to signs of mental illnesses and substance use disorders, especially ensuring students are referred to treatment.

States and school districts have also taken concrete action at the universal intervention level to improve school climate and supports to all students.

NOW IS THE TIME – MENTAL HEALTH

Ms. Lee: In your testimony you both emphasize the portions of the President's Now is the Time document aimed at identifying children and young adults with mental health problems and referring them for treatment. I agree that this must be a priority. Could you each explain to us where this treatment would take place, whether it occurs in school-based health clinics, community health centers, etc.?

Ms. Delisle: Every local community will provide treatment for children and young adults based on the local mental health system resources available to them, and it may include: school-based health clinics, in-school mental health services by licensed mental health professional, or through referral to public and private community mental health service providers, or out-patient mental health facilities associated with hospitals. Ideally, these systems of treatment care would be coordinated and integrated into a seamless system.

Serving the mental health needs of students in a school setting requires a comprehensive and integrated team of school professionals, from teachers, to administrators, to school mental health professionals to support the academic, social, emotional and behavioral development of all students. School mental health professionals includes school counselors, school psychologists, child and adolescent psychiatrists, school social workers, or other qualified psychologists. School-employed mental health professionals provide direct and indirect services for students, families and staff and also spend time in program management working to develop school-wide policies and practices to build protective factors for youth, create systems and infrastructure for screening and referral to treatment, implementing targeted interventions, and meeting acute mental health treatment needs of students.

Ms. Lee: Do we have the systems and capacity in place to care for a significantly larger number of children and young adults, if we are successful in getting them referred for treatment? And if not, what will it take to build that capacity?

Ms. Delisle: The mental health service delivery system currently has capacity issues in certain areas of the country, as well as in specialty areas (such as psychiatry). Meeting new service demands, as the Affordable Care Act expands coverage and the stigma of mental health is reduced, will continue to be a challenge.

Children's mental health disorders affect many children and families. Boys and girls of all ages, ethnic/racial backgrounds, and regions of the United States experience mental disorders. Based on the National Research Council and Institute of Medicine report (Preventing Mental, Emotional, and Behavioral Disorders Among Young People: Progress and Possibilities, 2009) it was estimated that 13 –20 percent of children living in

the United States (up to 1 out of 5 children) experience a mental disorder in a given year and an estimated \$247 billion is spent each year on childhood mental disorders. Because of the impact on children, families, and communities, children's mental disorders are an important public health issue in the United States. Currently, there are Health Professional Shortage Areas in the United States which are designated by HHS. There are three categories of HPSAs: primary care (shortage of primary care clinicians), dental (shortage of oral health professionals), and mental health (shortage of mental health professionals).

HHS has the key federal lead, and statutory authority, for increasing the overall capacity of the mental health system in the U.S., and SAMHSA Administrator Pam Hyde has recently testified before Congress on their investments and goals for increasing mental health system capacity.

Ms. Lee: How do the proposed initiatives differ from existing programs, such as the Elementary and Secondary School Counseling Program and the Safe Schools/Healthy Students Initiative? More than half of all mental illnesses begin before the age of 14, and three-quarters before the age of 24. It seems clear that we need to better support mental health screenings for youth, and in fact I have bill – the Student Support Act – that would increase the number of mental health professionals in schools.

Ms. Delisle: As part of the “Now is the Time” proposal and further articulated in the President’s FY 2014 budget, several new programs were proposed through the Department of Education and additional programs where ED will work closely with HHS and DOJ.

- **School Climate Grants:** In order to create a safer climate at schools across the country, we proposed \$50 million for a new initiative to help 8,000 schools create safer and more nurturing school climates. These grants will assist schools to use evidence-based strategies to prevent and positively intervene to address problem behaviors such as bullying, drug abuse, and poor attendance. It draws heavily from what the Department has learned through OSERS Positive Behavior Interventions and Support work, which research shows when implemented well, improves students’ social skills, leading to a reduction in problem behavior, bullying and peer victimization. Our proposal would scale up this initiative and provide funding for evidence based practices to provide different levels of support to students based on their needs.
- **Grants to Address Pervasive Violence:** In order to help break the cycle of violence and address the pervasive violence that affects many communities, we proposed \$25 million for a new initiative that will help schools address pervasive violence. Funding could be used to offer students mental health services for trauma or anxiety, conflict resolution programs, and other school-based violence prevention strategies. As opposed to Project SERV grants, which typically go to schools that experience a specific incident or natural disaster, these new competitive grants would go to school districts with high concentrations of

children who have been victims of, or witnesses to acts of violence, so they can help address the effects of violence and prevent future incidents.

In addition, ED will work closely with other agencies on the following school related proposals:

- **Comprehensive School Safety Program (DOJ):** In order to make schools safer, the Administration proposed \$150 million for a new program to provide funds for hiring school resource officers (SROs), school psychologists, social workers and counselors; purchasing school safety equipment, training crisis intervention teams, and other school safety activities. To work with the Department of Justice to implement this new program, we will build on our experience with the Department's School Counseling Program, though this program will be more focused on school safety. Resources provided through this new program will be flexible, so that communities can choose the type of support they need most. ED and DOJ will also work to ensure that SRO's have the appropriate training and expertise necessary to effectively work with students and support learning in schools and that schools and police departments understand how to appropriately use SROs.
- **Project AWARE (HHS):** In order to ensure that students have the mental health services they need, the Administration proposed \$55 million for an initiative to reach 750,000 young people through programs to identify mental illness early and refer them to treatment. This two part program would provide:
 - \$15 million for "Mental Health First Aid" training for teachers and others who work with youth to recognize young people who need help and encourage them to seek treatment; and
 - \$40 million to help school districts work with law enforcement, mental health agencies, and other local organizations to ensure students with signs of mental illness get referred to appropriate services. The "mental health first aid" is a new initiative that would focus on enhancing mental health literacy, and destigmatizing mental illness by certifying trainers to deliver the Mental Health First Aid curriculum. The goal is not to develop lay treatment providers but to provide tools to teachers and others who work with youth to understand, recognize, and respond to the signs of mental illness or substance abuse. This new approach is different from many past mental health initiatives and will provide a cost-effective way to detect mental illness and ensure people get the treatment they need.

The new \$40 million initiative is designed to capitalize on over a decade's worth of outcomes achieved by the Safe Schools/Healthy Students program which ED, DOJ, and HHS jointly administered, by offering states the opportunity to take the model to scale. A national evaluation of the Safe Schools/Healthy Students program found over 90% of school staff saw reduced school violence and nearly 80% reported reduced

community violence. There was a 263% increase in students who received school-based mental health services and 519% increase in those receiving community-based services.

Ms. Lee: What are some of the things schools can do – or are already doing – to better prepare people to recognize the early signs of mental illness, and what can this committee do to support those efforts?

Ms. Delisle: Growing evidence shows that school-based initiatives to promote mental health can help students cope with these common issues, support healthy development, and improve educational outcomes. To address barriers to learning, schools need to integrate resources into a comprehensive, cohesive continuum of support that promotes healthy, positive youth development and prevents problems, allows for early intervention to address problems as soon after onset and provides assistance to those with more chronic and severe problems.

To be truly effective and sustainable, it is recommended that school-based mental health services be linked to existing organizational structures in the school, coordinated with community-based resources to extend the continuum of care available to address more severe and acute needs, and evaluated based on data. Using a “public health framework,” these initiatives would encompass the development of multi-layered approaches, interventions, and services that address the continuum of student needs, including primary prevention and education, screening and detection, treatment, follow-up and crisis services, as well as case and systems management as necessary. A multi-tiered framework considers a variety of intervention points for meeting student mental health needs, such as, policies around behavior and discipline, classroom management practices, protocols for referrals for screening and service provision, the manner in which students receive an array of supporting services, and efforts to ensure that all approaches and interventions undertaken are coordinated, culturally, linguistically, and developmentally appropriate, and evidence-based.

Two new programs proposed as part of Now is the Time that would help in this area are the School Climate Transformation Grants and Project Aware outlined above.

Ms. Lee: What are the evidenced based treatments to address children's mental health issues, and how are SAMHSA and the OESE working to promote these?

Ms. Delisle: There are numerous evidence-based treatments, and HHS maintains the National Registry of Evidence-Based Programs and Practices (NREPP). NREPP is a searchable online registry of more than 160 interventions supporting mental health promotion, substance abuse prevention, and mental health and substance abuse treatment. We actively promote this as a resource and tool for our customers, and encourage those creating innovations in program and practice to evaluate their results and submit research and evidence to NREPP to be considered for inclusion in the registry.

THURSDAY, APRIL 25, 2013.

**BUDGET HEARING—DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

WITNESS

**HON. KATHLEEN SEBELIUS, SECRETARY, DEPARTMENT OF HEALTH
AND HUMAN SERVICES**

Mr. KINGSTON. The committee will come to order, and I welcome everyone for the final hearing of the year, for Labor Health and Human Services Education and related agency subcommittee. We have had a number of hearings. I think we would all like to spend more time and getting more questions with every agency, but we don't get to, but we are ending on a strong note with Secretary Sebelius today, and I know that everyone on all sides at all angles and all accounts have lots of different questions.

I think one of the questions that we will want to talk about it, and I think we have given some heads up on it, is the request for—about the reprogramming and transfer request, and we will discuss that in more detail, but let me yield the floor to Rosa DeLauro.

Ms. DELAURO. Thank you very much, Mr. Chairman, and welcome, Madam Secretary, delighted to have you here with us this morning.

As we discuss the President's budget, I believe it is important that we keep in mind a very key point. This budget assumes that the sequestration scheduled for 2014 is replaced with a more sensible and balanced deficit reduction package such as the one being proposed by the President. I very much hope we will succeed in doing that, but I have my doubts. And if we are not successful, the budget for HHS will look very different. Sequestration will reduce the 2014 cap on non-defense discretionary appropriations by roughly \$37,000,000,000, and the Labor HHS bill accounts for almost a third of the non-defense discretionary total. I would like to hear, Madam Secretary, what the impact of this will be.

Moving to the budget before us, one proposed increase I am particularly pleased to see is the focus on investment in early childhood. This is—there is a tremendous need in America for further investment in high quality and readily accessible child care and learning opportunities for infants and toddlers, and while I have some questions about the proposal, I am glad to see this budget moves us in the right direction.

The President's budget also requests appropriations to continue implementation of the health insurance marketplaces under the Affordable Care Act. That is exactly the right thing to do. The ACA is the law of the land, and our constituents deserve to access quality insurance options on its exchanges. It is unconscionable that Congress failed to provide the funding needed this year, and as a

result, HHS has been forced to divert resources away from other critical public health priorities.

The ACA has the potential to transform health care in this country, increasing preventive services, eliminating pre-existing conditions, and reinforcing our longstanding bipartisan support of community health centers.

I am encouraged that the administration requests additional funding for the National Institutes of Health. Patients across the country rely on research supported by the NIH, and other health agencies like the health care research and quality program in order to find out how we can prevent, diagnose earlier and better treat diseases like cancer.

We also rely on public health agencies like the CDC to protect us from new diseases, like the avian flu virus that has affected more than 100 individuals in China, and to detect and control diseases here at home. Even before sequestration, appropriations for the CDC had been reduced by more than \$725,000,000 in 2010. When you add sequestration, the numbers are even worse.

I am pleased that the administration has requested funding to restore cuts made to the Title X family planning program in recent years.

There are a few things in this budget, Madam Secretary, that I can't support. One is the proposed \$445,000,000 reduction to the Low Income Home Energy Assistance Program, LIHEAP. I am opposed to the proposed halving of the community services block grant.

Yet another is the fact that no additional discretionary appropriations will go to combat health care fraud and abuse. It now looks like the President will seek mandatory funding for this. Now, I also understand that the request has been made now 3 years in a row, and that we have had no increase from the majority side of our committee. So that what we need to do is increase this \$311,000,000 which allows us to be able to combat health care fraud and abuse. The effort returned \$7 to the Treasury for every \$1 it spent.

There are a number of other important issues I hope we can discuss today, including the strengthening of access to mental health services, especially in the wake of the tragedy at Sandy Hook Elementary School in Newtown.

As a member of the Connecticut delegation, I can only tell you that it doesn't get any easier to speak about, and our kids need access to quality services after traumatic events like Newtown. We need to do a better job of protecting our children, and we need to do a better job in making sure that they have access to mental health care.

I look forward to our discussion this morning and to your testimony. Thank you again for joining us today.

Thank you, Mr. Chairman.

Mr. KINGSTON. Mrs. Lowey.

Mrs. LOWEY. Thank you, Chairman Kingston, Ranking Member DeLauro. Thank you, Secretary Sebelius for appearing at today's hearing.

I joined this subcommittee 20 years ago. With hard work, bipartisanship and a healthy allocation, the subcommittee can profoundly

improve the lives of our constituents. I have been privileged to support efforts, including doubling biomedical research at the NIH to investigate the causes and treatments for breast cancer, autism, diabetes, Alzheimer's and a number of other diseases and disorders, strengthening our public health system through CDC investments, and expanding Head Start to give more children as many opportunities as possible.

As the subcommittee readies its fiscal year 2014 bill, we must keep in mind that \$2,500,000,000 in deficit reduction has been enacted, the vast majority of which is within the jurisdiction of the Appropriations Committee. Even without sequestration, discretionary spending is on a path to be at its lowest percentage of GDP in the last 45 years. HHS' initiatives cannot absorb further cuts.

While I am supportive of key increases in the budget request, particularly for NIH, the proposed increase is less than one-third the amount lost to sequestration this year. There are a number of examples of investments this subcommittee makes that save taxpayer dollars. The 3-year rolling average of return on investment for the Health Care Fraud and Abuse Control Program is 7.9 to 1. For every public dollar invested in family planning care, nearly \$4 in Medicaid expenditures are averted; and for chronic disease, the more we invest in prevention, the less we spend on treatment in future years.

The fiscal year 2014 budget request includes a number of promising new initiatives, including the President's BRAIN proposal, \$130,000,000 to help educators and parents recognize signs of mental illness, and increased resources for Head Start and child care.

However, I am concerned with a number of proposed reductions, including to children's hospital graduate medical education, LIHEAP and the Community Services Block Grant. Once again, I would like to thank the Secretary. I look forward to today's discussion. Thank you.

Mr. KINGSTON. Do any other members have an opening statement?

If not, Madam Secretary, the floor is yours for 5 minutes, and we are going to stick strictly to the five-minute rule as we always have, so—some committees are a little bit more relaxed about it, but we have a lot of people—we like to take several rounds, so thank you.

OPENING STATEMENT

Secretary SEBELIUS. Well, thank you, Chairman Kingston and Ranking Member Lowey and DeLauro and members of the subcommittee. I am pleased to have the chance to be with you today to discuss the President's 2014 budget for the Department of Health and Human Services.

This budget supports the overall goals of the President's budget by strengthening our economy and promoting middle class job growth. It ensures that the American people will continue to benefit from the Affordable Care Act. It provides much-needed support for mental health services and takes steps to address the ongoing tragedy of gun violence; strengthens education for our children during their critical early years, to help ensure they can succeed in a 21st century economy; ensures America's leadership in health inno-

vation so that we remain a magnet for jobs of the future; and it helps reduce the deficit in a balanced sustainable way.

I look forward to answering your questions about the budget, but first I would like to briefly cover a few of the highlights.

The Affordable Care Act is already benefiting millions of Americans, and our budget makes sure we can continue to implement the law. By supporting the creation of new health insurance marketplaces, the budget will ensure that starting next January, Americans in every State will be able to get quality health insurance at an affordable price. Our budget also addresses another issue that, as Congresswoman DeLauro has already said, has been on all of our minds recently, mental health services and the ongoing epidemic of gun violence.

While we know that the vast majority of Americans who struggle with mental illness are not violent, recent tragedies have reminded us of the staggering toll that untreated mental illness can take on our society, and that is why the budget proposes a major new investment to help ensure that students and young adults get the mental health care they need, including the training of 5,000 additional mental health professionals to join our behavioral health workforce.

Our budget also supports the President's call to provide every child in America with access high quality early learning services. It proposes additional investments in new early Head Start child care partnerships, and it provides additional support to raise the quality of child care programs and promote evidence-based home visiting for new parents.

Together, these investments will create long-lasting positive outcomes for families and provide huge returns for children and society at large. And our budget also ensures that America remains a world leader in health innovation. We make significant new investments in the NIH that will lead to new cures and treatments and help create good jobs. It provides further support for the development and use of compatible health electronic record systems and improved care coordination, and it includes funding to ensure that our Nation can respond effectively to chemical, biological and nuclear threats.

I want to especially thank committee members for your support of our efforts to provide a safe environment for unaccompanied children who enter our country. As you know, we have seen a growing number of children coming into the country without any parents or guardians, and our budget includes additional funds to help ensure an estimated 26,000 unaccompanied children are safe and healthy.

Even as our budget invests in these critical areas, it also helps reduce the long-term deficit by making sure that programs like Medicare are put on a stable fiscal trajectory. Medicare spending per beneficiary, as Ranking Member Lowey has said, grew at just four-tenths of 1 percent in 2012, thanks in part to the \$800,000,000,000 in savings in the Affordable Care Act.

But the President's 2014 budget would achieve even more savings. For example, this budget will allow low income Medicare beneficiaries to get their prescription drugs at lower Medicaid rates resulting in savings of more than \$120 billion over the next 10 years. In total, the budget would generate an additional

\$371,000,000,000 in Medicare savings over the next decade on top of the savings in the Affordable Care Act.

To that same end, our budget also aggressively reduces ways across our Department. It includes an increase in mandatory funding for our Health Care Fraud and Abuse Control Program, an initiative that saved taxpayers nearly \$8 for every dollar spent on it, and it supports additional efforts to reduce improper payments in Medicare, Medicaid and CHIP and to strengthen the Office of the Inspector General. This all adds up to a budget guided by the administration's north star of a thriving middle class, promoting job growth, keeping our economy strong in years to come, while helping to reduce the long-term deficit.

I am sure many of you have questions, Mr. Chairman, and I am happy to take those now. Thank you.

Mr. KINGSTON. Thank you very much, Madam Secretary.

**Testimony of
Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
before the
U.S. House of Representatives
Committee on Appropriations
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
April 25, 2013**

Chairman Kingston, Ranking Member DeLauro, and Members of the Committee, thank you for the invitation to discuss the President's Fiscal Year 2014 Budget for the U.S. Department of Health and Human Services.

This budget for the Department of Health and Human Services (HHS) provides critical investments in health care, disease prevention, social services, and scientific research in order to create healthier and safer families, stronger communities, and a thriving America. While it invests in areas that are critical to our long-term prosperity, the budget also helps tackle our deficit with legislative proposals that would save an estimated net \$361.1 billion over 10 years. The Budget totals \$967.3 billion in outlays and proposes \$80.1 billion in discretionary budget authority. With this funding HHS will continue to improve health care and expand coverage, create opportunity and give kids the chance to succeed, protect vulnerable populations, promote science and innovation, protect the nation's public health and national security, and focus on responsible stewardship of taxpayer dollars.

Improving Health Care and Expanding Coverage

Expanding Health Insurance Coverage. Implementation of the Exchanges, also referred to as Marketplaces, will improve access to insurance coverage for more than 25 million Americans. Marketplaces make purchasing private health insurance easier by providing eligible consumers and small businesses with one-stop-shopping where they can compare plans. New premium tax credits and the increased transparency and competition in the Marketplaces will improve affordability of private coverage. FY 2014 is the first coverage year for plans purchased through the Marketplaces; open enrollment begins October 1, 2013 for the coverage year beginning January 1, 2014. The Budget supports operations in the Federal Marketplaces, as well as oversight of and assistance to State-based Marketplaces.

Beginning in 2014, consumers will benefit from a number of new protections in the private health insurance market. Most health insurers will no longer be allowed to charge more or deny coverage to people because of pre-existing conditions. These new protections will also prohibit most health insurers from putting annual dollar limits on benefits and from varying premiums based on gender or any factor other than age, tobacco use, family size, or geography. In addition, new plans in the individual and small group market will be required to cover a comprehensive package of items and services known as Essential Health Benefits, which must include items and services within ten benefit categories. Finally, most individuals choosing to participate in clinical trials will generally not face limits in health insurance coverage for routine patient costs. This protection applies to all clinical trials that treat cancer or other life-threatening diseases.

Expanding Access to Care through Health Centers. The FY 2014 Budget includes \$3.8 billion for the Health Centers program, including \$2.2 billion in mandatory funding provided through the Affordable Care Act Community Health Center Fund. In FY 2014, 23 million patients will receive health care through more than 8,900 sites in medically

underserved communities throughout the nation. The Budget funds new health center sites for the provision of preventive health care services, expanding outreach and care to approximately 1.5 million additional patients.

Improving Patient Safety. HHS is committed to improving patient safety and reducing the risks and harm to patients. The Budget includes \$63 million for patient safety research at the Agency for Healthcare Research and Quality (AHRQ). This research focuses on the risks of harm inherent in the delivery of health care, which helps us understand the factors that can contribute to adverse events and how to prevent them. In FY 2014, AHRQ will fund projects on improving team performance, provider training, and coordination, as well as establishing cultures conducive to patient safety in health care organizations. This research will help the medical community reduce errors and improve patient safety.

Increasing Access to Mental Health Services

The FY 2014 Budget includes over \$1 billion for mental health programs at the Substance Abuse and Mental Health Services Administration (SAMSHA), including the \$460 million for the Community Mental Health Services Block Grant. This block grant provides States flexible funding to maintain community based mental health services for children and adults with serious mental illnesses, including rehabilitation, supported housing, and employment opportunities. The Budget also proposes funding within the block grant to encourage States to build provider capacity to bill public and private insurance. This will support States in an effective transition in the first year of the Affordable Care Act, which will include expanded coverage for mental health and substance abuse treatment services.

Expand Prevention and Treatment for Youth and Families. While the vast majority of Americans with a mental illness are not violent, and are in fact more likely to be the victims of violence, recent tragedies have brought to light a hidden crisis in America's mental health system. The Budget addresses these issues by investing \$130 million to help teachers and other adults recognize signs of mental illness in students and refer them to help if needed, support innovative state-based programs to improve mental health outcomes for young people ages 16-25, and train 5,000 more mental health professionals with a focus on serving students and young adults.

Helping Families and Children Succeed

In his State of the Union Address, the President proposed a series of new investments to create a continuum of high-quality early learning services for children beginning at birth through age five. As part of this initiative, HHS and the Department of Education are working together to make universal, high-quality preschool available to four-year olds from low- and moderate-income families through a partnership with states, expand the availability of high-quality care for infants and toddlers, and increase highly-effective, voluntary home visiting programs to provide health, social, and education supports to low-income families. Specifically, the FY 2014 HHS Budget includes:

Early Head Start—Child Care Partnerships. The Budget proposes \$1.4 billion in FY 2014 for new Early Head Start – Child Care Partnerships that will expand the availability of early learning programs that meet the highest standards of quality for infants and toddlers, serving children from birth through age three. In addition to the new Partnerships, the Budget provides \$222 million above FY 2012 to strengthen services for children currently enrolled in the program, avoid further enrollment reductions, and support the Head Start Designation Renewal System. Together, these investments total \$9.6 billion, an increase of \$1.7 billion over FY 2012.

Child Care Quality Fund. The request includes an additional \$700 million above FY 2012 to expand early learning opportunities. Within this total, \$200 million will help states raise the bar on quality by strengthening health and safety measures in child care settings, supporting professional development for providers, and promoting transparency and consumer education to help parents make informed child care choices. In addition to this funding, the Budget provides \$500 million above FY 2012 to serve 1.4 million children, approximately 100,000 more than would otherwise be served.

Home Visiting. The Budget extends and expands this voluntary evidence-based program that has shown to be critical in improving maternal and child health outcomes in the early years, leaving long-lasting, positive impacts on parenting skills; children's cognitive, language, and social-emotional development; and school readiness. The Budget proposes a long-term \$15 billion investment beginning in FY 2015.

Unaccompanied Alien Children. I would like to thank the Congress for providing an additional \$248 million for the refugee appropriation in FY 2013 to accommodate the increased number of unaccompanied alien children (UAC) while maintaining services for refugees. While sequestration and the across-the-board rescission still leave a shortfall, we are taking necessary action to ensure we can accommodate all UAC arrivals without reducing essential refugee services. The FY 2014 budget request includes \$1.1 billion, an increase of \$355 million over FY 2012, to accommodate 26,000 UAC while maintaining services for refugees. HHS has kept Congress informed about the continuing UAC increase and looks forward to working with Congress to ensure both UAC and refugees are served.

Protecting Vulnerable Populations

Addressing the Unique Needs of Communities. The Administration for Community Living (ACL) was formed in April 2012 as a single agency designed to help more people with disabilities and older adults have the option to live in their homes and participate fully in their communities. The FY 2014 Budget reflects the creation of ACL by bringing together the resources for the Administration on Aging, the Office on Disability, and the Administration on Intellectual and Developmental Disabilities, into a consolidated request. This newly organized agency works across HHS to harmonize efforts to promote community living, which can both save federal funds and allow people to choose to live with dignity in the communities they call home. ACL's Lifespan Respite Care program, as an example, focuses on providing a testbed for needed infrastructure changes and on filling gaps in service by putting in place coordinated systems of accessible, community-based respite care services for family caregivers of children and adults with special needs.

Ryan White. The Budget includes \$2.4 billion for the Ryan White HIV/AIDS program to continue its critical role in support of patients across the HIV/AIDS continuum, by linking patients to care, prescribing and improving adherence to antiretroviral medicine, and achieving viral suppression. Included in this total is \$943 million for the AIDS Drug Assistance Program (ADAP), an increase of \$10 million over FY 2012 to provide life-saving and life-extending medications to 218,900 individuals. This investment will allow ADAP to serve an additional 1,600 people living with HIV/AIDS relative to the estimated number of clients served in FY 2012.

Promoting Science and Innovation

Advancing Scientific Knowledge. The FY 2014 Budget includes \$31.3 billion for the National Institutes of Health (NIH), an increase of \$471 million over the FY 2012 level, reflecting the Administration's priority to invest in innovative biomedical and behavioral

research that spurs economic growth while advancing medical science. In FY 2014, NIH will focus on investing in today's basic research for tomorrow's breakthroughs, advancing translational sciences, and recruiting and retaining diverse scientific talent and creativity. Investment in NIH also helps drive the biotechnology sector and assure the nation's place as a leader in science and technology.

Alzheimer's Disease Initiatives. The Department continues to implement the National Plan to Address Alzheimer's Disease, as required by the National Alzheimer's Project Act. In FY 2014, the Budget includes a \$100 million initiative targeted to expanding research, education, and outreach on Alzheimer's disease, and to improving patient, family, and caregiver support. Included in this initiative is \$80 million within the NIH budget to be devoted to speeding drug development and testing new therapies. Also, the Prevention and Public Health Fund (Prevention Fund) allocation includes \$20 million for the Alzheimer's Disease Initiative. Of this, ACL will use \$15 million to strengthen state and local dementia intervention capabilities and for outreach to inform those who care for individuals with Alzheimer's disease about resources available to help them. HRSA will use the other \$5 million to expand efforts to provide training to healthcare providers on Alzheimer's disease and related dementias.

Protecting the Nation's Public Health and National Security

Project BioShield and Advanced Development. In FY 2014, HHS will continue to support the development and procurement of medical countermeasures (MCMs) against chemical, biological, radiological, and nuclear (CBRN) threats. This funding includes \$415 million to support advanced research and development of MCMs through the Biomedical Advanced Research and Development Authority. Additionally, the Budget includes \$250 million as the first installment of a multi-year commitment to support Project BioShield, aimed to facilitate the procurement of these MCMs for the Strategic National Stockpile. Together, these efforts will enhance the nation's ability to acquire MCMs that will be vital to mitigating or preventing the effects of CBRN threats.

Infectious Disease Surveillance Modernization. The Budget invests \$40 million to modernize CDC's surveillance technology and methods to better detect and track infectious disease. This investment will allow CDC to retool its national surveillance systems and detect and respond to emerging health threats in a timely manner. CDC's infectious disease surveillance technologies are becoming increasingly outdated and threaten the basic public health mission of the agency. In an effort to keep up with advances, CDC is making substantial investments in bioinformatics, database development, data warehousing, and analytics. This initiative requires strategic and sustained investment in the following areas: pathogen identification and detection using genomics, adaptation of new diagnostics, state assistance and coordination, enhanced and integrated sustainable laboratory systems, and tool development to support prediction and modeling for early disease detection.

Focusing on Responsible Stewardship of Taxpayer Dollars

Contributing to Deficit Reduction while Maintaining Promises to all Americans. The Budget makes the investments the nation needs right now while reducing the deficit in the long term and ensuring the programs that millions of Americans rely on will be there for generations to come.

The Budget maintains ongoing investments in areas most central to advancing the HHS mission while making reductions to lower priority areas, reducing duplication, and increasing administrative efficiencies. Overall, the FY 2014 Budget includes nearly \$2.3 billion in discretionary terminations and reductions.

Combating Fraud, Waste, and Abuse in Health Care. The FY 2014 Budget makes continuing to cut fraud, waste, and abuse a top Administration priority. In addition to the \$311 million in base discretionary Health Care Fraud and Abuse Control (HCFAC) funding, the Budget invests \$329 million in new mandatory funding in FY 2014 to ensure that HHS and the Department of Justice (DOJ) have the resources they need to conduct critical program integrity activities. Starting in FY 2015, the Budget proposes all new HCFAC investments be mandatory, consistent with levels in the Budget Control Act. This investment supports fraud prevention initiatives like the Fraud Prevention System and provider screening; reducing improper payments in Medicare, Medicaid and CHIP; and HHS-Department of Justice Health Care Fraud Prevention and Enforcement Action Team initiatives, including the Medicare Strike Force teams and the Fraud Prevention Partnership between the federal government, private insurers, and other key stakeholders.

From 1997 to 2012, HCFAC programs have returned over \$23.0 billion to the Medicare Trust Funds, and the current three-year return-on-investment of 7.9 to 1 is the highest in the history of the HCFAC program. The Budget's 10-year HCFAC investment yields a conservative estimate of \$6.7 billion in Medicare and Medicaid savings.

The Budget includes \$389 million in discretionary and mandatory funding for the Office of Inspector General (OIG), an increase of \$101 million above the FY 2012 level. A portion of this increase is funded through the additional mandatory HCFAC investment, which is a top priority in this Budget. This increase will enable OIG to expand Program Integrity efforts for the Health Care Fraud Prevention and Enforcement Action Team and improper payments, and also enhance investigative efforts focused on civil fraud, oversight of grants, and the operation of Affordable Care Act programs.

The Budget also includes \$82 million for the Office of Medicare Hearings and Appeals (OMHA), an increase of \$10 million from FY 2012, to address OMHA's adjudicatory capacity and staffing levels and maintain quality and accuracy of its decisions. The increase allows OMHA to establish a new field office in the Central time zone supported by additional Administrative Law Judge teams, attorneys, and operational staff.

Performance, Evaluations and Effectiveness

Assessing the Impact of Health Insurance Coverage Expansions on Safety Net Programs. The Budget includes \$3 million to the Assistant Secretary for Planning and Evaluation to evaluate the impact of health insurance coverage and benefit expansions among beneficiaries of HHS direct service programs. This request supports the continuation of research and evaluation studies, collection of data, and assessments of the costs, benefits and impacts of policies and programs under consideration by HHS or the Congress.

Improving the Use of Evidence-Based Interventions. The Budget includes proposals to improve the use of evidence-based interventions in SAMHSA's Mental Health Block Grant to ensure that federal resources are invested in strategies that work. This proposal will require states to target resources, through their formula grant allocations, to evidence-based interventions.

The Budget will also substantially increase support for the National Registry of Evidence-based Programs and Practices. This searchable online system supports states, communities, and tribes in identifying and implementing evidence-based mental health and substance abuse prevention and treatment interventions. Additional funding will be used to ensure the registry includes cutting edge innovations that work.

Thank you for the opportunity to testify. I will be happy to answer any questions you may have.

AFFORDABLE CARE ACT IMPLEMENTATION

Mr. KINGSTON. I think the first question that we have, or that I have is that the projection for implementation of Obamacare in 2013 was 1.2 billion, but now it looks like you are requesting, and are going to use 1.7 billion, which is certainly a big swing, but also, I have concerns where this money comes from. Some of it comes out of the CDC prevention programs, for example, or biomedical research, NIH and other programs like mental health training, suicide prevention, Alzheimer's disease and prevention outreach, just for a few examples, and so I would like to know, you know, I would like you to react to that, and I want to add up the additional fiscal year 2013 funds that I understand that are being used.

CMSS made it Obamacare base of 154,000,000 at CMS; residual Obamacare implementation fund, 223,000,000; proposed 1 percent transfer for authority, which we will review once the operating plans are submitted; and prevention public health funds of 554,000,000, and non-recurring expense funds of 450,000,000 that comes to this total of 1.7 million.

So it looks like you are cobbling together some money, and I don't—I guess the question is, at what point do you know if you have enough? And if you don't get this, how are you going to be able to implement Obamacare?

Secretary SEBELIUS. Well, Mr. Chairman, as you know, we did not have a 2013 budget, and we made a request in the debate over the continuing resolution for additional funding particularly for outreach and education. That was not granted by the United States Congress. It is our job to implement the law, and we have millions of Americans looking forward to the opportunity for affordable health care, so we have used the authorities that I have as Secretary to reprogram some of the prevention funding to use specifically for outreach and education, to use our non-recurring expense fund for one-time IT expenses, and to take advantage of the secretarial transfer authority to add additional resources.

I think the original bill contained \$1,000,000,000 in administrative funding, and at that time, the Congressional Budget Office estimated that the administrative costs would be closer to \$10,000,000,000.

So we are now here in 2013 administering this law. We are using every dollar that we have been allocated as carefully as possible, but the highest priority for public health in this country is to try and make sure that every American has good health, and access to preventive services and ongoing health care, and so we are continuing to implement the law.

Mr. KINGSTON. What is the total cost of implementation, do you think? Is that 1.7 going to do it?

Secretary SEBELIUS. Well, as you know, the budget before you, Mr. Chairman, asked for an additional \$1,500,000,000.

Mr. KINGSTON. And that would do it in its entirety—

Secretary SEBELIUS. Well, we are—

Mr. KINGSTON. Or what would you say would do it in its entirety?

Secretary SEBELIUS. I mean, we are, at this point, asking for the resources that we think are appropriate, the basic infrastructure to

run the Federal marketplaces and the Federal hub are built with the resources that we have. We are still relying on not only the resources we are able to put together, but outside partners to help with outreach and education, which is a critical part of the program success. If people don't know the choices they can make, if they don't have access to enrollment help and information, we will struggle to get people enrolled.

So, the resources we have requested, again, are in anticipation of additional funding coming in with user fees from the marketplaces once they are set up, but also to use for outreach and education.

Mr. KINGSTON. Okay. And if you take say the funds from CDC to do this, what will the impact be on CDC?

Secretary SEBELIUS. Well, what we have done, Mr. Chairman, these are not CDC budget dollars. They are the Prevention Fund dollars that are part of the Affordable Care Act. Many of those programs are administered by the Centers for Disease Control and Prevention. We have made some very tough choices continuing some of the basic operational issues around tobacco cessation and control, around obesity prevention, looking at chronic disease programs with the community, transformation grants, trying to keep whole the major initiatives, but also recognizing that the public health direction around the Prevention Fund is outreach and education involving preventive services, private insurance and Medicaid linking uninsured and underinsured individuals to preventive services on an ongoing basis, so we are balancing tough choices. We would prefer that our budget actually be fully funded. That is what our request was. That didn't happen, so we are trying to make it work.

Mr. KINGSTON. Okay. Ms. DeLauro. Thanks.

IMPLEMENTATION OF THE AFFORDABLE CARE ACT

Ms. DELAURO. Thank you very much, and thank you, Madam Secretary. It is important to point out that the request was made for the implementation fund, but it was denied by the Congress.

FIREARMS RESEARCH & NATIONAL VIOLENT DEATH REPORTING SYSTEM

With that, let me just talk about the budget proposal for two increases for the CDC injury prevention center. That is in conjunction with what the President has talked about as his "Now is the Time" initiative. This involve violence and firearms. One increase is to support additional research in this area; the other is to expand to all States the National Violent Death Reporting System that collects extensive data regarding deaths from all forms of violence.

What is the purpose of the violent death reporting system, what benefits would be obtained from expanding it to cover more States, what benefits would you hope to achieve from additional public health research into firearms-related violence?

Secretary SEBELIUS. Well, as you know, Congresswoman, Centers for Disease Control and Prevention is responsible for investigating, surveilling and gathering information around preventable injuries, around public health crises—and certainly firearms and deaths related to firearms are a significant issue here in the United States.

They cause about 87 deaths a day in America—suicides, unintentional firearm deaths, and intentional firearm deaths. There is over \$47 billion in related health costs, loss of productivity, loss of life, medical issues directly related to firearm injuries and deaths.

So, it is a significant public health issue, and making sure that the data is collected accurately, that it is reported accurately and that people can then assess what is happening and look for ways to lessen and reduce the impact of firearm violence is part of making America a healthier place and restoring some resilience in health community by community.

TITLE X

Ms. DELAURO. Thank you. With regard to Title X family planning, I mentioned the increase. The program offers major benefits in reducing unintended pregnancies and also a range of other services—treatment for STDs, screenings for cancer. What do you see as the public health benefits of a Title X program, what arguments would you want to make to this subcommittee regarding the importance of the proposed increase?

Secretary SEBELIUS. Well, I think, as you have already said, Congresswoman, Title X, which has been a very important public health initiative for decades, is serving about 5,000,000 clients a year and providing not only important family planning services, helping families make choices about spacing of pregnancies, but cancer screenings, cervical and breast cancer screenings, and primary health care in many facilities across this country. They serve a very low income population, often uninsured and underinsured, and more and more clients are making those their providers of choice, so we see this as a critical infrastructure for healthy families, healthy pregnancies, and screening for early detection of diseases.

In breast cancer alone, what we know is early detection, the survival rate after 5 years is almost 98 percent. If you wait until year 3 or 4, the death rate rises dramatically, so early detection really is a life-or-death issue in some of these screening cases. And again, Title X programs provide those very necessary health services.

PRESCRIPTION DRUG ABUSE

Ms. DELAURO. I know that from experience on ovarian cancer.

A survey by State directors for alcohol and drug abuse found that virtually all State directors consider prescription drug abuse and misuse to be a top issue impacting their States. I am going to get to the question because my time is going to run out.

Do you agree that we face a prescription drug abuse epidemic? I want to applaud CDC for the work that they are doing in this area. Are there things in your budget proposal to address that epidemic? I would note that overall, the budget request for SAMHSA proposes to cut substance abuse programs by more than \$100,000,000.

Secretary SEBELIUS. Well, actually, we have a cross-department group working actively in this area, collecting data, looking at all the information around prescription drug abuse. I do share the concern that it is a rising issue and one that has actually surpassed illegal drug use in some areas. So we are looking at all kinds of

ways we can partner with States, because States run a lot of the initial screening devices. They collect data. FDA just made a very important move, we think, recently, which is to take the original form of OxyContin off the market and substitute a new formulation for OxyContin that is much harder to use in illegal ways, and much harder to make into substances that either can be snorted or inserted, which is what was found to be happening.

So I think that move, in and of itself, will help control, but we are looking at all the tools that we have and we would love to work with this committee in these efforts.

Mr. KINGSTON. Mr. Alexander.

Ms. DELAURO. Thank you.

PUBLIC HEALTH SERVICE ACT EVALUATION TAP

Mr. ALEXANDER. Thank you, Mr. Chairman, comment and then a question. We have talked—we have heard you say something about outreach and education a couple of different times already this morning, and I find it interesting how that the National Institutes of Health, a few weeks ago we were talking with Dr. Collins about some of the concerns that he has. Two of his biggest concerns, he said, are Alzheimer's and obesity. Alzheimer's, we can't prevent, can't cure, can't prolong it, we die from it or die with it. Over here, obesity, we can cure, we can prevent it, we don't have to die from it, and we already know, as we are eating a bag of potato chips, that they are not good for us, so we have to question just the wisdom of spending a gob of money on education when we already know some of things that we do are not good for us.

But anyway, I want to ask a question that expands or touches on something that Chairman Kingston was talking about a while ago.

You are authorized to tax, or to tap, as you like to call it, authorize programs of up to 1 percent. Their appropriations, in order to conduct program evaluations, the administration has asked for an increase. In fact, in 2014 the request is to increase the tap to 3 percent or effectively move around \$1,300,000,000 of resources through this nontransparent budget trick.

Last year, the subcommittee held that tap to 1 percent. I am not sure why we continue using this mechanism. For example, while the request supposedly provides the National Institutes of Health \$31,000,000,000 for medical research, in reality it shifts about 1,000,000,000 to other activities within your Department. The intent of the authority is to provide support for program evaluations, of course, when in reality, again, the funds are to support program operations within your office.

So the question is, the projected \$1,300,000,000 in tap funds proposed for 2014, how much of those funds will be spent on actual program evaluations?

Secretary SEBELIUS. Well, Congressman, as you know, the Congress sets the amount of the tap and the dollar amount that we can use, and we will follow that closely. We have made a recommendation to you of what we think would appropriately cover everything from research and evaluation efforts going to program initiatives, but we will work with the committee, but ultimately, it is the decision of Congress what that amount is, and as you say, you limited

the amount to 1 percent. We will follow the directions and work with the committee about the appropriate amount.

Mr. ALEXANDER. Do you still think this is the way it should be done instead of just appropriating the amount for each program that we need to do so?

Secretary SEBELIUS. I think it is an effective tool to allow us to actually look at initiatives that may have more bearing 1 year than the next year, and rather than locking money into one place, it allows us to acknowledge that a lot of the programs in our Department impact all of the agencies, and all of the agencies contribute. I think AHRQ is a good example where they do unique efforts to work directly with providers, and the work they do with providers actually impacts a lot of the different agencies. It impacts NIH. It impacts CDC. So having an opportunity for those larger agencies to contribute to those important research and outreach efforts and change protocol and inform providers, I think, has a mutual benefit.

Mr. ALEXANDER. Thank you.

Mr. KINGSTON. Ms. Lowey.

HEAD START

Mrs. LOWEY. Thank you. Madam Secretary, after more than four decades of providing the support that children and families need to succeed, Head Start still reaches only about two-fifths of eligible preschool-age children. Early Head Start, which has been in place since the mid 1990s, reaches a mere 4 percent of eligible infants and toddlers. Clearly, there is a tremendous amount of work that still needs to be done to reach these families.

As you explain in your testimony, the President's budget is requesting \$1,400,000,000 in resources for a new Early Head Start competitive program with a goal of reaching more than 100,000 additional children under the age of three who do not currently have access to high quality early care. In the Recovery Act, Congress provided funding for a targeted expansion of Early Head Start, in particular.

Can you tell us if that has been successful? Am I correct that the research is clear that this period of time in a child's life is of critical importance and that the Early Head Start approach is especially effective?

Secretary SEBELIUS. Congresswoman, the proposal that the President has made in the 2014 budget and outlined a bit in the State of the Union is one of the most exciting second-term initiatives, and it really is a birth through five initiative, recognizing that the single best investment we can possibly make is getting all of the children in this country ready to be productive citizens and live up to his or her full potential.

So our portion of this is infants, toddlers, and home visiting; and as you say, the resources requested would increase the number of children in Early Head Start and actually add some cost-of-living increases and continue our quality initiatives for Head Start, which has been proven to be quite successful, not just in terms of getting children school-ready, but in terms of long-term impact on their lives—fewer dropouts from high school, fewer drug abusers, fewer end up in any kind of correctional facility, more long-term success

at jobs. Any studies that have followed high quality child care have proven that for high quality early education. So we think this initiative, home visiting plus Early Head Start and child care, raising the quality of child care, and there is also a piece of this that deals with child care, and then working with the States around expanded pre-K and kindergarten are probably the best ways we can get America ready for the 21st century.

Mrs. LOWEY. Thank you very much, and I hope that the bill will reflect the statistics because as a mother of three and a grandmother of eight and someone who visits schools all the time, you really see the impact of early education, so I thank you.

PREPAREDNESS

On hospital preparedness grants. Last week's terrorist attack in Boston serves as a reminder of how vital it is for hospitals to maintain a high level of readiness to deal with disasters and mass casualty incidents. That means having adequate stocks of the necessary supplies and equipment, but it also requires planning, coordination and enough drills and exercises to stay proficient.

Like New York, Boston happens to have a number of outstanding hospitals and trauma specialists who played a significant role in the impressive response to the bombings; however, I am concerned that HHS grants to maintain and improve hospital preparedness are being steadily reduced. Funding has been cut from \$420,000,000 in 2010 to \$375,000,000 in 2012. Now the President's budget request for 2014 proposes yet another cut to \$255,000,000. Why was that recommended? Can we be confident that it won't have a detrimental effect on hospital readiness?

Secretary SEBELIUS. Well, I think that the budget reflects an ongoing interest in, as you say, training, preparedness, and working with hospitals. Some of the cuts have been due to the fact that some of the early dollars bought one-time equipment. It doesn't need to be replaced because it is there. I think that there is no question either watching the recent New York example. When newborns were evacuated from NYU, and they knew exactly where they were going and vulnerable patients were evacuated from nursing homes, the hospital had search capacity, the ambulance contracts work was successful due to the fact that that had been planned for, and that had been talked about and had been practiced.

We saw it again in Boston where injured people were able to be quickly transported and taken care of, so we take these very seriously. It happens in communities around the country and that will be an ongoing effort for us to work on.

Mrs. LOWEY. Thank you, Mr. Chairman.

Mr. KINGSTON. Mr. Womack.

MEDICAID EXPANSION

Mr. WOMACK. Thank you, Mr. Chairman, and thank you, Madam Secretary.

As you know, this week, my home State of Arkansas signed into law, pursuant to the recent session of the general assembly, something rather innovative as it concerns insuring people between 100 and 133 percent of Federal poverty level, and providing you ap-

prove the proposal, our State is depending on you to be a stable funding partner.

I also recognize that the Arkansas legislation that was signed has an off ramp, a circuit breaker in the event that promises made today perhaps aren't kept, but I have this concern. The Supreme Court, in its ruling, said that Federal Government can't condition the first dollar of Medicaid on the expansion pursuant to the ACA; however, I am a little unclear as to whether that means that if Arkansas opts, as they have, into expansion and then decides later for whatever purpose, whatever reason, that they have to employ this circuit breaker, as it were, that we will be—we will be okay. I know you can't speak for the U.S. Supreme Court, but what assurances can you give our State that our circuit breaker is legit, is okay?

Secretary SEBELIUS. Well, Mr. Womack, I think it is an important question, and when the Supreme Court ruled last summer, they basically, if you will, divided Medicaid into the traditional program, and then this sort of new Medicaid program, which would allow States to take advantage of a funding partnership outlined in the Affordable Care Act.

We have said from the outset in our guidance to States that you can come in when you want into the new program and come out when you want. What Arkansas did in their legislation was sort of codify that. There is a lot of fear voiced with governors, not just Governor Beebe, but I talk to governors virtually every day and they say, well, what if Congress changes the deal, what if, you know, we look at this funding and it switches next year or the following year, which is why I think it was important that the President and Gene Sperling, his head of the Council of Economic Advisors made very clear that this President, at least, is committed to the funding formula, but beyond that, the guidance from HHS has been pretty clear from the outset. If this is a financial detriment, you come out of the new program and there is no impact on the traditional Medicaid, and that is really what the Supreme Court said, is that you can't use a threat of losing all of your Medicaid dollars as a lever to convince States to come into the new Medicaid program, so we really have two kind of separate groups of people.

Mr. WOMACK. Are you personally concerned that a few years from now that we may be having to trigger that circuit breaker?

Secretary SEBELIUS. Well, I am hopeful that won't be the case. I think that, again, there is some incredibly impressive work going on with governors and with the flexibility that we have given governors around the Medicaid program. And Arkansas, I have to tell you, is one of the States at the front of the line, looking not only at this particular new legislation, but looking at au pair systems, trying to figure out ways that they can be delivering better care at a more cost-effective price. We are really working closely with them.

As a former governor, I take these efforts very seriously. We have new dual eligible efforts underway, and for the first time last year, between 2011 and 2012, the spending on Medicaid per capita around the country went down 2 percent. It is a decrease, the first time really in the history of the program, so we think there is some very encouraging projects underway. I don't know what will happen

5 and 10 years from now, but certainly that protection is there for States.

Mr. WOMACK. I recognize my time, Mr. Chairman. I have got about 25 seconds left, so I know you are going to add that to my next round questions, provided I am here. I yield back.

Mr. KINGSTON. I think we all want to learn more about Arkansas.

Ms. DELAURO. Worth checking it twice.

Mr. KINGSTON. Yes. Ms. Roybal-Allard.

ADVISORY COMMITTEE ON HERITABLE DISORDERS

Ms. ROYBAL-ALLARD. Madam Secretary, I would like to begin, first of all, by thanking you for using your authority to continue the Advisory Committee on Heritable Disorders while Mr. Simpson and I are working to get the reauthorization of the Newborn Screening Saves Lives Act. We truly do appreciate that.

RACIAL AND ETHNIC APPROACHES TO COMMUNITY HEALTH

Two years ago, HHS released an unprecedented action plan to address racial and ethnic disparities, and that plan cited racial and ethnic approaches to community health known as REACH as an exemplary program. GAO also praised REACH, and there were more than 150 journal articles documenting the achievements of the REACH program in reducing health disparities.

Your fiscal year 2014 budget eliminates REACH and instead, points to the community transformation grants as the next stage of CDC community-based programs. What evidence can you provide to demonstrate that the CTG program will at least be comparable to REACH in reducing racial and ethnic health disparities?

Secretary SEBELIUS. Well, Congresswoman, as you say, for the first time, we do have an action plan based on health disparities, and I think there is no doubt that REACH was an initial test case for funding, and REACH, I think, funded about eight organizations aimed at specific efforts to reduce health disparities and deal with a lot of the chronic disease issues that affect particularly disparate communities.

The community transformation grants actually fund 107 organizations, half of which are also REACH organizations. So a lot of what REACH was doing is being taken over and amplified by community transformation. We have taken what we have learned from REACH and tried to actually expand it dramatically into communities across the country, and it will be, I think, a much larger lever to use in terms of reducing health disparities.

Ms. ROYBAL-ALLARD. I think the concern that has been expressed is that, that those who are either current or former REACH grantees have actually been unable to compete against the much larger agencies and non-profits winning the CTG grants, and so the result is that the organizations with REACH grants that have had the greatest success of measurable change in the health and wellbeing of racial and ethnic minorities with the greatest burden of disease are not going to be participating in the CTG, and the concern and what I am concerned about is that their inability to successfully compete in the CTG grants will impact their successful reductions

in health disparities in these most vulnerable minority communities.

And so there just seems to be a gap there that I think that we need to look at so that we don't backslide in those areas.

Secretary SEBELIUS. Well, I would agree wholeheartedly that we don't want to backslide, and my information is that half of the REACH organizations actually also are community transformation grant organizations, but we would be happy to work with you and your staff to look at the details of the organizations you are concerned about.

Ms. ROYBAL-ALLARD. And how do you plan to meet the goals of the action plan itself? And do you have certain benchmarks that have to be met?

Secretary SEBELIUS. We do. We are measuring them carefully. And I think while there are a number of initiatives that have proven successful, we think one of the single biggest initiatives that we can make is fully implementing the Affordable Care Act, so closing the gap with access to health insurance, access to preventive benefits, having a healthy home for families who right now struggle with that may make the largest difference we could possibly make in health disparities in this country.

Ms. ROYBAL-ALLARD. Okay. I can see that my time is almost up, so I will reserve for the second round.

Mr. KINGSTON. Was it Dr. Harris or Mr. Fleischmann.

AFFORDABLE CARE ACT IMPLEMENTATION

Mr. FLEISCHMANN. I think Doctor—oh, okay. Thank you.

Thank you, Mr. Chairman. Good morning, Madam Secretary. I am Chuck Fleischmann. I represent the Third District of Tennessee, and to follow up on some of my colleagues' questions, we have heard numerous mentions of the Department's intentions to transfer funds from various accounts to implement the Affordable Care Act.

I am particularly concerned about your proposals to use \$500,000,000 more for ACA implementation than you previously predicted you would need, especially given your Inspector General's concerns about exchange implementation. You have demonstrated a willingness to redirect funds for your purposes. I have two questions.

What changes have you made to support States that are looking at buying the expansion population into the exchange? And my second question is will you be pushing back the exchange implementation to adjust for unforeseen problems that have arisen and that have led you to seek additional funds for implementation?

Secretary SEBELIUS. Well, Congressman, first of all, I think we have sought funds in the budget process. We sought funds in the CR process. Having failed in both of those efforts through the work of the United States Congress, we are then using the resources available within the Department to make sure we implement the law of the land.

I am not quite sure I understand your question about the States who want the expansion population in the exchange, but as you heard Mr. Womack say, Arkansas, which has a plan to use their Medicaid dollars to purchase coverage for individuals from a com-

pany offering coverage in the exchange and then provide wrap-around coverage, we are working very closely with. We have not yet had a specific proposal from Governor Beebe around what their 1115 waiver would look like, but we are eager to get it now that the legislation has passed.

I have had many conversations with Governor Haslam about his interest in that possibility. He is watching, I would say, the Arkansas situation closely. We have expressed an eagerness to work with him outlining what the law allows us to do and what it doesn't allow us to do, but we are working with a number of governors around the expansion population and what the flexibility for the States may look like.

Mr. FLEISCHMANN. Well, okay, but let me ask you a follow up. Will you be pushing back the exchange implementation, though? Are you going to push it back, or what are your plans?

Secretary SEBELIUS. No, sir.

MEDICARE

Mr. FLEISCHMANN. Okay. Let me ask you a question, if I may, in the time I have got left about hospitals and the bad debt situation. My question regards the administration's proposal to cut Medicare, bad debt payments by \$25.5 billion while asking for rather sizable funding increases in other parts of the budget. This cut to providers, in and of itself, seems to be particularly misguided at a time when Medicare already underpays hospitals, according to MEDPAC, and when seniors in my district are struggling to make ends meet, but what I find most curious is the administration's rationale for the cut, and I quote, "this proposal would more closely align Medicare policy with private payers."

I am sure you are aware that the fixed price system under Medicare is completely disconnected from the private pay area where hospitals have the flexibility to negotiate. There is no negotiation today under Medicare's fee for service system. Government sets the price as well as the beneficiary cost share amount, period.

May I respectfully remind the Secretary that the administration has stood in the way of repeated efforts to modernize Medicare and really allowing policy with private payers instead of paying lip service to it when you want to cut the hospitals but not grant them the same tools to negotiate what they now have in the private system.

How can you reconcile this inconsistency?

Secretary SEBELIUS. Well, Congressman, I think that what has happened with Medicare over the past several years is we have been working very closely with private payers around the country, and they are extremely enthusiastic about the framework given to us, thanks to the Affordable Care Act—to begin to shift Medicare to a value-based payer as opposed to a volume payer. We are starting to implement a number of those changes. We are pleased with the 250 or more accountable care organizations, many of which include hospitals which have now come together voluntarily to look at different ways to deliver care and actually share in the savings.

We have hospitals really engaged in efforts around reducing hospital-acquired infections and other issues which drive up cost and lower patient care. So I think the framework around Medicare

dealing with hospitals is very different than it looked 4 years ago, and, in fact, is, I think, moving in a very positive direction for patients and for providers.

Mr. KINGSTON. Ms. Lee.

Ms. LEE. Thank you very much. Good to see you, Madam Secretary, and thank you for being here.

RYAN WHITE

I am pleased to see that the budget included the needed increase for the minority AIDS Initiatives as well as the Ryan White program, so continued support of Ryan White is very critical while we assess the impact on—as it relates to HIV and AIDS, as it relates to the Affordable Care Act and how this transition is going to happen.

RACIAL AND ETHNIC APPROACHES TO COMMUNITY HEALTH

Let me follow up with Congresswoman Roybal-Allard's question as it relates to ethnic and health disparities. You know, I was disappointed to learn that half of the available \$949,000,000 in the preventive—it is what, Prevention and Public Health Fund, would be used for the Affordable Care Act, that half of that has been cut. Secondly, of course, the cut to the REACH program, which Congresswoman Roybal-Allard laid out. Then what we are looking at also is the fact that now the exchange health plans, they really don't include community physicians who have traditionally provided care to low income and minority communities. Many of the minority providers that I have spoken with who practice independently are already experiencing competition with community health centers and other federally qualified health centers, specifically African American physicians are really going to be impacted by this.

And so what I see now is sort of a, you know, a compilation of cuts and provisions of the Affordable Care Act and budget and sequestration that really will impact minority communities in terms of our efforts to close these disparities. It seems like we are getting attacked over and over and over again, and so I am wondering how we are going to pick up the pieces now because we have made so much progress, but I just see this going backwards and people are very concerned.

Secretary SEBELIUS. Well, I share your concerns that the worst of all worlds is to retreat from what has been implemented, an aggressive approach to closing health gaps. What I would tell you, Congresswoman, is we would have much preferred to have had the resources given directly for the Affordable Care Act so we could fully implement the law and have the full funding of the Prevention Fund go to a variety of programs.

That was not the case when Congress finished with our CR, so we made some decisions, and the dollars that are being redirected for this year from the Prevention Fund will be for outreach efforts, education efforts and enrollment efforts connecting people who are uninsured and underinsured with the new benefits available to them in the Affordable Care Act.

So, many of the communities of color, many of the communities who have huge health gaps will, for the first time, be looking at the opportunity to have fully covered health benefits, but unless

they are enrolled, unless they know what is coming, unless they have people helping with the application process, it won't happen.

So I think that while on one hand there are some specific program cuts or flattening of budgets, on the other hand, there will be a huge outreach and enrollment effort that will involve many of those same individuals and connecting them with health.

Ms. LEE. But the trend, though, is going the opposite direction. I understand what you are saying, but you have cut actually 15 million say from the Office of Minority Health Services. That cut—

Secretary SEBELIUS. Well, the overall spending on minority health issues has actually increased in our department-wide efforts. It is not necessarily in that office.

Ms. LEE. I understand that, but that office was the centralized office. It was going to try to make sure that this works. And now what I am worried about is it is so dissipated that it may not work, that we are going to have to pick up the pieces in a few more years to get back to where we are now.

Secretary SEBELIUS. Well, again, we would be happy to give you and Congresswoman Roybal-Allard a report on what the plan says, where we are, what the metrics say, where we see ourselves going at the end of 2013. We will do a detailed update on the issues of concern.

Ms. LEE. Okay. And are we going to have a second round, Mr. Chairman, because I want to get back to the traditional community providers?

Mr. KINGSTON. Yes.

Ms. LEE. Okay. Thank you very much. Thank you, Madam Secretary.

Mr. KINGSTON. Dr. Harris.

INDEPENDENT PAYMENT ADVISORY BOARD

Mr. HARRIS. Thank you very much and thank you for coming before the committee.

As a physician, I have got to ask you a couple of questions from what I hear some of the concerns in the physician community. First and foremost is the Independent Payment Advisory Board. My understanding is that the members were supposed to have been recommended by last September. It is now April. Is there a timeline for appointment of these members?

Well, there is a timeline. We already know the President has already missed it. Is there a new timeline or revised timeline? Are these appointments ever going to be made or are you going to ultimately have to make those decisions?

Secretary SEBELIUS. Congressman, the law provides for the President to make appointments to the Independent Payment Advisory Board. In consultation with Congress, he has actually written to the leaders in both the House and the Senate, the minority and majority, in asking for suggestions for Members to be appointed. Ultimately he would nominate and the appointees would then go to the United States Senate for confirmation.

Secretary SEBELIUS. According to the independent actuary and the Congressional Budget Office, given the trend lines of Medicare,

it is not anticipated that any IPAB recommendation would even be targeted until 2019.

Mr. HARRIS. Sure, and I understand that, Madam Secretary.

Secretary SEBELIUS. The consultation is underway.

Mr. HARRIS. Okay, in the absence of the Independent Payment Advisory Board being appointed, though, all I am saying is, you would have to make the decisions. Is that right?

Secretary SEBELIUS. No, sir, that is all under the construct of the Independent Payment Advisory Board.

Mr. HARRIS. So if they are never appointed, what happens?

Secretary SEBELIUS. It doesn't exist.

RECOVERY AUDIT CONTRACTORS AUDITS

Mr. HARRIS. Okay. The second one is the RACs audits. We are hearing, you know, from the hospital association, especially, they say when they survey their hospitals, about 70 percent of those, when they are appealed, they are overturned. You can just get back to me off-line about that. I mean, that is of great concern to me because both hospitals and physicians spend a great inordinate amount of time dealing with these RACs audits, and it never shows up, you know, when we claim that Medicare is so efficient, you know, we don't take into account the back office costs of dealing with these RACs audits.

Secretary SEBELIUS. Well, sir, if I could just respond for one moment. I think that while there are a number of claims overturned, less than 3 percent of the claims are ever appealed. So about 97 percent of the RAC recommendations actually are implemented, and then of the ones that are appealed, a portion are overturned.

Mr. HARRIS. That is on part B, Madam Secretary. I am not sure the same is true on the hospital side. On part B that is true.

RATE REVIEW

In your opening statement you said, and I will quote you, "Every American will get quality insurance at an affordable price." And I think you used the word "every." Now, here is the problem I have got. Yesterday, our nonprofit insurer, CareFirst BlueCross BlueShield of Maryland insures 70 percent of the individual market in Maryland, announced it will have to raise its rates on the exchange an average of 25 percent, with a range of a slight decrease to 150 percent increase for the youngest, healthiest, who apply for insurance.

So I have got to tell you, that certainly, that person who is going to get that 150 percent increase is not going to feel that they are getting quality insurance at an affordable price, because Madam Secretary, I will tell you that, you know, you have been quoted saying, well, they get a better benefits package. Well, in fact, in their filing, they said that only 2 percent of that average increase was due to an increase in benefits because Maryland, as you know, already has the second best benefits in the country because of our mandated package. So, in fact, they said in their filing that the taxes actually account for a larger part of that increase than the increase in benefits.

How am I going to explain to those individuals that their increase is—these are individuals. These are the ones, and again,

Maryland has a high-risk pool, so we have already factored into account that had affordable care not worked, everybody with a pre-existing condition could have gotten insurance in the high-risk pool.

How am I going to tell them that this was actually good for that 25-year old healthy person who now has to make the choice between paying that small penalty or paying a whole lot more for the insurance under the exchange.

Secretary SEBELIUS. Well, I think there are several things, Congressman. I have not gotten any independent information about Maryland other than The Washington Post article, so I am taking my data from that. First of all—

Mr. HARRIS. I would be more than happy to share with you their filing.

Secretary SEBELIUS. Well, the company has submitted a filing and there is a rigorous review process now. So this is the starting place and I can tell you as a former insurance commissioner, that is unlikely to be the end of the discussion.

The second piece of news is that it appears Maryland will have more competition thanks to the Affordable Care Act than they do right now. Two new companies are coming in the market, and several other companies filed rates at the same time that First Care filed rates that are significantly lower, and don't have the kind of whopping increase that First Care has requested. Thirdly, for a lot of the young and healthy, the under 30-year-olds, they will have a choice of a catastrophic policy, or the full benefit policy, which is likely not only to be significantly less, but also have some subsidies to help pay those premiums.

So I think there are a variety of factors, but it looks like the Maryland market will be significantly more competitive than it is now, and for the first time, consumers will be able to see the rates side by side and make some choices.

Mr. KINGSTON. Mr. Joyce.

AFFORDABLE CARE ACT IMPLEMENTATION PLAN

Mr. JOYCE. Thank you, Mr. Chairman. Good morning, Madam Secretary.

Secretary SEBELIUS. Good morning.

Mr. JOYCE. There have been many concerns raised about the Affordable Care Act. Is there any written plan of implementation that you have been considering?

Secretary SEBELIUS. I don't know what you are referring to. There is no one written plan. I mean, there are timelines. There are build plans. There are contracts.

Mr. JOYCE. Right, is there something we can review now on a quarterly basis to know how it is being implemented?

Secretary SEBELIUS. Absolutely.

Mr. JOYCE. Can you make that available to us?

Secretary SEBELIUS. We would be happy to share what we can, certainly.

Mr. JOYCE. Okay, because the other problem I have is exchanges, at least in Ohio, it views the same way, that the prices are going to continue to go up. Do you have anything to contradict that?

Secretary SEBELIUS. Well, again, sir, rates are just beginning to be filed. There will be a negotiation process in every State in the country between now and the fall when the final rates will be published. I have no current information from the State of Ohio.

INDIRECT MEDICAL EDUCATION FUNDING

Mr. JOYCE. Okay. There is a—the other problem that we have in the Cleveland area, we have the UH, and the Cleveland Clinic, and obviously, they are facing a 91,000 physician shortage, and at 130,000 physicians that should grow to by 2025. And while I appreciate the administration's emphasis on primary care, surely, it is split evenly between specialists and primary care physicians. The budget proposes a 10 percent decrease in Medicare indirect medical education funding. Teaching hospitals receive this funding to compensate them for higher costs associated with sicker, more complex patients that they care for, and they provide unique services that are not available at other hospitals, such trauma centers, burn units and standby capacity.

A 10 percent cut will not help finance them in the training of next-generation physicians when we know there is already a looming shortage and will do nothing to expand the need for primary care. In some areas there is a shortage in subspecialty areas. In teaching hospitals maintaining a top level of trauma center, standby services are expensive. Has the administration considered the impact of this cut on teaching hospitals and their ability to maintain these critical services?

Secretary SEBELIUS. Yes, sir, we have, and again, in a more robust budget time, we would make different decisions. We are looking carefully at MedPAC's, the advisory body that looks at Medicare costs and expenditures, recommendations in this area and they have suggested that the cut would be not only fully compensate hospitals for the training program, but could come out of the overhead. So we are trying to make sure that we have the same number of training slots, but reduce some of the overhead that wasn't directly related to the residency slots in hospitals as we go forward. But this recommendation came directly from MedPAC.

Mr. JOYCE. Thank you, I yield back my time.

HEAD START

Mr. KINGSTON. Thank you. Madam Secretary, I wanted to get back to your comments to Ms. Lowey on Head Start, and I have not been a critic of Head Start, but I have read the study, or scanned the study. I don't want to say I have read the whole thing, but this was a study that HHS did, and it certainly contradicts the statements that were made, and I will just read directly from it.

It says: "In summary, there were initial positive impacts from having access to Head Start, but by the end of third grade, there were very few impacts found for either cohort, or any other four domains of cognitive, social, emotional health, and parenting practices. The few impacts that were found did not show a clear path of favorable or unfavorable impacts on children."

And you know, as we try to figure out, you know, in Head Start, I don't think you can find a more noble concept, but the results aren't there. I visited many, many Head Start classrooms, and I am

always impressed with what I see going on, but the statistics don't bear out because I go there and I get emotional about it, and it looks good, and it feels good and all that, but the science, if you will, doesn't bear that out.

Where did you get your statistics on the proven reduction in dropout rates and better grades, and the numbers you just studied, because it is not on here.

Secretary SEBELIUS. That is correct, Mr. Chairman. You are citing the impact study which looked at kids who were in Head Start in 2003, about 10 years ago. The Impact Study tracted them.

Mr. KINGSTON. I think it started in 2008, didn't it?

Secretary SEBELIUS. No, I think the report was out in 2008. The kids were in the program 10 years ago, and then they tracked them, and there is no question that what they found is a leveling out of what had been significant improvements. As children leave the Head Start program, they may not continue that.

What has been found in studies that actually longitudinally follow children for a longer period of time, is that the positive—

Mr. KINGSTON. Well, can you tell me what studies those are specifically?

Secretary SEBELIUS. Yes, I would be happy to get them for you, these are longitudinal studies that follow kids for 20 years, and they look at—

Mr. KINGSTON. Well, the reason I said that, is Head Start, unfortunately, has moved into a more political kind of arena that I think any of us would want it to, meaning that, you know, if you are for Head Start, you love children, if you are against it, you obviously hate children. You hate teachers. You hate education. I mean, it is one of those things where in Washington, things spin out of control rapidly in the rhetoric debate. And so we have got a lot of studies out there and you know, the New Jersey study is pro, and the California study is against it. But this was your study.

Secretary SEBELIUS. I understand, sir, and we are taking those findings seriously. We have done a lot to implement some of the changes that we felt were important, improving teacher quality, looking at more curriculum. I would say that there is a much stronger partnership right now with the Department of Education which is part of this Early Education Initiative, as well as the fact that with the President's insistence, the lower-performing Head Start programs are now recompeting for grants for the first time ever in the program. We are not just assuming that if you have been a Head Start operator, you can continue to be a Head Start operator.

So the 25 percent lowest performing programs are recompeting across this country as we speak, and that has never been done before. We would like to make sure that if children are enrolled in early education, they are in the highest quality programs possible.

Mr. KINGSTON. But you have studies to show that there is a lower dropout rate, and higher grades?

Secretary SEBELIUS. Yes, there is a study that indicates that with early education, just 1 year of early education, that children have a much different lifetime performance. The long-term payoff to Society means less school dropouts, drug use, engagement in

criminal activity—The study showed a reduction in those instances, and I would be happy to provide that for you.

Mr. KINGSTON. Yes, and also, if you would tell me where this longitudinal study was wrong? Where, you know, you are saying the impact—

Secretary SEBELIUS. No, I am saying they are looking at children in the third grade. You wouldn't have children dropping out in the third grade one way or the other. So some of the factors that we are looking at that—

Mr. KINGSTON. But, I mean, the premise of the study, this was what they were asked to study, and this is how we are going to make our investment decision, and the study came back with a—

Secretary SEBELIUS. Well, what it said, there was a definite impact on these children as they entered school.

Mr. KINGSTON. And then what?

Secretary SEBELIUS. They definitely were caught up with their peers as they enter school. Those positive impacts begin to fade as they get closer to the third grade. Whether that is what is happening to them in the elementary school, the lack of the Head Start wraparound, I mean, I think there are a number of factors. But the fact that they are school ready when they hit school is part of what Head Start was all about.

Mr. KINGSTON. Yeah, and well, I think what I would be interested in is, you know, a blind, let's look at this as if it was a new program. Is this where you would put—

Secretary SEBELIUS. Sure.

Mr. KINGSTON [continuing]. Money or not. And so I think that is what we would like to see, and I yield to Rosa.

Ms. DELAURO. Just a quick point on that. The study's number one finding was that Head Start children enter kindergarten performing above their peers in all measurable categories. The study you reference looked at children who entered 10 years ago. The significance of that is that since then, a number of changes have been made to the Head Start program because of some of the findings here, and that includes improvement in the quality and credentialing of teachers. You have got 92 percent of Head Start teachers have an AA, a BA and an advanced degree in the field related to early childhood education.

That is well over the 50 percent threshold that was set in the 2007 reauthorization for that year, so there have been a number of changes. And maybe, Mr. Chairman, you and the Secretary can talk about this, about the changes that have been made, I don't want to go into all of them.

Secretary SEBELIUS. Sure.

Ms. DELAURO. And for instance, there is a 2010 report of Maryland Montgomery County Public Schools showing that students who went to full-day Head Start pre-K needed only half of the special education services as their fellow kindergartners. So I think there needs to be that fulsome conversation about that, because there were some issues. They have been dealt with, and I think we need to then look at where the changes are. It is one of the most important of programs that we have ever embarked on in terms of making our children ready to learn as they enter school.

AFFORDABLE CARE ACT PROGRESS AND SUCCESSES

Madam Secretary, there is agreement that one of the keys to improving the long-term budget picture is finding ways to reduce the growth of health care costs while improving quality and access. The Department has taken a number of initiatives and demonstration projects aimed at the goal, mostly under the auspices of the Affordable Care Act.

I would like you to tell us about some of those efforts, how they are progressing. I am going to throw in this last question as well. This there are provisions in the ACA designed to reduce the rate of increase in health insurance premiums. Medical-loss ratio as an example, rebates to customers when too much of what an insurance company collects in premiums is used for other things.

In this context, what results have you observed from the new rules so far? What are some of your efforts to cut the costs? What have medical-loss ratio or other things of that nature already in place done?

Secretary SEBELIUS. Well, Congresswoman, as you know, there are sort of two pieces of this puzzle. One is the insurance market, and there has been a lot of attention and focus on the insurance market, the new marketplaces, which frankly, will affect a number of Americans, but certainly not all Americans.

Most people with employer-based coverage will see very little change with the new marketplace. A lot of folks who are in self-insured plans or large government plans, won't see much change.

So on the new market side, you are absolutely right. There has been a lot of attention on new rules for insurance companies, and one of them is that \$0.80 of every premium dollar collected has to be spent on health costs, not overhead costs, the so-called 80/20 rule. So last year about \$2,000,000,000 was sent back to customers across the country.

Ms. DELAURO. \$2,000,000,000?

Secretary SEBELIUS. \$2,000,000,000.

Ms. DELAURO. Thank you.

Secretary SEBELIUS. So people got checks from their insurance companies, and we have seen companies actually file the lowest level of rate increases over the last 3 years than has been the trend line for over a decade because there is now much more rigorous review at the State level. And I think that is all good news for consumers.

On the delivery side, which I think is frankly the more significant piece of the Affordable Care Act because it really affects everybody insured and uninsured. What kind of care do you get? What sort of population health do we have? How are we spending those underlying health care dollars? There is a lot of incredible innovation underway; a lot of it driven by the private sector using electronic tools to empower consumers, using electronic health records to finally measure results and figure out what is going on and locate the cost outliers.

We are driving programs to these accountable care organizations; new collaborative efforts between doctors and hospitals to figure out ways to improve health and lower care; medical home models,

trying to keep people out of the hospital in the first place; looking at preventable readmissions.

For the first time in decades, we are seeing an actual decrease in the number of Medicare patients who are released from the hospital and go right back in because of the care they are receiving in that interim period of time, and one new study—I know I am on a yellow light, but since we all love babies here, you will, I think, find this interesting.

Mr. KINGSTON. Why don't you hold that, because we do love babies and we will get back to the baby question.

Secretary SEBELIUS. All right.

Mr. KINGSTON. It sounds like a piece of good news, and we look forward to it. Mr. Alexander.

PREVENTIVE HEALTH AND HEALTH SERVICES BLOCK GRANT

Mr. ALEXANDER. Madam Secretary, the Preventive Health and Health Services Block Grant. Your budget request eliminates that again. For more than 30 years, State and local health departments have relied upon the flexibility of this block grant to meet their unique needs and problems with local solutions, ranging from preventative cancer screening to emergency medical services. A large percentage of these funds are used to address the prevention and control of chronic diseases.

Last year, this subcommittee provided \$100,000,000 for the block grant an increase of over the fiscal year 2012 budget. Your budget justification says that these activities could be more effectively and efficiently implemented elsewhere. It is not often that people come into our office and say hey, this Federal program is working. Let's not change it. Let's not improve it. It works from the local to the State level, but yet we are trying to change it. We are trying to eliminate it.

Now, your budget justification assumes that the Affordable Care Act prevention and public health funds will be available to help meet these needs, but as we have heard today, oftentimes these funds are being used to just implement the Affordable Care Act.

So the question is, can you elaborate on the rationale behind the elimination of this program, and what impact do you think these cuts will have on the States that we all represent.

Secretary SEBELIUS. Well, Congressman, first of all, I think the effort to refocus our health system on preventive health, and try to keep people healthier in the first place is probably the single best way that we can reduce health costs. So efforts are underway to focus on a number of the key drivers of chronic disease and health costs. Smoking is a number one target, and we now have a variety of efforts in place that look at ways to reduce smoking, and I would say that the funding proposal offered by the President for the Early Childhood Initiative may be a significant additional piece of that puzzle, which is increasing the cigarette tax, because we know that young smokers are particularly price sensitive.

So that effort is funded outside of the block grant. We now have the prevention funds available through the Affordable Care Act, and will have over \$500,000,000 throughout the country dedicated to various prevention efforts, including the Community Trans-

formation Grants which are in 107 areas, and looking at chronic disease prevention and ways to reduce the toll of preventive issues.

And as people engage in the fully insured market, either with access to Medicaid or with access to new private health insurance, private health plans must include a package of preventive health benefits that are offered with no copay and no coinsurance; childhood immunizations, and cancer screenings, are of particular help to individuals to stay healthy. So we think those efforts actually not only focus on preventive care, but ramp it up significantly, and it is not necessary to run parallel programs any longer.

Mr. ALEXANDER. I yield back, Mr. Chairman.

Mr. KINGSTON. Thank you, Ms. Roybal-Allard.

HEALTH CAREER OPPORTUNITY PROGRAM AND AREA HEALTH
EDUCATION CENTERS PROGRAMS

Ms. ROYBAL-ALLARD. Madam Secretary, two other goals in the HHS action plan to reduce racial and ethnic health disparities were to increase racial and health and ethnic diversity in the health professions, and to increase the diversity and cultural competency of clinicians. To date, the only HHS programs that help accomplish these goals are the HRSA Title VII programs. Your fiscal year 2014 budget cuts them by 15 percent and eliminates both the Health Careers Opportunity Program, and the Area Health Education Centers Program.

As the Nation prepares to implement the largest health care coverage expansion in history, I am trying to understand why the only two pipeline programs that address the needs of a growing minority in this country are being eliminated.

How do you expect your fiscal year 2014 budget to help increase racial and ethnic diversity in today's and in tomorrow's workforce, and specifically, what programs are you supporting or depending on to ensure the linguistic and cultural competency of clinicians and their retention in the health professions?

Secretary SEBELIUS. Well, yesterday, Congresswoman, we published some new guidelines around cultural competency—language competency for health providers that have been underway for some time because we do take very seriously the notion that if you have language or cultural barriers, that could be as large a barrier as having any access to a health provider. So those have been underway with our Office of Civil Rights, and have just been promulgated, and I will be happy to get a copy to your office knowing of your interest in this.

We also have some very specific programs aimed at health professionals overall, and I would say our office leaders are very sensitive to the notion that we have to have additional recruitment and retention efforts around minority providers, so doubling of the National Health Service Corps which is underway is one of those efforts which brings a lot of, not only providers from underserved communities to participate, but they get to go home and practice medicine and get rid of their debt. And that has been enormously successful.

So we are going to have 7,100 new National Health Service Corps slots. We have new programs for physicians assistants and

nurses, again, with a recruitment effort that is also aiming at the minority community as part of that.

I would say we have more general workforce efforts that are trying to increase capacity, and we feel that that may be a stronger way to encourage and recruit minority providers than separate disparate programs which only have a small funding stream. But to make that a part of what the health disparities plan calls on, is that every program, every leader, every asset that we have should be focused on reducing racial and ethnic barriers.

So rather than running little streams of money that are focused on certain things and letting everybody else off the hook, we have made it clear to all senior leaders that every effort, so all of the programs HRSA is running, have an eye on minority recruitment and minority retention.

NIH is paying special attention to the diversity of researchers, which has been a real problem and developed everything from mentoring programs to special training programs to try and reach out at a much earlier stage and make sure that the research community has a more diverse look about it, and so we are trying to pay attention to this at every step along the way.

Ms. ROYBAL-ALLARD. Okay. I have to share the feeling that Congresswoman Lee has that somehow we are going backwards. So I think it is going to be important that we do have that sit-down meeting to better understand, you know, what it is you are trying to accomplish there.

Secretary SEBELIUS. Sure. I would be glad to do that.

Ms. ROYBAL-ALLARD. Okay. Thank you.

Mr. KINGSTON. Dr. Harris.

INDEPENDENT PAYMENT ADVISORY BOARD

Mr. HARRIS. Thank you very much. Madam Secretary, you just have to get back to me on this, but I had the staff pull the code on the Independent Payment Advisory Board and under paragraph 5, it clearly says that if the board fails to submit a proposal, then actually the Secretary shall develop it. So you will just have to get back to me online why you think this doesn't apply to you.

CHILDREN'S GRADUATE MEDICAL EDUCATION

In regard to your statement about the importance of mental health, you know, I notice that the CHGME program at Children's Hospital is cut by about two-thirds, and obviously, those funds do fund pediatric psychiatry. Don't you think that we are, in fact, going to have a problem training people who are able to deal with psychiatric problems in children which could lead to gun violence by cutting back this training?

Secretary SEBELIUS. Well, again, Congressman, we have tried to allocate in this budget the funding for the training slots, and not the indirect costs related to pediatric training. We have analyzed the costs for residents in the pediatric hospitals. That is what this budget reflects, so we will train the same number of pediatric residents. We just don't have the overhead—

Mr. HARRIS. Madam Secretary, you know, this idea that somehow we can ensure, you know, 10 or 20 million more people and cost less, that we can train the same number of people with less

money, you know, that just flies in the face of every rule of economics, but again, you know, I am concerned about a two-thirds cut to pediatric training programs because having been on a medical faculty, I would just ask you just to make sure that, you know, Maryland Medicare Waiver is threatened, and, you know, I just ask to make sure that your Department works with our departments to make sure that that gets considered, our Medicare waiver.

CONSCIENCE PROTECTIONS

I want to spend the rest of the few minutes on an area of great concern to me which is the conscience protection under the HHS mandate. My first question is, what is the time frame for issuing the final rule now that the comment period is over?

Secretary SEBELIUS. Congressman, we are in the process of analyzing the comments, and the rule will be promulgated in the next couple of months.

Mr. HARRIS. Okay, next couple of months. Now, let me ask you, and I have to get very specific because, you know, I looked and you are named in a whole lot of lawsuits on this. A lot of people obviously feel very strongly on this topic of the HHS mandate because of the religious, I think, the encroachment on religious beliefs that it has. And the one I am going to ask about specifically is Hobby Lobby because actually have a store, a shop—actually, they have a shop in many districts.

This very specific problem is with, you know, the week-after pill, which is not really a week-after pill. It is the 5-day after pill, Ella. I want to ask you first, since you have mandated that it be covered, do you believe that it can cause an abortion, that it is an abortifacient drug, Ella. Not any other drug, Ella, which is ulipristal.

Secretary SEBELIUS. I am not a scientist, and don't pretend to be one. I know that the FDA scientists do not believe that Ella, or Plan B, are abortifacients based on their impact on the reproductive cycle. That is how they are classified. They are classified as a contraception, not an abortifacient.

Mr. HARRIS. Well, I understand that is the way are classified, but I am going to disagree. I think the FDA is not clear on Ella. And the European Medical Agency says, quote: "The ability to delay maturation of the endometrium likely results in a prevention of implantation," which is basically how an abortifacient would work. So I take it your answer is, you believe it is not an abortifacient and you are progressing based on that.

Secretary SEBELIUS. Again, I don't designate. You should be very thankful that I don't designate drug classifications.

Mr. HARRIS. Well, Madam Secretary, it is not really true that you are not classifying them because what you are doing—

Secretary SEBELIUS. But the scientists do, and they have examined this and they have listed the only recommendation—

Mr. HARRIS. Madam Secretary, what do you mean, the scientists? The European Medical Agency has said it can do it.

Secretary SEBELIUS. FDA has scientists who look at drugs and compounds, and do clinical trials, and look at medical results. The only thing that the IOM recommendation said, which we incorporated, is that FDA-approved contraception and contraceptive devices should be included as—

Mr. HARRIS. So even if they are abortifacients, and even if—

Ms. DELAURO. Would the gentleman yield?

Mr. HARRIS. I am not going to yield time on this topic. I have reviewed—

Ms. DELAURO. You said something that was inaccurate.

Mr. HARRIS. Madam Secretary, by functioning, by saying that abortion is not covered, but these abortifacients are, because it is controversial whether they are, you are, in fact, saying they are abortifacients. And I will tell you, I can't understand why in the world you would not make an exception for that that would allow the Hobby Lobby to go, to comply with their conscience on that issue?

Now, there are other issues involved, but for them it is specific. And the cost of this is \$40. That is it. It is not a drug you take every day. It is \$40. And that is what this argument is about. And you all are dug in. I am disappointed. But let me turn to the—well, if with we have a third round, we will turn to the other problem which is that your requirement on religious institutions make them pass the unethical behavior on to a third party which is a real ethical problem. And I don't think you and your Department appreciate what an ethical problem it is, but I will get to that in-depth if we go a third round. Thank you, Mr. Chairman.

Mr. KINGSTON. I was going to get some coffee, but I don't need it. We appreciate the passion on the panel up here. Ms. Lee.

OFFICE OF MINORITY HEALTH

Ms. LEE. There is a lot of passion here, let me tell you. Thank you, Mr. Chairman. This is National Minority Health Month. The Tri-Caucus Black, Hispanic, Asian Pacific American Caucus, we are going to the floor at noon to talk about minority health, ethnic disparities, and the benefits of the Affordable Care Act to minority communities.

A couple of things, Madam Secretary, I wanted to say. First of all, the diffusion of these efforts, and I understand what you are saying in terms of the general workforce effort to increase capacity and make sure everyone is focused on diversity efforts, but you have to have, I guess, a centralized focus so that these efforts will work, and with cutting the Office of Minority Health by \$15,000,000, I am really worried that a lot of these efforts are going to go away.

COMMUNITY & SAFETY NET PROVIDERS

The question I asked earlier about the—let me just quickly reiterate it. The traditional providers in our community who provide access to care, they have been around for a long time, community physicians, they have traditionally cared for many of the underserved. They don't have this infrastructure in place that the Affordable Care Act requires, and there are no requirements in the exchange plans to include Safety Net providers including community physicians who have traditionally provided care, such as African-American and Latino physicians, and they are really feeling the squeeze.

We are sending you a letter on this, Madam Secretary. I want to talk to you about it. But can you kind of give us some sense

what to do, what they should do at this point because they are not included, and they are going to be wiped out for the most part?

Secretary SEBELIUS. Well, I am a little baffled as to why they wouldn't be included in network plans. I assume that many of the providers that you are talking about are currently part of a network plan.

Ms. LEE. Not really. A lot of the—a lot of the minority physicians are not, and that is the problem because they are not—the exchange health plans don't require the Safety Net providers to be part of these plans now. And the majority of them aren't.

Secretary SEBELIUS. I guess I need the letter from you, because I am not quite sure. If they are not part of an insurance network, I mean, if they are part of any insurance network, any company, that would make them automatically part of the exchange.

So if someone can go with their Blue Cross card to a minority provider, someone could go with their Humana card to a minority provider, then they would be part of the exchange by virtue of that plan being offered on the exchange. If you are talking about designating individual doctors as essential community providers, that is not something that was done in the bill, and I am not sure, in fact, how we would ever do that. There are categories of providers that are designated as essential community providers, but individual doctors are not.

Ms. LEE. Okay, I understand that and we will send you a letter. The National Medical Association is very concerned about this and other groups around the country about how this will ultimately play out.

NURSING SHORTAGE & MINORITY NURSES

Let me ask you about nurses. Registered nurses, advanced practice nurses, they are expert clinicians who provide high-quality and cost-effective care in every care setting in every community. And they are especially in demand in our medically underserved areas. Despite, you know, this need, according—and this is the American Association of Colleges of Nursing—their enrollment and graduation survey, they are saying the nursing schools were forced to turn away 79,000 qualified applications from entry-level baccalaureate graduate nursing programs in 2012, citing faculty vacancy as a top reason.

And so we are trying to figure out in your budget request, I think it was level to the 2012 enacted amount of \$24,500,000, yet this huge need, this huge shortfall is a big issue in terms of our health care system's growing reliance on the need for nurses. And I have a mother who was 88, a sister with multiple sclerosis. I am in hospitals, emergency rooms all the time, and I can tell you, the nursing shortage is tremendous. The lack of minority nurses is glaring, and travel nurses, you know, do a great job, but you know, they shouldn't have to travel. You know, we should have nurses in our own communities to provide the badly needed services that they provide.

Secretary SEBELIUS. Well, I certainly share your belief, in all deference to Dr. Harris, that nurses lift more than half the sky in most health systems, and most patient contact is often with a nurse in providing the patient information. So HRSA has spent a

lot of time and effort directing new funding to nurses, to nurse practitioners, and to advanced nurse practitioners. We are trying to work with States around their often restrictive scope of practice.

Mr. KINGSTON. Madam Secretary.

Secretary SEBELIUS. Oh, I am sorry.

Mr. KINGSTON. We are going to try to do a third round, so Mr. Joyce.

Mr. JOYCE. Thank you, Mr. Chairman. I will yield my time to Dr. Harris.

STATE LICENSING AUTHORITY FOR MEDICAL PROFESSIONALS

Mr. HARRIS. Thank you very much. Let me just follow up on that the States have restrictive scope of practice but that is within the realm of a State's licensing authority, is that correct?

Secretary SEBELIUS. Yes, sir.

Mr. HARRIS. I mean, there is no Federal licensing authority in scope of practice?

Secretary SEBELIUS. I said, we are trying to work with some States, yes.

Mr. HARRIS. But you claim that they are restrictive, but from their point of view, they are proper. I mean, I understand, and believe me, I love nurses. My daughter is a nurse. She is going to be a nurse practitioner. I understand, but this is the problem that the Federal Government looks at the States and says, see, what you are doing, we think is not right. You are too restrictive. But it is up to the States to make that final decision. I just want to emphasize that. It is up to the States.

Secretary SEBELIUS. But if a State has a serious undershortage of primary care providers and have not allowed trained providers to practice—

Mr. HARRIS. Well, Madam Secretary—

Secretary SEBELIUS. All we do is have a conversation. It is totally up to them.

Mr. HARRIS. Madam Secretary, in your opinion, they are trained to be equivalent, but it is up to the States in the end, and I hope the Department doesn't take coercive action on those grounds.

Secretary SEBELIUS. We have never suggested taking coercive action.

Mr. HARRIS. Well, again, to claim that they are restrictive, when in fact, they are adequate for the State, that is a States-right issue, and a strong States-rights issue.

CONSCIENCE PROTECTIONS

But let's get back to what we were talking about a little bit before. Because I still want to express a grave concern over a company like Hobby Lobby, which is privately owned, it is not public, and its owners feel strongly, they hold strong religious beliefs that conflict with some of the HHS mandate.

What is their option going to be when the new rule comes out virtually unchanged, they are subject to the mandate, and if they continue to insure their employees as they want to, they would be violating their conscience. My understanding is their choice is, you either violate your conscience or you don't provide health insurance. Am I missing something in between?

Secretary SEBELIUS. Well, I think, Congressman, the law of the land will apply to employers across the board with some exceptions that we have outlined, and in the case of Hobby Lobby or other nonreligious employers, imposing their religious views on their employee choice is not really an option.

Mr. HARRIS. Madam Secretary, it is not imposing a religious view on their employees. They are paying out of their private moneys, these are privately-held companies, they are paying for this insurance. So their options, in my mind, will be we either violate our ethics, which I would suggest they should never do because of a Federal Government mandate, or they will just choose to pay the penalty and send people into the exchanges, violating the President's promise that if you like your plan you get to keep it. Because I will bet the vast majority of the Hobby Lobby employees, in fact, like their plan.

And Madam Secretary, they will not get to keep it under the current structure of the HHS mandate. But let me talk, because I think the Department is missing a very, very significant ethical question here, and that is, we will talk about the quote "religious institutions," the subject of a lot of these lawsuits, because their position is quite clear, and you know, students of ethics will understand this, that if by providing insurance for their employees, no matter what scheme or shell game you play with who is going to pay for the morally objectionable coverage, they will be allowing their employees to have access to that, no matter who pays for it.

The analogy is, you know, a Catholic hospital, for instance, can't refer for abortion. They can't say, you know what, we don't want to do this, but as long as somebody else does it, or somebody else pays for it, that is okay. Because Madam Secretary, that is just plain unethical. So what is the options if they feel that way, their ethical religious construct is that, aren't their options exactly the same?

We either violate our ethical religious construct, and we are not talking about Hobby Lobby. We are talking about the University of Notre Dame, a Catholic institution, one of the plaintiffs, the Archdiocese of New York, the Diocese of Dallas, the Archdiocese of Washington. They would have to violate their moral ethical construct, or they just have to send all of their employees into the exchange. And again, most of their employees probably feel they kind of like the insurance product they have, but once again, they are not going to be able to keep it because of the HHS mandate. Am I missing something? Those really are the only two choices. You either comply with what the Federal Government mandates, or too bad.

Secretary SEBELIUS. A couple of things. First of all, no diocese is included in this law at all. They may be in the lawsuit. They are not in the law because they have fallen under the total exemption that involves churches. Secondly, the commitment was to find an appropriate balance between having a religious employer not offer, pay for, or refer people to coverage that they find objectionable. On the other hand, giving employees the right to exercise his or her own religious values and choose coverage that they would find to be healthy for themselves and their families. And I think that is

what our commitment is. That is what we intend to do when we promulgate the final rule.

We have actually had a number of very positive comments from entities like the Catholic Health Association, who has been working with us. Other entities that are looking at this with regard to their—you might find that amusing, but they are enthusiastic about what the rules would allow them to do and feel that it very much is in line with their—

Mr. HARRIS. None of these lawsuits were dropped. The Catholic Health Association does not represent any of these plaintiffs. Mr. Chairman, I yield back the time.

MARKETPLACES

Mr. KINGSTON. Madam Secretary, we are going to go to another round, try to do 3-minute questions, so we will try as you can tell, we have a lot of interest.

What my question is, and in terms of if a State has rejected setting up an exchange, then the Federal Government steps in and does the exchange. But I understand that there is an administrative fee for that, 3.5 percent, true, or is it—

Secretary SEBELIUS. The user fee is for the companies who will be offering plans in exchange, and they will pay a user fee. Yes, sir.

Mr. KINGSTON. What is the statutory basis for that, and—

Secretary SEBELIUS. The law requires the exchanges eventually to be self-sustaining and the user fees are the way to get us there.

Mr. KINGSTON. Is there any challenge to that 3.5 percent or is everybody accepting it?

Secretary SEBELIUS. So far as I know, there is no litigation, no. And these are new customers, clearly, for the insurance companies.

Mr. KINGSTON. Yes. And have you put out the process for selecting, if the Federal Government comes in and sets up an exchange, then are you doing it with Federal employees? Are you doing it with contractors, and you are accepting bids for proposals?

Secretary SEBELIUS. Well, there are a couple of pieces of the puzzle. There is a Federal hub, if you will, that all marketplaces will use a data center to verify as Social Security numbers, and income numbers, and qualifications for the tax credit. Then there are individual exchange hubs, private plans in each State, in Georgia, which has chosen not to operate a State-based exchange, and there will be a Federal exchange, but it will be a Georgia-specific plan with Georgia companies who offer products to Georgia citizens. The benchmark will be based on the small group market in Georgia, so I think as far as the consumer's experience goes, I am not sure they will have any idea whether or not it is a Georgia plan or run by the Federal Government.

Mr. KINGSTON. And have you put out the criteria for who would run, who would qualify to submit proposals? Is that out there yet?

Secretary SEBELIUS. Yes, sir. That is what we are talking about in terms of rates coming in. Insurance companies are now submitting rates to be part of these marketplaces, and they will negotiate about whether or not the rates that they submit are actually ones that are justifiable based on an actuarial analysis, and then those

rates will be finalized, and then those market plans will then be available to consumers starting October 1st.

Mr. KINGSTON. Okay. Rosa.

ADVANCED MOLECULAR DETECTION

Ms. DELAURO. Thank you, Mr. Chairman. I just have one comment. I think when your boss' ideology determines your health care, we are certainly into a whole new world. Let me just talk about CDC for a moment, and the advanced molecular detection proposal.

Secretary SEBELIUS. Tom Frieden will be so pleased.

Ms. DELAURO. This is one of the places where I am excited about additional funding for food safety, for control of health care associated infections, and for this new advanced molecular detection initiative.

My understanding is that the basic idea is to modernize the CDC's capacity to use the technologies to do a better job, if you will, of tracking pathogens, recognizing patterns of diseases. And my understanding is also that CDC has fallen behind in the adoption of new technology. It used to be the gold standard and that has fallen behind, and now there is an urgent need to modernize.

So I don't know if you are an expert in this area. I certainly am not, but can you give us your understanding of what this initiative is, and what it is meant to do and why it is needed?

Secretary SEBELIUS. Well, you are absolutely right. Congresswoman, the CDC has been the gold standard in surveillance, monitoring, and identification, and we are seeing, actually, some of that good work bear very important fruit with the emergence of this new avian flu in China. CDC, actually over the last number of years, has worked very closely with China to help build their CDC capacity and in fact, provided a lot of technical assistance.

So we now have a relationship where we are getting daily communications from China. We are able to track what is going on. One of the important CDC scientists is in China as we speak as part of their team monitoring this disease. But CDC needs new capacities, and the advanced molecular detection system is a multiyear expenditure that would greatly enhance, increase, and update their surveillance capacity. There is an increase in the budget this year, but we would see this as a several-year effort that would actually bring CDC's lab capabilities up to the gold standard once again.

Ms. DELAURO. Okay, tell us about the babies. You have 35 seconds. If—

Secretary SEBELIUS. Well, let's just say in terms of saving money in a very, I think, encouraging way, one of the areas that was looked at was so-called elective early deliveries. Deliveries not because of any kind of health emergencies, but babies were being delivered prior to 39 weeks, for the convenience of the doctor, the convenience of the patient, and a variety of things. There are huge health differences between a baby is carried to full term, and a 36- or 37-week baby. Focusing on that, providing some best practices, drilling down on that experience has helped hospitals in some cases go from 20 percent early elective deliveries to almost none. Great reduction in NICU days, great reduction in lifetime issues around

the baby, and it is just an example of identifying an easy fix and then having hospitals really engage in it.

Ms. DELAURO. Thank you. Thank you very much.

Mr. KINGSTON. Mr. Joyce.

Mr. JOYCE. Thanks. I will yield my time to Dr. Harris.

RELIGIOUS EXEMPTION TO MANDATE

Mr. HARRIS. Thank you very much. Let me just follow-up a little bit about the religious exception here because of course, the churches itself, are not the—the churches themselves are exempt, but everything else the churches do, the archdiocese, the diocese, they, of course, are not exempt. They are subject to the rule. And the rule being, again, and I guess I have to ask you, I mean, that is the basis of their lawsuits. It is not that you didn't exempt them. It is that you didn't exempt their related activities, their charities, their hospitals, their schools. Is that the basis of their lawsuit from what you understand? Obviously, they are exempt, so they—

Secretary SEBELIUS. Yes.

Mr. HARRIS. Okay, so what you are doing is under the current structure of the rule, and again, it really is an accounting gimmick. What you are doing is saying, you can offer the insurance, but by offering the insurance, so I am just going to get it straight, the construct that you are creating, by them offering insurance to their employees, their objection is that that creates the ability, in fact the necessity, of their employees getting coverage for something they find morally objectionable. Because under the exception, their employees have to get it. There is no choice. They have to get it. A third party will do it, or the TPO will contract with someone or the insurer will attempt to bury the costs somewhere else.

Secretary SEBELIUS. If the employee chooses that coverage, they would use it, yes.

Mr. HARRIS. That is right, so the option is—

Secretary SEBELIUS. They would have the option to choose the coverage.

Mr. HARRIS [continuing]. To be not covered, or to be subject to this which would violate the ethical construct of the organization that, because I am not talking about the employee now. I am talking about from the employer's point of view. Their point is, they would either have to offer this product to everyone, or they offer it to no one.

Secretary SEBELIUS. Again, the employer would not pay for, would not refer, and would not provide the coverage.

Mr. HARRIS. Madam Secretary, how is that not referring? If automatically upon offering an insurance product, that person automatically gets the other product. How is that not referring?

Secretary SEBELIUS. Well, it isn't automatic, Doctor, and what we have done is outline a variety of possibilities. In one case, the insurance company would directly offer an alternate policy directly to employees, not referred to by their employer, but directly to employees. And in fact, insurance company data indicates that providing contraceptive coverage is actually a reduction in the plan, so the benefit would go to the employer. If there is a third-party administrator, the third-party administrator would offer the coverage

and then there is some alternate possibilities. And we are evaluating comments and we will promulgate a final rule.

Mr. HARRIS. Ethically, how is that different from the church organization offering the coverage themselves? How is that ethically different? You have somehow separated it ethically, but it is exactly the same.

Secretary SEBELIUS. They do not refer, they do not pay for, and they do not recommend the coverage. I don't know how it could be clearer. They are not involved.

Mr. HARRIS. Thank you.

Mr. KINGSTON. Mr. Joyce.

AFFORDABLE CARE ACT IMPLEMENTATION TIMELINE

Mr. JOYCE. Thank you, Secretary. And I want to follow up on what I first asked you because maybe I wasn't very clear, but since I am new. You are obviously a very intelligent lady, and somewhere you probably have some documents in which you lay out for yourself or can sort of show the implementation of the Affordable Care Act as it is moving along. I was wondering if there is somewhere I could make those same things available for myself so I could explain it to the people at home, and if there is something that is going to be updated on a quarterly basis, because I would like to stay up to speed, because there are so many questions being asked, and I don't seem to have the answers and I haven't heard all of the answers here today.

Secretary SEBELIUS. Well, we would be happy, Congressman, to provide you with documents that give you a timeline, and what is coming, and where we are, and what we anticipate coming in the next quarter and the quarter beyond that, yes, sir.

Mr. JOYCE. And whether or not the exchanges will be coming on time.

Secretary SEBELIUS. Yes, sir.

Mr. JOYCE. Okay. Great, thank you very much. I have no further questions.

Secretary SEBELIUS. Sure.

COMMUNITY TRANSFORMATION GRANTS

Mr. KINGSTON. Madam Secretary, I wanted to ask a little bit about Community Transition Grants, and I have raised the issue with Tom Frieden on that, and I am certainly a CDC fan, but I do feel that Community Transition Grants is kind of junk science. I mean, you go out and get the health departments and you get them all ginned up about superficial stuff, and they come back and say let's reduce sugary beverages, like, oh, I haven't thought about that one.

And as you may know, the stimulus bill actually had \$266,000,000 in Community Transition Grants just for the CDC. And I think it was in 2010 or 2011, but to me, gosh, \$266,000,000, put it to a lab and a chemist in the back room. Let them do, as you had mentioned earlier, what FDA just came back with on the OxyContin, something society needed, something everybody wanted. But here is an example of a grant solicitation, and I am reading directly, it says: "To limit the density of fast-food outlets," and it is featuring high calorie, high sodium, low nutritional foods, and

encouraged retail venues to provide access for healthier foods; zoning to regulate the number of fast-food restaurants in a given area.

I mean, it just seems so silly, first, to be doing it on a Federal level, you know. If, for example, I like to ride my bike and I think in Irving, California, 14 percent of the people ride bikes. And that is really to me a good thing, and you know, you can find out about that. But that didn't take a Federal grant to come up with that. And then here is one, a Philadelphia grantee, in their report, came back, campaigned for a \$0.02 tax on sugary beverages, and it came up one short vote in city council. Now, nothing makes our constituents more livid than paying tax dollars to lobby for a policy, whatever it is, whether you agree about it or not, but you know, again, you know, why not put the money in the lab with the scientists who can really figure out how to cure cancer?

Secretary SEBELIUS. Well, I would like to do both, and I think if you look at chronic disease, a lot of it is not going to be solved by a pill or a cure. It really is going to be solved by, helping to make the healthier choice, the easier choice.

Mr. KINGSTON. I guess the part of my—and I hate to interrupt you, but part of my concern is, none of this is original thinking. You know, and for \$256,000,000, we want to have original thinking, and I understand the local community group wants to solicit for higher taxes on something and lower zone in a fast food, but it is to me, you know, they are not really adding anything to the table. And you know, it is—

Secretary SEBELIUS. I would say, chairman, we have had a health system that spends 92 cents on every dollar treating sick people, and about 8 cents of every dollar trying to get people healthy in the first place and keep them healthy. So there were some Recovery Act dollars spent really pushing money to communities, and it was called Communities Putting Prevention to Work, so we engaged with mayors and city councils and community activist groups who did everything from bike paths and walking trails, looking at food deserts and trying to give incentives to people to bring fresh fruit and vegetables into areas where there weren't enough, working with local schools to update and upgrade what the kids were eating and—

Mr. KINGSTON. And my time has expired. Here is what I told my friends in the, you know, the agencies that kind of make it easier on us. You know, in this budget constraint—

Secretary SEBELIUS. I hear you.

Mr. KINGSTON. We can't have this, but you know, let's see, you know, if you come up—look, for example, and you know the—the 1 percent reduction in cancer each year and the reduction of polio, now the three countries and all that, that is something everybody can get behind and, you know, the taxpayers feel better about it, our constituents do, and so let me yield.

AFFORDABLE CARE ACT

Ms. DELAURO. Thank you, Jack. I would just say this to you, that the fact of sugar in obesity has been determined by scientists, so it is based on science and there is something there.

Let me just make a final comment, and I know the Secretary has to leave. I just would say this. The House voted for the Affordable

Care Act, the Senate voted for it, the President signed it, the Supreme Court upheld it. We had an election in which it was vilified, and in fact, it was overwhelmingly the President was elected.

We now have the Affordable Care Act. Our job is to implement it and to make sure that it works well, and I just want to say to you, Madam Secretary, I want to just say thank you.

Some of the problems that were there about people who are uninsured, those who can't afford insurance, lifetime limits, premiums, gender rating, the threat of coverage being canceled based on technicalities, all of those things are being addressed, phasing out of annual and lifetime limits on coverage, prohibition on denying coverage for children based on pre-existing conditions, ban on rescissions of coverage.

We are moving forward. Much has been implemented. The fact of the matter is let's get on with it, let's make changes where there need to be changes, but let's be able to do what the law of the land says. We are going to work to provide insurance. In fact, at this moment, the Affordable Care Act has helped to hold down premium increases, and there are new consumer protections. The marketplace will increase that effort, and we will have more transparency in what we know is in our insurance policies.

I say to those who can't deal with the fact of life that we have this law of the land, let's move forward and do the right thing and get over it and not try to deny the funding for it that it needs in order to survive to say, aha, it didn't work. It will work if we work at it collectively.

Thank you very much, Madam Secretary.

Mr. KINGSTON. Dr. Harris.

LOBBYING

Mr. HARRIS. Yeah, just very, very briefly, Madam Secretary, just to follow up with what the chairman's last line of questioning was. Those community preventive service task force grants and the community anti-drug coalition of America grants that, you know, were alleged now to have involved State or Federal lobbying, I got to ask you a question. Does the Department intend to go after them for recouping that just like you left the hospitals and doctors? I mean, are you going to recoup those grants from those organizations that violated their agreements not to do Federal or State lobbying with the monies, or bring action or ask the Attorney General to take action against them?

Secretary SEBELIUS. That is not underway. We have definitely gone back to grantees indicating that there is a strict prohibition. We have done retraining of all grantees. We are watching very closely. I think there is one instance where a community grantee, in addition to a lot of other things that they were doing, did lobby a local entity, and that was immediately stopped by the CDC.

Mr. HARRIS. And do you give the physicians and hospitals the same opportunity when your auditors find something to actually just perhaps advise them, or do you just go ahead and ask for recoupment of the money?

Secretary SEBELIUS. I think there is the same kind of negotiation to figure out what it is that they have done, whether or not they

indeed violated, and often there is a negotiated settlement, and that is the way it is done.

Mr. HARRIS. Thank you very much. Thank you, Mr. Chairman.

Mr. KINGSTON. Thank you. And Madam Secretary, I just wanted to touch base on one thing that we can talk about later, but, you know, with the situation with Boston and here and there, I just think we are, you know, in a world now where we can expect attacks, and because of that, I do have some worry and I think we don't discuss about BioShield enough in our country. The BioShield fund has been reduced. I am worried about pharmaceuticals being able to develop the things and have the market. I mean, that is one area where I think Republicans and Democrats can agree. There has to be a subsidy for the research and development, and it is reduced in this, and so I—do you want to comment on that? I see—

Secretary SEBELIUS. I think there is a budget recommendation for BioShield. It is a one-year recommendation given the fact that again we are now operating under a CR. We have not had an increase in BioShield since 2012, so we think it is a very important program and we would love to work with you on it.

Mr. KINGSTON. Well, I think there are things that we can, you know, really find great common ground on, and I think we are finished here. I mean, there is tons more questions. We can just bring her back tomorrow. I would like to have—

Ms. DELAURO. Talk about sugary drinks.

Mr. KINGSTON. The hobby lobby would like to yield some time to Rosa now.

We will adjourn. I do want—there were some things I had talked to you about in terms of Georgia.

Secretary SEBELIUS. Yes.

Mr. KINGSTON. About waivers and seafood, I think that Rosa—

Secretary SEBELIUS. Maryland has an issue also, and I can check up on that.

Mr. KINGSTON. If you could—

Secretary SEBELIUS. Sure.

Mr. KINGSTON [continuing]. Follow up with us, and we certainly appreciate your time, and thanks for being with us.

Secretary SEBELIUS. Sure.

[The following questions were submitted for the record.]

Department of Labor, Health and Human Services and Education and Related Agencies

Budget Hearing with Secretary Sebelius

April 25, 2013

**COMBINED QUESTIONS
TO BE SUBMITTED FOR THE PUBLIC HEARING RECORD**

Questions for the Record – Chairman Kingston

1) ObamaCare FY 2013 Funding

1A) It is an amazing increase of \$500 million or about 42 percent above last year's CMS requested increase level – please detail the criteria you used to make the resource allocation decision between further reductions to public health, prevention, bio-medical research, and mental health training to support an increase of this magnitude for CMS and ObamaCare?

Response: While Congressional Budget Office projections estimated that between \$5 billion and \$10 billion would be needed for the Department of Health and Human Services and other Federal agencies to implement the Affordable Care Act, only \$1 billion was provided under the law. The Department requested additional funds to implement the law in the FY 2013 President's Budget, and again as part of the FY 2013 continuing resolution. Unfortunately, no additional funding was provided and the Department had no choice but to leverage its existing resources. The Department is working hard to ensure that the Marketplaces are operational on October 1, and will reach out to people who are uninsured and inform them about the insurance options available in the Health Insurance Marketplaces.

1B) What are the key indicators for implementation of ObamaCare that you are monitoring that drove you decision to increase the funding \$500 million over the 2013 estimated CMS request?

Response: The FY 2014 request represents updated estimates of the funding needed to successfully operate the Marketplace in FY 2014.

1C) What is the projected impact on public health, prevention, bio-medical research, and mental health training based on your decisions to siphon off additional funds in FY 2013 for ObamaCare?

Response: Implementing the Health Insurance Marketplace and assisting Americans in gaining affordable health insurance is a top health care priority for the Department and will improve prevention efforts and public health. New coverage options available in the Marketplaces will increase access to preventive care and improve health outcomes for

millions of Americans who will be able to enroll in affordable private health plans. Unfortunately, because no additional funding was provided in FY 2013 for implementation of the Affordable Care Act, the Department had no choice but to leverage its existing resources to provide short term and immediate funding for these efforts. In recognition that some key prevention and public health activities should be continued at resource levels higher than can be provided through the Prevention Fund alone in FY 2013, HHS is providing additional base resources for specific programs within CDC and SAMHSA through the use of transfer authority within the Department.

1D) How much do you expect the full cost of implementation of ObamaCare from when it passed to complete implementation to cost the taxpayer?

Response: At the time the Affordable Care Act was enacted, the Congressional Budget Office estimated that HHS and other Federal agencies would need \$5-\$10 billion to implement its provisions, and that the Department of Treasury's Internal Revenue Service would need an additional \$5-\$10 billion. HHS has identified efficiencies and ways to be frugal to make the best use of the resources available in challenging budget times. Additionally, the most recent CBO analyses continue to project deficit reductions as a result of the Affordable Care Act, saving the taxpayers money.

1E) What steps have you put in place to ensure there is full accountability for all the ObamaCare funds and how do you validate that these funds are spend appropriately?

Response: All funds available to the Department of Health and Human Services (HHS) and the Center for Medicare & Medicaid Services (CMS) for the implementation of the Affordable Care Act are provided based on careful planning specific to each provision of the legislation. ACA responsibilities are now a part of CMS' core mission and many of the activities are supported through our base operations; therefore, it is difficult to breakout all of our expenditures related to ACA. Funds apportioned are tightly controlled, comply with all OMB directives and use CMS automated processes to ensure funds are managed in accordance with the CMS Acting Administrator's policy direction. These processes and procedures ensure the Anti-Deficiency Act is not violated and the funds are used for their intended purpose. Funds usage is validated by audit, performed by the Accounting Division as part of CMS' annual financial statement audit and A-123 reviews.

2) CMS Burden on Hospitals and Review Request

It has come to my attention that there are potential unintended consequences of the Medicare Recovery Audit Program (RAC). Specifically, Georgia hospitals have reported that 80% of the cases heard by the Administrative Law Judges are being overturned in favor of the provider.

I understand from the Office of Hearings and Appeals that in total about 50% of all appeals are fully or partially overturned. Plus, of the remaining 50% another almost 37% were fully or partially overturned at the Departmental Appeal Review process.

I support efforts to reduce improper payments. I often suggest more focus be placed on combating fraudulent activity at the front end. I am concerned that based on the extremely high overturn rates, it seems there is a flaw in the current RAC process and types of cases being reviewed. This is creating an overly burdensome process on hospital operations, increasing the cost to taxpayers.

2A) Are you aware that about 80 percent of the RAC cases are being overturned?

Response: By virtue of CMS's oversight that ensures Recovery Auditors make accurate improper payment decisions, we continually strive to reduce the appeal rate, which, in turn, decreases provider burden and administrative costs. CMS has multiple layers of oversight and incentives to ensure Recovery Auditors make accurate payment decisions. Every month, for example, CMS, through an independent review contractor, reviews a random sample of claims from each Recovery Auditor to determine an accuracy rate representing how often the Recovery Auditors accurately determine overpayments or underpayments. The Recovery Auditors' accuracy scores are consistently above 90 percent. Moreover, Recovery Auditors are required to return any contingency fee if an improper payment is overturned at any level of appeal. CMS reports appeal statistics in the annual Report to Congress and on its website at: www.cms.gov/rac. Appeals can be overturned for a number of reasons including the provider or supplier presenting additional documentation during the appeal that makes the claim correct.

2B) Request for Review: I would like to work with you to help CMS met the intent of the RAC in a manner more appropriate to the hospital community while also addressing improper payments. Would you please establish a review of how CMS and the RAC systematically review the claims overturned through the appeal process to improve the front-end process? The aim should be toward reducing the appeal overturns by not having misidentified claims. This will not only reduce the federal workload but more importantly reduce the workload and burden on the medical providers and hospital systems.

Response: CMS is continually striving to reduce the Recovery Audit appeal rate to decrease provider burden and administrative costs. In order to limit incorrect determinations, CMS approves all audit matters before widespread review occurs. This approval includes a review of the Recovery Auditors' methodology and the application of CMS regulations and policies. This effort ensures that the Recovery Auditors are properly performing the reviews based on applicable statutes, regulations, and policies. CMS is continually working to improve the Recovery Audit program and would be happy to work with you on any improvements.

3) Implementing HHS OIG Recommendations

On March 5th we had a hearing with a number of your organizations that highlighted a number of potential duplication issues as these agencies seem to perform work in overlapping areas.

On March 19 the HHS OIG, Inspector General Levinson participated in a hearing. He highlighted how important it is to pay attention to internal controls across to ensure appropriate use of taxpayer funds. On ObamaCare, the OIG's top management challenges include implementing the exchanges. I hope your staff is working with the Inspector General's staff to ensure appropriate fiscal controls are in place to prevent fraud up front in lieu of paying and chasing after the money.

I understand the HHS OIG identified over 900 recommendations since January 2011. Further, about 1,000 remain unimplemented. I assume you value work and knowledge that the OIG brings forward in its report. Please explain why so many of these recommendations are not implemented? Plus, when do you expect to get most of these old recommendations implemented?

And, what actions are you taking to eliminate duplication and overlap across HHS to become more efficient and effective?

Response: HHS takes program integrity very seriously, and in FY 2012 the Department accepted 190 OIG quality and management improvement recommendations. We will continue to work with our colleagues in OIG to combat fraud, waste, and abuse in HHS programs.

The annual budget process is the Department's primary method to identify and eliminate duplication and overlap across programs. The process begins in the spring of each year, when HHS operating divisions are required to submit budget justifications to the Assistant Secretary for Financial Resources. Those justifications undergo rigorous examination, which includes review by the Secretary's Budget Council. Once Departmental decisions are finalized, revised justifications are submitted to the Office of Management and Budget. The result is a streamlined budget request to Congress, which provides critical investments in health care, disease prevention, social services, and scientific research in order to create healthier and safer families, stronger communities, and a thriving America.

4) **Prevention and Public Health Fund (PPH Fund) Raid**

A read of the Prevention and Public Health Fund (PPH Fund) bill language clearly indicates that they are only intended to support a narrow set of programs. Specifically, to provide for expanded and sustained national investment in prevention and public health programs for programs authorized by the Public Health Service Act for prevention, wellness, and public health activities.

I am not a big supporter of the way HHS has spent the PPH Funds in the past, specifically I do not support funds for programs like the Community Transformation Grant (CTG) program. I would rather see support for programs like the Preventative Health Block

Grant, which as I understand it provides flexible funds to the States to address real public health issues.

The recent HHS raid on FY 2013 PPH Funds to divert about 50 percent of the \$1 billion to support ObamaCare does not seem legal. It does not align with what I understood to be Congressional intent; that is to use these funds to support existing public health programs.

The HHS website notes the PPH Funds will pay for “health insurance enrollment support specifically through activities that will assist with eligibility determinations in need of intervention and activities to make people aware of insurance options and enrollment assistance available to them.” Obviously this is not public health as generally understood by most folks.

Please explain how in your personal opinion that using public health funds for health insurance enrollment determination is in-line with Congressional intent and the plain language of the law to use PPH Funds to pay for public health activities?

What is the impact of diverting these funds on the nation’s public health system?

Response: The purpose of the Prevention and Public Health Fund is to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs. Assisting Americans in gaining affordable health care aligns with the purpose of the funds, which may be used for prevention, wellness, and public health activities. Implementing the Health Insurance Marketplace is the Administration’s top public health activity which has large potential to improve prevention in the next year by enabling individuals to enroll in coverage through private health insurance. For example, the Navigator program is intended to help increase access to insurance by assisting with eligibility determinations and enrollment into the Marketplaces. Various other activities funded by the PPHF help Americans get the information they need by building awareness and sharing information. These activities include the education and outreach campaign regarding preventive services as well as funding for tobacco prevention like the media campaign and quitlines. Similar to quitlines helping smokers navigate tobacco cessation, Navigators help consumers navigate the health insurance marketplace. Increasing access to care and in particular preventive services is a component of our national efforts to restrain the cost of health care by encouraging healthier lifestyles, which is a key intent of the Prevention Fund. One of the proven ways to improve health outcomes is to improve access to insurance coverage. Not only does it provide security and peace of mind, but several studies have shown that health insurance coverage improves health outcomes. For example:

- In a 2008 study, the Urban Institute noted that the absence of health insurance creates a range of consequences, including lower quality of life, increased morbidity and mortality, and higher financial burdens.
- A 2009 study in the American Journal of Public Health found that uninsurance is associated with mortality and that the uninsured are more likely to go without

needed care than the insured. It also found that the chronically ill uninsured are also less likely to have a usual source of medical care, decreasing their likelihood of receiving preventive and primary care.

- A study by the Institute of Medicine showed that working-age Americans without health insurance are more likely to: Receive too little medical care and receive it too late; Be sicker and die sooner; Receive poorer care when they are in the hospital even for acute situations like a motor vehicle crash.

In addition to funding the marketplaces, the FY 2013 allocation also continues other important public health and evidence based programs such as tobacco prevention and the Community Transformation Grant program, which is specifically cited as an example within the Prevention Fund authority. In recognition that some key prevention and public health activities should be continued in FY 2013, HHS is providing additional base resources for specific programs within CDC and SAMHSA through the use of transfer authority within the Department. The FY 2013 allocation totaling \$949 million, after accounting for sequestration reductions, reflects a broad and strategic portfolio of activities that supports the Administration's highest prevention and public health priorities.

5) **ObamaCare**

5A) Section 1311 of the law says that each state "shall" establish an American Health Benefits Exchange by January 1, 2014 . 26 states have declined to do so. Under the law, the federal government is to establish an exchange for these states.

- a. Can you tell the Committee, will these federal exchanges be run directly by HHS or indirectly by HHS through private contractors?
- b. If indirectly, what office or agency within HHS will oversee the federal exchange operations?

Response:

a.) A Federally-facilitated Marketplace developed and overseen by CMS will operate in states that have chosen not to build their own Marketplace. CMS has awarded a contract to build and support the information technology systems of the Federally-facilitated Marketplace. Contractors will also support the eligibility, outreach and plan management functions of the Federally-facilitated Marketplace.

b.) The Center for Consumer Information and Insurance Oversight, within the Centers for Medicare & Medicaid Services, oversees the operation of the Federally-facilitated Marketplace.

5B) If private contractors administer the exchanges on behalf of the federal government, has the Department established specific criteria that the government will use in selecting these contractors?

- c. Is it a competitive process?
- d. Can you share these criteria with the Committee?

Response:

c.) The Federally-facilitated Marketplace will be operated by the federal government, not by contractors, though contractors will support many Federally-facilitated Marketplace operations. All contracts are awarded following standard acquisitions law and policies.

d.) The Federally-facilitated Marketplace will be operated by the federal government, not by contractors. Any contracts are awarded following standard acquisitions law and policies.

5C) Is there any provision to prevent any contractor running a federal exchange from providing services in the exchange that they administer, either any medical good or service or health plan?

e. Has the Department established a mechanism or guideline or regulation to prevent a conflict of interest in this respect?

Response:

The Federally-facilitated Marketplace will be operated by the federal government, not by contractors. Any contractor supporting the Federally-facilitated Marketplace must follow regulations and standard operating procedures set forth by the Federally-facilitated Marketplace.

5D) The Affordable Care Act provides that the governance of the exchange run by a state either be a government institution or a non-profit agency.

f. What will be the status of contractors running the federal exchanges?

g. Will they be profit or non-profit organizations?

Response:

f.) The Federally-facilitated Marketplace will be operated by the federal government, not by contractors. The federal government may choose to award contracts for specific functions over which the federal government would maintain oversight responsibility.

g.) The Federally-facilitated Marketplace will be operated by the federal government, not by contractors.

5E) There will be a 3.5 percent administrative fee imposed on residents of states where the exchange is run by the federal government. For the record, could you specify the statutory basis for this administrative fee?

Response:

Section 1311(d)(5)(A) of the Affordable Care Act contemplates a Marketplace charging assessments or user fees to participating health insurance issuers to generate funding to support its operations. Based on this statutory authority, HHS has the authority to collect and spend user fees in states in which the Federally-facilitated Marketplace will operate. In addition, 31 U.S.C. 9701 provides for an agency to establish a charge for a service provided by the agency.

5F) There is some controversy over whether or not enrollees in the federal exchanges can be recipients of federal subsidies. According to the Attorney General of Oklahoma, the plain language of the law specifically provides that insurance subsidies will be delivered through state exchanges, but not federal exchanges.

Response:

Eligible enrollees in the Federally Facilitated Marketplace can benefit from cost-sharing reductions consistent with Sections 1402 and 1412 of the Affordable Care Act and premium tax credits consistent with Section 36B of the Internal Revenue Code, added by Section 1401 of the Affordable Care Act.

5G) The Internal Revenue Service has determined that subsidies can be delivered through federal exchanges, notwithstanding the statutory language.

- h. For the record, has the HHS General Counsel written an opinion on the provision of insurance subsidies through the federal exchanges?
- i. Have you been briefed on this issue by the HHS General Counsel, or the White House or Justice Department, on the legality of subsidies delivered through the federal exchanges?
- j. Please provide a copy of the opinion and/or briefing.

Response:

HHS defers to the Department of Treasury and its General Counsel to interpret provisions of the Affordable Care Act that relate to eligibility for the premium tax credit.

5H) On October 1, 2013, Americans are to enroll in the health insurance exchanges. In the Fall of this year, the Office of Personnel Management (OPM) will announce the projected premiums for the calendar year 2014 for plans participating in the Federal Employees Health benefits program. Will your Department be able to make similar projections for enrollees in the federal exchanges that the Department will administer or oversee?

Response:

Beginning on October 1, 2013, information on plans offered in the Federally-facilitated Marketplace, including calendar year 2014 premiums and benefits, will be publicly available on the HealthCare.gov website. Individuals will be able to enroll directly through the website or call a toll-free phone hotline.

5I) On January 1 2014, based on a legal opinion from the United States Office of Personnel Management, all members of Congress and their personal staffs will be required to get their health insurance through the state or federal exchanges. Will Members of Congress and their staffs also start enrolling in these exchanges on October 1, 2013 like other American citizens?

Response:

Open enrollment for plans in the both the state and Federally-facilitated Marketplaces begins October 1, 2013, for coverage beginning January 1, 2014. The issue of enrollment for Members of Congress and Congressional staff is currently being considered by the Office of Personnel Management.

5J) Since Members of Congress will henceforth be required to enroll in the health insurance exchanges, will they have a choice of enrolling in the District of Columbia exchange, the exchange in their state, or will they have a choice of enrollment in either one?

Response:

This issue is currently being considered by the Office of Personnel Management

5K) For the record, do you have any idea as to why Congressional Leadership office staff have been exempted from the broad requirement that Members of Congress and their personal staffs henceforth get their coverage through the health insurance exchanges rather than the Federal Employees' Health benefits program?

Response:

HHS is unable to comment on the intent of Congress when enacting Section 1312 (d) (1) (D) of the Affordable Care Act.

5L) Is it correct that taxpayer subsidies for insurance in the health exchanges are to be capped at the level of the growth in the Consumer Price Index?

k. And if that is true, can you tell the Committee why the CPI standard was established and not the target level of GDP plus 1 percent that applies in the Medicare program beginning in 2018?

Response:

HHS defers to the Department of Treasury to interpret provisions of the Affordable Care Act that relate to eligibility for the premium tax credit.

5M) According to April 12 2010 edition of The New York Times, President Obama indicated that he will volunteer to enroll in a health insurance exchange?

1. For the record, will you also enroll in the appropriate health insurance exchange?

Response: Cabinet Secretaries are included in the Federal Employee Health Benefits Program and already have access to employer-sponsored health insurance. Congress established the Exchanges, now known as Marketplaces, to extend health insurance options to the millions of Americans who do not have the benefit of health insurance, go without health care for routine preventive services and face the risks of financial ruin when they get sick.

When the health insurance Marketplaces are open for enrollment on October 1, Americans will be able to log on and compare their insurance options based on price, benefits, and quality, which will be available in plain language that makes sense. They can use that information to purchase the plan that makes the most sense for them, and will have peace of mind knowing that insurance companies can't refuse to cover them or charge them more just because of a chronic or pre-existing condition.

In the meantime, we are working hard to ensure that the Marketplaces are operational, and will be informing Americans, especially underinsured or uninsured Americans, about the benefits of the Affordable Care Act.

6) **Prosthetic Audits**

In September, 2011, immediately following the release of the OIG Report entitled "Questionable Billing Practices in Orthotics and Prosthetics," CMS' DME MAC contractors issued a "Dear Physician" letter that announced new documentation requirements for orthotic and prosthetic devices provided to Medicare beneficiaries. It also adopted a 'zero tolerance' policy, so that if there was any imperfection in the claim submission, no matter how immaterial, payment of the claim should be denied. In the past, when the preponderance of evidence indicated that there was no fraud or abuse present, the claim would be approved.

I am hearing from my constituents that small prosthetics businesses which provide care to seniors who need prostheses, are having as many as 90% of their claims denied for minor technicalities or paperwork that hasn't been completed by physicians. In the meantime, small prosthetics businesses are carrying hundreds of thousands of dollars' of legitimate, but unreimbursed costs – or limiting the number of seniors they care for under Medicare – or are going out of business altogether. In light of this crisis, I would like to ask the following questions:

6A). What is CMS's policy to ensure that RACs and other anti-fraud activities, while necessarily rigorous, do not place undue and/or counterproductive burdens on providers?

Response: CMS strives to reduce audit burden on providers. The Medicare Administrative Contractors (MACs) process claims and follow a process known as Progressive Corrective Action (PCA). The PCA process starts with the MAC reviewing a small number of claims on a pre-payment basis to determine if any of the claims would have been paid improperly. Based on the results of those reviews, if a provider has a high improper payment rate, the MAC increases the number of medical reviews for that provider and performs educational activities in an effort to improve their compliance with CMS policies. Conversely, if the PCA process shows the provider consistently bills correctly, the MAC suspend the reviews and focuses on other priorities.

The Recovery Auditors review claims mostly on a post-payment basis. The CMS has implemented several measures to ease provider burden and to ensure accurate RAC decisions. First, all new areas to be reviewed are approved by CMS before the Recovery

Auditors can begin review. Second, the Recovery Auditors lose their contingency fee if their decision is overturned at any level of appeal. Third, CMS has limited the number of additional documentation requests a Recovery Auditor can send to a provider. On April 3, 2013 CMS created a separate additional documentation request limit category for prosthetists/orthotists. Recovery Auditors can request a maximum of ten medical records per prosthetist/orthotist every 45 days. Before, Recovery Auditors could request up to 10 percent of their records.

6B). What policies does CMS employ to ensure that providers that are suspected of fraud are the primary targets of the audits?

Response: Payment made for the furnishing of an item that does not meet one or more of Medicare's coverage, coding and payment rules is an improper payment. It is important to keep in mind that all fraud is considered to be improper payments, but not all improper payments are fraud. In 2011, the Department of Health and Human Services Office of Inspector General (OIG) released a report that found that there was a significant amount of improper payment for lower limb prosthetics. Since the publication of the report, the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) have begun reviewing these claims as recommended by the OIG. CMS also offers a range of educational materials through online manuals and websites to assist prosthetists and orthotists, providers and suppliers with Medicare policies, billing procedures and required documentation. If the DME MAC suspects that the supplier is participating in fraud, they are required to refer the case to CMS' Zone Program Integrity Contractor who is responsible for investigating potential fraud.

6C). Does CMS have any policies in place that take into account longstanding Medicare providers with a history of dedication to high-quality integrity, without documented or suspected fraudulent activity? Is it appropriate for Medicare to subject them to the same level of scrutiny, payment delay, and payment denial as high-risk providers?

Response: The Medicare Administrative Contractors process claims and follow a process known as Progressive Corrective Action. As explained in Chapter 3, Section 3.7.1 of CMS's Program Integrity Manual, CMS's contractors "shall ensure that actions imposed upon Medicare providers or suppliers for failure to meet Medicare rules, regulations and other requirements are appropriate given the level of non-compliance." The manual offers examples of "minor," "moderate," and "major" concerns and discusses the type of corrective action appropriate for each.

6D). What length of time does CMS believe it is appropriate to withhold payment to prosthetics providers for minor documentation technicalities, or for documentation failures that are the responsibility of the physician, not the prosthetics provider?

Response: Payment made for the furnishing of an item that does not meet one or more of Medicare's coverage, coding and payment rules is an improper payment. Section 1833(e) of the Social Security Act states that "[n]o payment shall be made to any provider of services or other person [under Medicare Part B] ... unless there has been

furnished such information as may be necessary in order to determine the amounts due such provider or other person....” Documentation is essential to meet the requirement in the statute. Chapter 3, Section 3.3.1.1 of CMS’s Program Integrity Manual discusses the timeframe for certain medical review activities.

In regard to prepayment review, this section states, in part, that when one of CMS’s Medicare Administrative Contractors (MACs) “receives requested documentation for prepayment review within 45 calendar days, the MAC shall ... within 60 calendar days of receiving the requested documentation ... make and document the review determination.”

6E). Where providers have the financial and legal resources to appeal RAC payment denials to the Administrative Law Judge level, those RAC determinations are overturned at a very high rate – in some cases, more than 80% of the time. At what point does CMS examine RAC determinations – including costs to the agency-that are consistently being overturned upon appeal?

Response: Through oversight to ensure Recovery Auditors make accurate improper payment decisions, CMS continually strives to reduce the appeal rate, which, in turn, decreases provider burden and administrative costs. The Fiscal Year 2011 Recovery Audit Report to Congress reported that more than 90 percent of Recovery Audit overpayment determinations were not appealed, and that just 2.9 percent of all Recovery Auditor overpayment determinations were overturned on appeal.

CMS has multiple layers of oversight and incentives to ensure Recovery Auditors make accurate payment decisions. Every month, for example, CMS, through an independent review contractor, reviews a random sample of claims from each Recovery Auditor to determine an accuracy rate representing how often the Recovery Auditors accurately determine overpayments or underpayments. The Recovery Auditors' accuracy scores are consistently above 90 percent. The CMS reports appeal statistics in the annual Report to Congress and on its website at: www.cms.gov/rac. Moreover, Recovery Auditors are required to return any contingency fee if an improper payment is overturned.

6F). Manufacturer records show practitioners have retreated to less advanced, less costly, less functional artificial limbs and components, reflecting aversion to risk of non-payment. Has CMS measured the impact of contractor actions on patient care in prosthetics since August, 2011, including how delivery times may have slowed in the face of these new requirements? Is Medicare satisfied to see the program reducing the level of care provided to Medicare amputee beneficiaries?

Response: Medicare beneficiaries are receiving high quality prosthetics and orthotics that help them live active and healthy lives, and CMS continues to ensure they have access to appropriate prosthetics and orthotics. In 2011, the HHS Office of Inspector General Daniel R. Levinson released a report that found that there was a significant amount of improper payment for lower limb prosthetics. CMS is working to educate providers and suppliers on Medicare coverage and documentation requirements for lower limb prosthetics to reduce the improper payment rate. In addition, CMS is developing a

clinical template in consultation with prosthetic and orthotic suppliers to assist providers in complying with Medicare coverage policies. To date, there are no data available to CMS to suggest any access to care issues.

6G). The current “all or nothing” approach to audits, where a minor paperwork flaw may block the entire payment on a \$35,000 prosthetic limb, seems inequitable and unnecessarily punitive to small businesses that are providing necessary, high quality services to disabled senior citizens. In other settings, CMS has limited its audit/claw back to the specific challenged codes/components, while paying for those codes/components which are not contested. Why hasn’t a similar policy been implemented for O&P?

Response: In 2009, the U.S. Court of Appeals issued a decision in *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009) regarding the application of the least costly alternative. The Court of Appeals held that the Medicare coverage decision is binary: an item or service is either reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all. Similarly, if a supplier bills for a level 3 prosthetic but the beneficiary only qualified for a level 1 prosthetic, the review contractor cannot simply reduce the payment to the level 1 payment amount; the review contractor must issue a full denial.

7) Influenza Vaccines for Preparedness

The FY 14 Budget Justification material for the Public Health and Social Services Emergency Fund recognizes the \$1.5 billion investment that has been made to acquire and maintain the pre-pandemic influenza vaccine stockpiles, a core element of the National Strategy for Pandemic Influenza. It includes over 200 million doses of vaccines and 125 million doses of adjuvants.

The FY 14 (no year) budget request is only \$20 million to support storage, analytical and clinical testing, maintenance, and replenishment of H5N1, H3N2v and other influenza vaccines and adjuvants for pandemic preparedness. That represents only 1.3% of the value of the asset.

Is \$20 million sufficient to ensure the appropriateness and readiness of the asset, and a sufficient market to encourage continued investment by the government’s private sector vaccines partners?

Response: This amount represents the annual costs for these activities during the normal course of events and the emergence of new influenza viruses (e.g., H3N2v) deemed at lower risk than H5N1 viruses.

8) Cancer Prevention and Control

Since 1991, National Breast and Cervical Cancer Early Detection Program (NBCCEDP) funded programs support cervical cancer screening examinations.

Please explain why CDC is propose to cut \$38 million in funding for what many believe is an effective women's cancer screenings program?

Response: CDC's proposed FY 2014 request to decrease funding for Cancer Prevention and Control by \$38 million is attributable to two factors: 1) there was a one-time \$10 million increase in FY 2012 for special screening projects, and 2) anticipated health insurance expansion, including expanded coverage of cancer screenings for breast and cervical. Through the Affordable Care Act most health plans are required to cover mammograms, pap smears, and other cancer screenings without co-pays or deductibles. In 2014, the Affordable Care Act provides for new opportunities for health insurance coverage through the new Health Insurance Marketplace and greater access to Medicaid. The law also requires new health plans to cover prevention counseling for women who are at a greater risk for breast cancer and, starting in 2014, it ensures that no one can be denied health insurance because of a pre-existing condition. The President's Budget takes into account the opportunities for expanded health insurance coverage made possible by the Affordable Care Act and as such, directs limited discretionary resources to public health initiatives, such as healthcare-associated infections and food safety. Funding for direct screenings such as breast and cervical screening will likely be covered by insurance and therefore will see reductions in federal funding.

Capacity Building for Graduate Research Institutions

Secretary Sebelius, this subcommittee continues to prioritize efforts to address the capacity building needs of graduate research institutions. As you know, grants provided through the Research Centers in Minority Institutions (RCMI) program assist in the recruitment, training, mentoring, and career success of racial and ethnic minority candidates in biomedical research. These funds also support an institution's ability to recruit and retain highly qualified professors and researchers to train graduate students and pursue biomedical research focused on minority health and health disparities.

Given NIH Director Collin's efforts to address the disparate numbers of minority biomedical researchers in the workforce and the demonstrated gap in R01 grant funding awards amongst African American and other minority researchers, how has the RCMI program helped to address these challenges?

Do you believe that through additional resources, the 18 RCMI-supported institutions could respond in an even more effective manner?

Response: NIH recognizes that minority-serving institutions are uniquely positioned to engage racial/ethnic minority populations in research and in the translation of research advances into culturally competent, measurable, and sustained improvements in health outcomes. The discovery, development, and translation of clinical science into future medical therapies require a robust platform for innovative research.

The NIMHD Research Centers in Minority Institutions (RCMI) program provides resources for several critical areas of support for biomedical, clinical, behavioral, and

social sciences research. Infrastructure development creates a foundation for the research enterprise through renovation/alteration of new research facilities and the development of specialized research support capabilities such as biomedical informatics and research design/biostatistics expertise. Activities under the RCMI program broaden the opportunities to conduct clinical and translational research through collaborative projects with an emphasis on improving minority health and reducing health disparities. In addition, instructive training and mentored research training experiences for early-stage investigators interested in health disparities research facilitate career advancement for junior faculty members.

Together these activities address many of the challenges faced in promoting diversity in the biomedical, clinical, behavioral, and social sciences research workforce. Even with relatively smaller student enrollment, the institutions supported through RCMI have historically produced a diverse, highly trained cadre of scientists involved in conducting a wide variety of research projects. The academically enriched environment for the conduct of research and the opportunity for career advancement in respective scientific disciplines have been invaluable.

The ultimate impact of RCMI institutions on enhancing the diversity of the biomedical, clinical, behavioral, and social sciences research workforce is influenced by the availability of resources. However, much can be accomplished by fostering collaborations, partnerships, and networking with the RCMI institutions and other institutions including the private sector. NIH remains committed to the goals and objectives of the RCMI programs and exploring any opportunity available to enhance its contribution to the health and well-being of the Nation.

9) Biomedical Research Workforce Diversity

In response to the recent findings of the significant gap in R01 grant funding awards for African American researchers, the NIH Director's "Working Group on Diversity in the Biomedical Research Workforce" announced an action plan focused on increasing the diversity of the NIH-funded workforce. The Building Infrastructure Leading to Diversity (BUILD) program, an integral part of this initiative, will provide tuition scholarships and mentoring opportunities for undergraduate participants, faculty salary support and other infrastructure support for participating institutions.

With the recent NIH announcement related to the availability of six-month planning grants for interested institutions in the BUILD program, I like many members of the subcommittee remain enthusiastic of the agency's efforts to address these disparities.

9A) Given the multi-institution structure of the BUILD program, can you provide additional details beyond those provided in the Funding Opportunity Announcement, related to the expected collaboration between the Primary, Pipeline, Research and Graduate/Medical Partner institutions?

Response: Funding will be targeted for institutions that meet the eligibility requirements for “Primary Institution;” collaborating “Partner” institutions may receive funds through the Primary institution. If the candidate Primary institution may benefit from having a larger pool of eligible students, partnerships with “Pipeline” institutions are encouraged. Through such collaboration, eligible students from Pipeline institutions would have an opportunity to benefit from this initiative. Since, by definition, Primary institutions are not research-intensive, it is expected that students and faculty from many of these institutions will benefit from access to a richer research environment that can be provided by “Research Partner” institutions. Research-intensive institutions must be able and willing to provide mentors and research experiences for the students as well as research-intensive sabbatical opportunities for faculty from Primary institutions. “Graduate/Medical Partner Institutions” comprise a separate category of institutions that do not educate undergraduates but have demonstrated commitment and success in training students from diverse backgrounds underrepresented in biomedical/biobehavioral research. These institutions will work collaboratively with Primary institutions to provide joint training and research opportunities for both undergraduate and graduate students. The Primary institutions and all categories of Partner institutions are provided flexibility to collaboratively develop and test novel and innovative methods for recruitment and retention of individuals from underrepresented groups into the NIH-funded workforce.

9B) Historically Black Colleges and Universities (HBCUs), Historically Black Medical Schools (HBMSs) and some graduate institutions have demonstrated a long-standing commitment to training and ensuring the career success of minority candidates in biomedical research and the health professions.

Given their well-documented achievement in recruiting, training, and ensuring the career success of minority researchers, does NIH plan to partner with or prioritize grant considerations from institutions with a long-held commitment to addressing these disparities?

Response: Most HBCUs and HBMSs will meet the eligibility criteria and will thus be able to compete for the BUILD awards. In determining the eligibility criteria, our intent was to assure that those institutions with a well-documented history of educating and graduating students from diverse backgrounds underrepresented in biomedical research would be included. The FOA specifically instructs applicants to describe past successes in recruiting students from underrepresented groups into research careers and in preparing them to be successful in research. A convincing documentation of historical commitment and achievement in this regard is an expectation for a successful award. The category of “Graduate/Medical” institutions was included with the recognition that HBMSs do not have undergraduate students but have a history of commitment and achievement in educating underrepresented students who are successful in pursuing careers in biomedical research.

9C) How will these institutions be included in the NIH's efforts to address these gaps? Could these schools be helpful in developing best practices for institutions participating in the BUILD program?

Response: These institutions (HBCUs and HBMSs) are eligible for the BUILD program awards. It is anticipated that many of these institutions will apply for the award; those that are successful will be represented in some capacity in the BUILD consortium. One of the expected outcomes of the award is the development of best practices and other innovative approaches to develop and test new models for recruitment and retention of individuals from underrepresented groups into the NIH-funded workforce. Our expectation is that some of these institutions will play a leading or contributory role in this process. We further expect that a few of these innovations will be catalytic and lead to adoption by other institutions, both BUILD and non-BUILD and both HBCU and non-HBCU institutions.

9D) As the Committee continues to measure the success of biomedical researchers training and support programs through the attainment of gainful employment for program participants, can the agency provide an estimate for employment capacity for research graduates in the field of biomedical research?

Response: In spite of the very high employment rate among PhD graduates in the biomedical sciences and medical graduates (MDs), there is an underrepresentation of individuals from diverse backgrounds in the workforce. This underscores the need for the NIH's enhanced efforts to diversify the biomedical research workforce with programs such as BUILD that can ultimately help to expand the pool of talented researchers from all groups.

U.S. trained PhD graduates in the biomedical sciences have an overall unemployment rate of 2%. Only 13% of the employed are in non-science related careers. The remaining is employed in government research (6%), academic research or teaching (43%), industrial research (18%), and science-related non-research (18%). Many MDs also conduct biomedical research. Extensive data are collected on MDs (primarily by the American Medical Association and the Association of American Medical Colleges) but the available data do not identify clearly those who conduct research. This information should become available at the conclusion of an MD workforce study that is currently being conducted by a working group that is advisory to the NIH director.

9E) Are there certain research specialties, like those focused on minority health and health disparities, at which the capacity is greater?

Response: Although anecdotal data exist, we do not have good quantitative data on employment broken down by research specialties. NIH is considering implementing a tracking system for all trainees for which NIH funds are expended. If implemented, employment data by research specialties would be available with such a tracking system.

- 10) What impact has the availability of the Project BioShield Special Reserve Fund had on the development and procurement of medical countermeasures for national security threats over the past decade?

Response: The Special Reserve Fund has resulted in HHS's creation of a robust development pipeline containing more than 80 medical countermeasure candidates for chemical, biological, radiological, and nuclear threats. This development has resulted in the delivery of 11 new medical countermeasures (MCMs) to the Strategic National Stockpile (accessible by Emergency Usage Authorization) and the FDA licensure of two of these MCMs.

- 11) This week, we have had some frightening reminders of the threats we continue to face in this country. The bombs in Boston and the ricin laced letters addressed to our Senate colleague and the President demonstrate that we must remain committed to preparing for the threats we know about, as well as build capacity to respond to those we can't anticipate. The Project BioShield Special Reserve Fund (SRF) and the Biomedical Advanced Research and Development Authority (BARDA) are critical parts of the medical countermeasure enterprise, providing funding for the research, development, procurement, and stockpiling of products to fight these kinds of threats.

- 11A) What impact do you believe the BioShield SRF has had on the department's ability to develop and procure medical countermeasures? How will reduced funding for biodefense in the President's budget, specifically a mere \$250 million for the SRF, affect the nation's preparedness? In your professional opinion, what impact do you think shifting to an annual appropriation will have on the biodefense enterprise?

Response: The Special Reserve Fund has resulted in HHS's creation of a robust development pipeline containing more than 80 medical countermeasure candidates for chemical, biological, radiological, and nuclear threats. This development has resulted in the delivery of 11 new medical countermeasures (MCMs) to the Strategic National Stockpile (accessible by Emergency Usage Authorization) and the FDA licensure of two of these MCMs.

The FY 2014 President's Budget requests funding for BARDA across three categories: Advanced Research and Development (ARD), Pandemic Influenza and Project BioShield. Based on MCM development and procurement across multiple years and relevant PHEMCE priorities, BARDA determined that \$250 million was needed for procurements in FY 2014. This funding request will support the replenishment of Modified vaccinia Ankara (MVA) vaccine (smallpox), vendor-managed inventory (VMI) costs for an anti-neutropenia cytokine acquisition to treat acute radiation syndrome, and a new BioShield award for artificial skin to treat thermal burn patients. The FY 2014 President's Budget also explicitly commits to a renewed multi-year funding commitment supporting the procurement of MCMs via Project BioShield for the Strategic National Stockpile (SNS). BARDA expects that at least 12 new MCMs in the present advanced development pipeline will mature sufficiently from FY 2014-2018 for consideration of

procurement under Project BioShield. Moving forward, BARDA will continue to support the development and procurement of new MCMs, substantially improving the nation's preparedness.

For future funding of BioShield, the FY 2014 President's Budget requests \$250 million available until expended. HHS requests no-year funding to maximize the flexibility and provide stability to align with the original BioShield appropriation.

Originally, Project BioShield's funding of \$5.6 billion was expected to be a sufficient incentive to bring large, fully-integrated pharmaceutical companies into the biodefense market space. Unfortunately, a limitation on these funds was that, with minor exceptions, they could not be used to pay MCM vendors until a product was delivered to the SNS, thereby placing the majority of risk on the private sector. Over the past nine years, HHS has developed additional tools to foster its relationship with these partners to address this concern. This development has included the establishment of BARDA, the provision of ARD funding, and the expansion of authorities under Project BioShield – most notably the introduction of milestone payments in contracts. More recently, per recommendations from the Secretary's Review of the Public Health Emergency Medical Counter Measure Enterprise (PHEMCE) following the 2009 H1N1 pandemic, came the establishment of Centers of Innovation for the Advanced Development and Manufacturing (CIADM). These public-private partnerships allow BARDA to pair large established pharmaceutical companies with smaller firms. These pairings mitigate the scientific and manufacturing risks associated with MCM development by providing the necessary expertise to bring promising technologies to the marketplace. Additionally, the PHEMCE Review recommended the establishment of a MCM Strategic Investor, an independent non-profit entity, which uses HHS funding to support capital investments in private companies with promising technologies. By providing critical capital in exchange for a strategic role in the management of these small firms, HHS is able to mitigate the financial and management risk that some small firms face, thereby increasing the probability of successful technologies and products.

Since the development and procurement of MCMs is an inherently risky endeavor, BARDA remains focused on keeping sufficient incentives in place for its industry partners. This effort includes an HHS intra-agency multi-year budgeting practice driven by the long-lead time necessary for MCM development and acquisition. Large pharmaceutical companies (e.g., Amgen, GlaxoSmithKline, etc.) are now joining the biodefense MCM sector, using long-range budget planning routinely as a good business management practice. Venture capital investors, which fund many small biotech companies in the biodefense sector, may choose to support biotech companies in a different sector that has a better benefit-to-risk profile than biodefense. These circumstances support the critical need to ensure a long-term funding commitment is maintained with annual appropriations in the future. Maintaining the progress that has been achieved in the recent years requires Congress' continued support for these future activities.

11B) Congress recently reauthorized the Pandemic and All-Hazards Preparedness Act (PAHPA). One of the key components of the recently enacted legislation is a provision to reauthorize the Project BioShield Special Reserve Fund (SRF) at \$2.8 billion to be available for the next 5 years. The SRF was originally created as a guaranteed market incentive to encourage companies to develop and produce medicines and vaccines to protect Americans from identified threats, since there is no commercial demand for these products. Over the last 10 years, the SRF has provided for the procurement and stockpiling of nine MCMs for threats such as anthrax and smallpox. Additionally, the SRF provided funds through the Biomedical Advanced Research and Development Authority (BARDA) for the development of more than 70. I am very concerned by the level of funding provided to the SRF in the President's Budget. Shifting to an annual appropriation, and at only \$250 million, would create extreme uncertainty in the medical countermeasures market.

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11C) How will you ensure that the Project BioShield Special Reserve Fund is available for the next 5 years to give confidence to companies that are developing and delivering essential medicines to our national stockpile to use in the event of an emergency?

Response: The Department agrees that providing industry with a clear indication of long-term support of medical countermeasure development is important to the success of Project BioShield. The Budget explicitly states the FY 2014 request represents a multi-year renewed commitment to Project BioShield. Additionally, as an added incentive, the FY 2014 President’s Budget proposes language to provide BARDA with the authority to modify the standard government-wide authority for multi-year contracting (41 USC 3903). The modified language included in the FY 2014 President’s Budget authorizes BARDA to enter into an “incrementally-funded”, multi-year contract for up to ten years. Additionally, the language modifies the existing authority’s requirement of set-aside

contract termination costs by allowing BARDA to repurpose any un-used termination costs to pay contract invoices in subsequent years. This differs from traditional multi-year contracting authority, which specifies termination costs can be used for that purpose alone. These modifications allow BARDA to effectively utilize multi-year contracting authority to engage in long-term contracts with companies that develop medical countermeasures.

11D) How many products does BARDA have in the advanced development pipeline that you think will be available for procurement over the next 5 years? What is the average BioShield contract award?

Response: BARDA expects that at least 12 new MCMs in the present advanced development pipeline will mature sufficiently from FY 2014-2018 for consideration of procurement under Project BioShield. The funding obligated on a Project BioShield contract ranges from \$160 million to \$542 million, with an average of \$300 million.

11E) It is my understanding that the \$250 million request for the BioShield Special Reserve Fund was based on BARDA's assessment of which products will be ready for procurement in 2014. To better understand this, please provide details on the Department's 5-year biodefense spend plan -- including NIAID, BARDA's advanced development program, SRF procurements and SNS stockpile maintenance.

Response: The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) requires HHS to produce a multi-year budget for medical countermeasure programs across the Department. Agencies within HHS are currently collaborating to compile budget data for investments for FYs 2013-2018 consistent with this requirement.

11F) It appears that overall biodefense investments across HHS are heavily weighted towards basic research (over \$1 billion at NIAID) rather than the later, more expensive stages of drug and vaccine development (only \$415 million at BARDA for advanced development). It is my understanding that the advanced development stage is more costly. Explain why you believe this funding distribution is appropriate.

Response: Basic research enables us to better understand viruses, bacteria, and other infectious agents that cause diseases of public health concern. This research provides the foundation for developing medical products and strategies to diagnose, treat and prevent a wide range of infectious diseases, whether those diseases emerge naturally or are deliberately introduced as an act of bioterrorism. Basic research adds to the foundation of scientific knowledge which will later allow useable medical countermeasures to be developed; in the early development stage funding is available for many projects to be explored because not all studies are guaranteed to be successful.

The advanced development portfolio's mission is focused on fulfilling a later stage of the developmental pipeline and is concentrated on the highest priority medical countermeasure products. Following the Public Health Emergency Medical Countermeasures Enterprise Review, the Department began to transition from the "one

bug one drug” approach to countermeasure development to a flexible, nimble development strategy that emphasizes platform technologies and broad spectrum, multiple application products. Additionally, the request for advanced development seeks to enhance public –private partnerships by leveraging funding in investments such as the Centers for Advanced Development and Manufacturing and the Strategic Investor. Investments such as these further support and develop the medical countermeasure development industry. The FY 2014 Budget renews the commitment to both advanced development and procurement of medical countermeasures by requesting new budget authority to support these efforts.

11G) How are HHS investments across the enterprise (including NIAID) prioritized? Do you have a prioritized threat list aside from the long list of Material Threat Determinations (MTDs) provided by DHS?

Response: The Public Health Medical Emergency Counter Measures Enterprise (PHEMCE) Strategic Plan (2012) guides prioritization of investments on discovery, early development, advanced development, acquisition, stockpiling, and replenishment activities by HHS and the Department of Defense (DoD). Criteria for prioritization include the following:

- addressing the most significant threats;
- fostering approaches with the potential to provide protection against multiple important threats; and
- maintaining the capability to effectively use the assets developed.

Moderating criteria include:

- addressing the needs of all segments of the U.S. civilian population, including at-risk populations;
- balancing rapid acquisition of current materials against significant gains in capabilities that may be possible through alternative long-term efforts; and
- considering lifecycle costs of MCMs.

For additional information regarding the PHEMCE Strategic Plan, please visit: <http://www.phe.gov/Preparedness/mcm/phemce/Documents/2012-PHEMCE-Strategy.pdf>

The HHS and DoD agency programs, milestones, and timelines are outlined in the PHEMCE Implementation Plan (2012) to address the goals and objectives of the PHEMCE Strategic Plan. PHEMCE MCM priorities for overall goals, NIH, and BARDA are outlined in Tables 1-3 of the Implementation Plan.

For additional information regarding the PHEMCE Implementation plan, please visit: <http://www.phe.gov/Preparedness/mcm/phemce/Documents/2012-PHEMCE-Implementation-Plan.pdf>

HHS utilizes the prioritized threat list provided by DHS as material threat assessments (MTAs) in statutory compliance with the Project BioShield Act of 2004.

Additionally, other DHS threat risk assessments also inform the threat prioritization process.

11H). How are Strategic National Stockpile lifecycle management costs evaluated? When a new medical countermeasure is identified and developed, what kind of planning is done to make sure that product can be maintained over time?

Response: Strategic National Stockpile (SNS) lifecycle costs are evaluated and updated twice a year for each product held in the SNS utilizing operations research methodology. These updates involve life cycle cost modeling with a product profile, inventory cost projections, and evaluation of all applicable cost drivers to determine total lifecycle costs for the current SNS formulary.

As new medical countermeasures (MCM) are proposed, they are reviewed by Public Health Emergency Countermeasures Enterprise (PHEMCE) partners, including CDC, to determine suitability for inclusion in the SNS. The costs to maintain new and existing MCM in the SNS are addressed through prioritization of MCM through the PHEMCE process in the SNS Annual Review.

11I) I am concerned about funding for the Strategic Investor and the Centers for Innovation in Advanced Development and Manufacturing coming out of BARDA's advanced development funding. Do you think it is more important to fund those new programs than to support the advanced development of specific countermeasures to address material threats?

Response: The Strategic Investor (SI) and the Centers for Innovation in Advanced Development and Manufacturing (CIADM) are initiatives recommended by the PHEMCE Medical Counter Measure Report (2010) to address limitations common to biodefense MCM developers. These initiatives complement BARDA's direct support of biodefense MCM developers, by providing assistance beyond direct funding including considerable technical and regulatory expertise, separate networks for clinical studies, and animal studies, and fill/finish manufacturing. In addition to funding, the SI initiative will provide technical and business assistance to MCM developers that have products with biodefense and commercial application. The CIADM initiative directly assists biodefense developers on a routine basis with 23 different development activities and with manufacturing of clinical investigational and commercial-scale lots of MCMs. The CIADMs save the developer the costs associated with importing contract professional services and building manufacturing facilities while also saving the indirect costs associated with development and manufacturing activities on direct contracts with biodefense developers.

11J) Explain how HHS is coordinating investments in medical countermeasure development, procurement, and infrastructure building with DOD (e.g. 4 new advanced development and manufacturing centers across the two departments).

Response: Throughout the entire planning and procurement phases of the advanced development and manufacturing centers (ADMs), HHS and DoD have been in full coordination, specifically addressing the scope, number, and types of facilities necessary to address the MCM needs of each department. Additionally, each department provided technical expertise in the evaluation of proposals submitted to establish the ADMs. During the construction and start-up operational phases of the ADM initiative over the next two years, HHS and DoD will be guided by a Memorandum of Understanding (MoU) that outlines the common governance structure, MCM prioritization process, agency responsibilities towards the ADMs, and integration into the PHEMCE and its priorities. Afterwards the MoU will afford decision-making and oversight processes for the ADM operations and maintenance.

11K) Explain why the new multi-year contracting language proposed in the President's Budget is needed and what the impact is expected to be.

Response: The modified multi-year contracting authority language proposed in the FY 2014 President's Budget is aimed to maximize BARDA's ability to facilitate the development of medical countermeasures within existing resources. This modification will enable BARDA to effectively use this authority and is aimed address the industry's concerns related to the long-term funding commitment of Project BioShield.

Currently, there is limited government-wide authority for multi-year contracting (41 USC 3903), which authorizes "incremental" funding of severable and non-severable multi-year contracts. Unfortunately, the existing government-wide language has two significant limitations that inhibit BARDA's ability to effectively utilize the authority without modification.

1- Contracts under the existing authority must be limited to five years; however Project BioShield procurements require contracts in place for up to ten years.

2- Under the existing authority, when a contract is signed the initial obligation must include the cost that would be incurred if the government were to terminate the contract at the end of the first year rather than continuing to fund it. That termination amount generally declines across the life of a multi-year contract. The modified authorization allows BARDA to repurpose un-used termination costs to pay contract invoices. This differs from traditional multi-year contracting authority, with specifies termination costs can be used for termination alone.

11L) Do you believe that preparing for naturally emerging diseases prepares for biological weapons? Do you think different strategies/countermeasures are needed, given that a natural disease outbreak would result in relatively few primary cases that accumulate over time whereas a deliberate biological attack can result in hundreds of thousands of primary cases?

Response: Emergency preparedness requires actions to protect against specific types of hazards but also to increase our nation's preparedness for any type of hazard. Recent

events have shown that an accidental, intentional, or naturally occurring public health emergency can occur anywhere, and often with little or no warning.

Our increasingly global society makes Americans more vulnerable to novel infectious diseases which may emerge suddenly and spread quickly – such as the SARS outbreak in 2002. Novel influenza viruses may move more slowly than a bioterror attack, but the morbidity and mortality impact can still be devastating. It is important to be prepared – including efforts to expand our knowledge base about the wide variety of strains and increase our domestic vaccine production capacity. Efforts to prepare for chemical, biological, radiological or nuclear attacks are equally important, and preparedness for both types of health hazards requires fully-functioning public health and medical systems which are able to implement preparedness plans immediately when needed. By employing an all-hazards preparedness approach, including preparing for natural or intentional biological threats, we can work to promote health and safety for all Americans.

11M) Who in the White House is responsible for coordinating and overseeing biodefense efforts across the interagency?

Response: The White House National Security Staff coordinate and oversee biodefense efforts across the interagency.

11N) The Department proposed creating a Strategic Investor for biodefense medical countermeasures a few years ago. Congress did not support that and did not provide that new authority in the recently enacted Pandemic and All-Hazards Preparedness Reauthorization Act. Is your proposal this year any different than before?

Response: The Strategic Investor is an important priority to the Administration. Although authority to establish the Strategic Investor was not included in the recent reauthorization of PAHPRA, HHS continues to request the authority to implement the Strategic Investor in the FY 2014 President's Budget request. This authority would provide financial support and business expertise to newly emerging businesses in the biodefense sector, which would provide substantial contributions to MCM advanced development.

11O) Last month, Congress enacted the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA). This new law demonstrates Congress' commitment to preparing for chemical, biological, and nuclear threats. Unfortunately, bombs in Boston and a ricin laced letter addressed to our Senate colleague remind us of these threats. One of the key components of PAHPRA was the reauthorization of the Project BioShield Special Reserve Fund (SRF) at \$2.8 billion for the next 5 years. I am concerned that the President's Budget shifts to a small annual appropriation for this program with new multi-year contracting authority. I do not believe that will be sufficient to sustain the biodefense enterprise.

What impact do you believe the Project BioShield Special Reserve Fund has had on our nation's ability to develop and stockpile medical countermeasures? In your

professional opinion, what impact do you think shifting to an annual appropriation will have on the biodefense enterprise?

Response: The Special Reserve Fund has resulted in HHS's creation of a robust development pipeline containing more than 80 medical countermeasure candidates for chemical, biological, radiological, and nuclear threats. This development has resulted in the delivery of 11 new medical countermeasures (MCMs) to the Strategic National Stockpile (accessible by Emergency Usage Authorization) and the FDA licensure of two of these MCMs.

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marketplace. Additionally, the PHEMCE Review recommended the establishment of a MCM Strategic Investor, an independent non-profit entity, which uses HHS funding to support capital investments in private companies with promising technologies. By providing critical capital in exchange for a strategic role in the management of these small firms, HHS is able to mitigate the financial and management risk that some small firms face, thereby increasing the probability of successful technologies and products.

Since the development and procurement of MCMs is an inherently risky endeavor, BARDA remains focused on keeping sufficient incentives in place for its industry partners. This effort includes an HHS intra-agency multi-year budgeting practice driven by the long-lead time necessary for MCM development and acquisition. Large pharmaceutical companies (e.g., Amgen, GlaxoSmithKline, etc.) are now joining the biodefense MCM sector, using long-range budget planning routinely as a good business management practice. Venture capital investors, which fund many small biotech companies in the biodefense sector, may choose to support biotech companies in a different sector that has a better benefit-to-risk profile than biodefense. These circumstances support the critical need to ensure a long-term funding commitment is maintained with annual appropriations in the future. Maintaining the progress that has been achieved in the recent years requires Congress' continued support for these future activities.

- 12) Please resubmit all the operation division tables included the HHS Congressional Justification (CJ) volumes with the FY 2013 post sequester operating plan column in lieu of the FY 2013 column in the CJ. Please also include a final adjustment column that shows all transfers and tap adjustments for FY 2013. It should also include a delta column between the FY 2014 request and final adjusted FY 2013 column. It should include all the mechanism tables and similar tables with revised and projected number of grants (new, continuations, etc.) to be supported in FY 2013.

Response: The FY 2013 figures in the FY 2014 Congressional Justifications represent the annualized funding levels provided by the Continuing Appropriations Act through March 27, 2013 (P.L. 112-175), and do not reflect the cuts required by sequestration. HHS provided notifications on the use of the Nonrecurring Expense Fund, the Prevention and Public Health Fund, and the Secretary's transfer authority, which adheres to the authority provided by Congress. HHS will provide revised FY 2013 operating plans that reflect sequestration, reprogramming, and use of the Secretary's transfer authority, and will continue to inform Congress of any additional transfer and reprogrammings as appropriate. Final FY 2013 amounts will be provided in the FY 2015 President's Budget.

- 13) I understand CMS and Medicare are ending the Health Quality Partners (HQP) that according to what some had told me reduces the hospitalizations by 33 percent and cut Medicare costs by 22 percent. Please explain how the HQP model of home visits by nurses to seniors on Medicare that reduces chronic health care costs through prevention and frequent proactive follow-up will be incorporated in the

Accountable Care Organizations (ACOs) or other specific aspects of changes to Medicare due to the implementation of ObamaCare? If the specific lessons of the HQPs are not being incorporated in the ObamaCare and the ACOs – please explain why and provide justification as to what other method was tested and deemed to be more costs effective than the HQP model.

Response:

CMS is continuing to evaluate the future of this program and will provide further updates as they become available. CMS is currently testing a variety of programs to enhance coordination of care, including the Affordable Care Act's Independence at Home demonstration. Home-based primary care allows health care providers to spend more time with their patients, perform assessments in a patient's home environment, and assume greater accountability for all aspects of the patient's care. This focus on timely and appropriate care is designed to improve overall quality of care and quality of life for patients served, while lowering health care costs by forestalling the need for care in institutional settings. The Independence at Home Demonstration will build on these existing benefits by providing chronically ill patients with a complete range of primary care services in the home setting. Medical practices led by physicians or nurse practitioners will provide primary care home visits tailored to the needs of beneficiaries with multiple chronic conditions and functional limitations. The Independence at Home Demonstration also will test whether home-based care can reduce the need for hospitalization, improve patient and caregiver satisfaction, and lead to better health and lower costs to Medicare.

14) The NIH budget request provides for random increases to most NIH institutes and centers. Please provide the criteria and decision matrix used by NIH to make the allocation of the requested increase for each NIH IC.

Response: NIH considered many factors in setting Institute and Center (IC) request levels for the FY 2014 President's Budget. The primary factors were the following:

- Since Congress had not yet taken action on FY 2013 appropriations when the Budget was formulated, many requests from the FY 2013 President's Budget were re-proposed for FY 2014. For example:
 - NIH again proposed to consolidate funding for the National Center for Biotechnology Information and the Public Access program in the National Library of Medicine, which had a minor impact on the budgets of every IC (see NIH Congressional Justification, Volume 1, page ST-4 for more specific details); and
 - NIH continued to seek implementation of those parts of the original plan for the National Center for Advancing Translational Sciences (NCATS) that were not possible at the FY 2012 funding level. This required additional funds in FY 2014 above the FY 2013 request for NCATS to support the Cures Acceleration Network and the Molecular Libraries program when it hits the ten-year mark and should transition out of the

Common Fund (making those amounts available for new Common Fund projects).

- The FY 2014 request reflects more substantial changes than prior years in the proposed AIDS portfolios of the Institutes and Centers, as funding has been shifted to high priority basic research that provides the underlying foundation for all HIV research; to research on developing vaccines and microbicides; and to research on new and innovative approaches toward a cure (see NIH Congressional Justification, Volume 1, page OAR-3 for more specific details).
- Additional resources are proposed for areas of exceptional scientific opportunity, such as the Alzheimer's disease research initiative, the Brain Research through Application of Innovative Neurotechnologies (BRAIN) initiative, **and the NIH Director's Early Independence Award Program in the Common Fund.**

15) Please provide an update on the activity CMS has undertaken to promote and use the IT Sandbox included in the FY 2012 bill and continued under the FY 2013 CR.

Response: In 2012, CMS funded a Data Enclave Pilot to examine, compare, and test different methods for allowing access into CMS' existing Chronic Conditions Data Warehouse (CCW). While CMS is committed to increasing access to Medicare program data to support innovative analytics, the pilot sought to identify how CMS could balance these priorities with the need to protect beneficiary privacy and to assure that protected health information is made available with appropriate safeguards. Based on lessons learned from the Data Enclave Pilot, CMS allocated two million dollars of the "sandbox" funding to purchase initial IT infrastructure and begin the development of required access control tools to fully operationalize a CMS Data Enclave.

Currently, CMS has completed installation of the initial infrastructure equipment to support approximately 200 Data Enclave users and is finalizing the development of tools for managing the environment and supporting the users. In addition, development of output review procedures and enclave access pricing models, as well as a systematic review of CMS's data access policies and procedures, is underway. CMS expects initial enclave functionality to be operational within the CCW by late Spring 2013.

While progress has been made in making program data accessible, CMS is concerned the rapidly increasing demand for its program data will quickly stress the capacity of the initial infrastructure. Further, CMS is considering the feasibility of using the initial Data Enclave infrastructure to test the viability of allowing commercial entities access to the agency's program data.

The development of a CMS Data Enclave supporting virtual access to enrollment and medical billing information for over 100 million of the country's most vulnerable patients is an important first step to achieving the agency's goal of providing transparency for its program operations. The Data Enclave also offers an environment where data

entrepreneurs can test and develop creative solutions to both improve the care that beneficiaries receive and inform CMS operations.

While CMS is taking steps to make its program data more accessible to outside users and researchers, it is concerned about the stress these increased demands will place on the infrastructure. As a result, CMS continues to make investments in its IT infrastructure, especially in the areas of data capacity and identity management. In FY 2012, CMS invested an additional three million dollars in two ongoing projects: the Integrated Data Repository (IDR) and Enterprise Identity and Access Management (EIAM). Both of these projects support the success of the sandbox. EIAM strengthens remote identity proofing for potential users of CMS's data. The IDR consolidates CMS' data in one place, ensures its integrity, quality, and consistency, and enables shared access with external business partners. Together the IDR and the CCW are CMS' enterprise data warehouse.

In FY13, CMS expects to spend five million dollars on the sandbox, building out the enclave infrastructure, enhancing data assets in the enclave, and developing a governing structure for users to access the sandbox.

- 16) Please provide a breakout of the ACA and non-ACA costs in the FY 2014 request, FY 2013 enacted, and FY 2012 actual for CMS Program Management. In addition, provide a table to show the total ACA costs and estimated costs by each HHS OpDiv for FY 2012, 2013 enacted, and 2014 requested.

Response:

CMS has implemented many parts of the Affordable Care Act from initial setup of the Federally-facilitated Marketplace (FFM) to establishing model programs under the Center for Medicare and Medicaid Innovation. ACA responsibilities are now a part of CMS' core mission and many of the activities are supported through CMS base operations; therefore, it is difficult to breakout all of our expenditures related to ACA. CMS is able to breakout the costs associated with CMS' Marketplace responsibilities. In FY 2011 and FY 2012, CMS spent \$118 million and \$304 million on Marketplace activities, respectively, from the \$1 Billion Implementation Fund, CMS Program Management, and the Secretary's Transfer. In FY 2013, CMS is planning to spend \$1.5 billion from Program Management, the Secretary's Transfer Authority, Non-Recurring Expenses Fund, the \$1 Billion Implementation Fund, and the Prevention Fund. In the FY 2014 President's Budget, CMS requested a total of \$2 billion for the Marketplace implementation, including \$1.5 billion in appropriated funds and \$450 million in user fees.

- 17) Lobbying Update: Please provide an update on procedures each OpDiv and HHS Office have in place to ensure no federal funds are used to support lobbying activities prohibited by law.

Response: The Department is committed to ensuring the proper use of federal funds and compliance with all applicable restrictions on lobbying, and has in place long-standing

Department-wide guidance to grantees, which has always prohibited lobbying at both the federal and state level. The Department has upheld this prohibition for years.

In April 2012, HHS revised the Department-wide guidance to reflect differences between the lobbying restriction provision in the FY 2012 Appropriations act and the analogous provision in prior years' acts. This updated guidance was provided to grantees via an Action Transmittal, which clearly communicated each of the policy requirements of the FY 2012 Appropriations provisions.

- 18) Please explain the resource allocation criteria and procedures used by the Secretary in making funding allocation decisions for FY 2013 for each of the following: Health Reform Implementation Fund; Transfer Authority; Prevention and Public Health Fund; and Nonrecurring Expense Fund that for each identifies any business case on the gives and takes from conflicting resource allocation decisions or related to transfer out of programs and accounts based on the FY 2013 projected allocation in the 2013 request or 2012 actual spending.

Response: The current fiscal environment required the Secretary to assess programmatic needs and available resources across an inventory of agencies and funding sources. In determining the funding allocations from the Health Reform Implementation Fund, Transfer Authority, Prevention and Public Health Fund, and Nonrecurring Expenses Fund, the Secretary incorporated several criteria, such as implementation timelines, current funding, and programmatic impact.

- 19) Please identify the management controls that are in-place and used by the Secretary on a routine basis to ensure federal funds support only the stated purposes authorized by law.

Response: HHS has the following controls to ensure that federal funds support only the stated purposes authorized by law:

Delegation of Disbursing Authority. The Secretary receives a delegation of disbursing authority from the U.S. Treasury as the Head of the Agency. The Secretary delegates this responsibility to the HHS Chief Financial Officer (CFO), who delegates to the HHS Deputy CFO. The Deputy CFO delegates this responsibility to each of the Operating Division (OPDIV) CFOs, who carry out administrative control of funds at each of the respective operating divisions and/or staff divisions. Each operating division administers its own funding as appropriated by Congress.

OMB Oversight. The Office of Management and Budget (OMB) under 31 USC 1513(b); Executive Order 11541 approves apportionments that can limit obligations that may be incurred to specified spending levels, time periods, programs, activities, and projects. OMB reviews and approves HHS apportionment requests.

Department Oversight. The Department reviews and submits apportionment requests to OMB in accordance with appropriated purposes and amounts. The Department also

submits quarterly status of funds report for each apportionment for OMB's review, as required by 31 U.S.C. 1511-1513.

OPDIV Oversight and Routine Monitoring. OPDIVs submit transactions to obligate funds in accordance with appropriated purposes and amounts. The transactions must be approved by the appropriate level of management, as well as the funds certification official, who is responsible for reviewing the obligation amount, checking that funding does not exceed the apportionment and allotment levels, and certifying availability of funds prior to obligation. Additionally, OPDIVs establish responsibility for spending at the organization level, and issue allotments of funds that cannot be exceeded. Routine monitoring of the status of funds occurs to ensure that obligations do not exceed the apportionment and allotment of funds.

Financial System Controls. HHS financial systems limit the obligation of funds to the apportionment and allotment levels. Appropriated amounts are entered by OPDIV budget staff into the HHS financial systems, which would reflect the upper limits that may be spent during the fiscal year. Operating divisions allot appropriations to specific organizations in accordance with spending authorized by the appropriation. The total allotments may not exceed the total appropriation available. Each allotment holder within each organization is responsible to monitor and limit spending in accordance with the allotment, and in total the OPDIV CFO is responsible to ensure that spending does not exceed the appropriation. These limitations are set by either financial system limitations where the system stops spending that would exceed the appropriation and/or allotment, or by manual compensating controls and management report reviews of status of funds.

- 20) A recent GAO study on CBRN and medical countermeasures in the SNS notes an increased need to emphasize needs of the pediatric population. Does the FY 2014 request for SNS fully allow HHS to address the concerns identified through the GAO report? If not, please identify what other actions are need and provide a time horizon for significant furtherance of these actions.

Response: As identified in the report, significant challenges exist in procuring sufficient quantities of pediatric MCMs, beyond budgetary limitations. Through the PHEMCE process, requirements for pediatric MCMs are identified for procurement and inclusion in the SNS where licensed products are commercially available. However, in most cases, issues preventing stockpiling of pediatric MCM include a lack of licensed products, barriers to pediatric licensing, limited supplies and high cost of existing licensed products, and storage and shelf life concerns for certain pediatric products.

As an example, the funding required to fulfill the entire requirement for oral suspension is cost prohibitive (requiring an additional \$1.3 billion beyond current maintenance and replacement costs). Even if this level of funding were available, fulfillment of this requirement could take several years, because production is limited. Outside of the SNS, additional pediatric studies could provide more information about how to readily use existing MCMs safely in the pediatric and obstetric populations.

21) The 2014 NIH request includes an allocation of additional resources in a disproportional manner that was noted by NIH as being related to strategic choices. Please provide the detailed criteria and resource allocation method used to make the NIH Institutes and Centers (IC) funding allocation. Plus, for each of the initiative listed in the NIH Overview volume. For each initiative, please provide the total funding in FY 2012, 2013, 2014, and relevant out year estimates for each that breakouts out by year the funding for each IC. Plus, for each initiative, identify the performance measure for each for FY 2013, 2014, and the long-term target.

Response: NIH considered many factors in setting Institute and Center (IC) request levels for the FY 2014 President's Budget. The primary factors were the following:

- Since Congress had not yet taken action on FY 2013 appropriations when the Budget was formulated, many requests from the FY 2013 President's Budget were re-proposed for FY 2014. For example:
 - NIH again proposed to consolidate funding for the National Center for Biotechnology Information and the Public Access program in the National Library of Medicine, which had a minor impact on the budgets of every IC (see NIH Congressional Justification, Volume 1, page ST-4 for more specific details); and
 - NIH continued to seek implementation of those parts of the original plan for the National Center for Advancing Translational Sciences (NCATS) that were not possible at the FY 2012 funding level. This required additional funds in FY 2014 above the FY 2013 request for NCATS to support the Cures Acceleration Network and the Molecular Libraries program when it hits the ten-year mark and should transition out of the Common Fund (making those amounts available for new Common Fund projects).
- The FY 2014 request reflects more substantial changes than prior years in the proposed AIDS portfolios of the Institutes and Centers, as funding has been shifted to high priority basic research that provide the underlying foundation for all HIV research; research on developing vaccines and microbicides; and research on new and innovative approaches toward a cure (see NIH Congressional Justification, Volume 1, page OAR-3 for more specific details).
- Additional resources are proposed for areas of exceptional scientific opportunity, such as the Alzheimer's disease research initiative, the Brain Research through Application of Innovative Neurotechnologies (BRAIN) initiative, and the NIH Director's Early Independence Award Program in the Common Fund.

Outyear estimates for initiatives are not available at this time. Performance measures for initiatives are under development.

IC-specific Funding for Overview Volume Initiatives
(Dollars in millions)

Initiative	FY 2012	FY 2013	FY 2014
<u>BRAIN:</u>			40.0
Blueprint for Neuroscience Research			10.0
OD			10.0
NINDS			7.5
NIMH			7.5
NIDA			4.0
NIBIB			1.0
<u>Big Data to Knowledge (BD2K):</u>			
Common Fund		0.8	40.9
OD		21.1	1.1
<u>Diversity:</u>			
Common Fund		3.8	32.3
OD			1.2
<u>Biomedical Research Workforce:</u>			
Common Fund		3.8	6.9
OD			1.4
<u>Alzheimer's Disease Initiative* :</u>			
NIA	7.8		80.0
OD	2.0	40.0	
NHGRI	25.0		

*Also includes NIH-wide funding of \$20.8 million in FY 2012, for a total of \$55.6 million.

22) The 2014 CDC request overview section identifies a list called "Increased Program Investments" as strategic choices. Please provide the detailed criteria and resource allocation method used by CDC to select these investment recommendations for Congress to consider. Plus, for each Increased Program Investments listed provide the total funding in FY 2012, 2013, 2014, and relevant out year estimates for each that breakouts out by year the funding and performance measure for the same years (to include the long-term target of each). Plus identify the specific justification and expected change in performance measures for all the activities listed in the section "Program Decreases and Eliminations."

Response: CDC works throughout the year with its Centers and Institutes and Offices, HHS and OMB to consider how best to prioritize investment recommendations for

Congress to consider. In 2010, CDC established a small number of priority areas referred to as “winnable battles” – chosen because:

- Each area is a leading cause of illness, injury, disability, or death and/or represents enormous societal costs;
- Evidence-based, scalable interventions already exist and can be broadly implemented; and
- CDC’s efforts can result in significant health improvements within 5 years.

Over the past few years, CDC’s budget request and resource decisions have aligned to and supported these key areas of food safety and the prevention of healthcare acquired infections, tobacco use, and HIV.

Increased Program Investments	Funding (comparable to FY14)		
	FY 2012	FY 2013	FY 2014 PB

Protecting Americans from Infectious Diseases

Vaccines for Children	\$4,005,941	\$3,607,256	\$4,293,383
Advanced Molecular Detection and Response to Infectious Disease	--	--	\$40,000
Food Safety	\$32,618	\$32,826	\$49,223
Domestic HIV/AIDS Prevention and Research	\$822,633	\$827,667	\$836,124
National Healthcare Safety Network	\$19,071	\$19,192	\$31,562

Ensuring Global Disease Protection

Polio Eradication	\$115,904	\$116,644	\$131,053
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Preventing the Leading Causes of Disease, Disability, and Death

National Violent Death Reporting System	\$3,570	\$3,592	\$23,570
Tobacco	\$198,523	\$116,262	\$212,360
Gun Violence Prevention Research	--	--	\$10,000
Million Hearts™	--	--	\$5,000
Rape Prevention and Education	\$41,709	\$41,974	\$46,729

Monitoring Health

Health Statistics	\$159,062	\$160,036	\$181,475
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Keeping Americans Safe from Environmental and Work-related Hazards

World Trade Center Health Program	\$187,560	\$239,230	\$241,000
Healthy Homes/Lead Poisoning Prevention	\$2,520	\$2,536	\$4,988

Program Decreases and Eliminations	Funding (comparable to FY14)		
	FY 2012	FY 2013	FY 2014 PB
Community Transformation Grants	\$226,000	--	\$146,340
Preventive Health and Health Services Block Grant	\$79,545	\$80,055	\$0
Immunization	\$642,215	\$455,102	\$580,959
Occupational Safety and Health	\$325,281	\$327,327	\$271,911

Racial and Ethnic Approaches to Community Health	\$53,940	\$14,029	--
Strategic National Stockpile	\$548,468	\$521,786	\$510,278
Breast and Cervical Cancer and Colorectal Screening	\$263,737	\$258,665	\$258,724
Buildings and Facilities	\$24,946	\$25,106	\$14,591
Workplace Wellness	\$10,000	--	--
State and Local Preparedness and Response Capability	\$666,245	\$670,513	\$658,026
Environmental Health Tracking Network	\$35,000	--	\$29,000
Hospitals Promoting Breastfeeding	\$7,050	--	\$2,500
Prevention Research Centers	\$28,912	\$19,033	\$25,041

Note: The FY 2013 funding levels represent that amounts displayed in the FY 2014 President's Budget as final FY 2013 funding levels were not yet available as of the date of the hearing. These amounts do not include allocations from the Prevention and Public Health Fund.

Program decreases and eliminations

Decreases and eliminations described in this section represent overall program level decreases for CDC, as compared to the FY 2012 level, including budget authority, PHS Evaluation funds, and resources from the Public Health and Social Services Emergency Fund and the Prevention and Public Health Fund.

Community Transformation Grants (-\$80 million)

The FY 2014 budget request includes a decrease of \$80 million for Community Transformation Grants (CTG). These resources were associated with the small communities component of the CTG program, which was fully funded in FY 2012, thus continuation of these resources are not needed in FY 2014. CTG activities in these small communities may request to continue activities into FY 2015 if their funding allows. In FY 2014, the CTG program will continue to amplify efforts to promote healthy behaviors that control healthcare costs.

Preventive Health and Health Services Block Grant (-\$80 million)

The FY 2014 budget request reflects the elimination of the Preventive Health and Health Services Block Grant program. These activities may be more effectively and efficiently implemented through the Chronic Disease Prevention and Health Promotion Program's combined Funding Opportunity Announcement, which provides the ability for states to coordinate activities across several related categorical funding streams. Resources to state health departments from PPHF investments may also help meet these needs. Elimination of this program provides an opportunity to find savings while expanding core public health activities and for other CDC priorities such as food safety and the reduction of healthcare-acquired infections.

Immunization (-\$61 million)

The FY 2014 budget request includes a decrease of \$61 million for the Section 317 immunization program. Health insurance expansion will further increase access to immunizations and decrease the number of uninsured and underinsured individuals in need of Section 317 vaccine for routine immunizations. Since September 2010, new

health plans have been required to cover Advisory Committee on Immunization Practices recommended vaccines without charging a deductible, copayment, or coinsurance when administered by an in-network provider. This reduction aligns with CDC's new policy implemented in 2012 to only fund vaccine purchased for routine vaccination of uninsured individuals and for response to outbreaks and other urgent public health vaccine needs.

The FY 2014 budget request will continue to provide for critical immunization program operations, including \$25 million for implementing billing systems for immunization services at public health clinics to sustain high levels of vaccine coverage, and support for the scientific evidence base informing immunization policies, and critical vaccine purchase for uninsured individuals and outbreak response.

Occupational Safety and Health (-\$54 million)

The FY 2014 budget request includes a decrease of \$54 million for Occupational Safety and Health, which reflects elimination of the Education and Research Centers, and the Agriculture, Forestry, and Fishing sector of the National Occupational Research Agenda. While these programs have made positive accomplishments in advancing workplace safety and health, they have been proposed for elimination in a limited-resource environment.

Racial and Ethnic Approaches to Community Health (-\$54 million)

The FY 2014 budget request eliminates funding for the Racial and Ethnic Approaches to Community Health (REACH) program. The Community Transformation Grants (CTG) program, which builds on past program successes and lessons learned, marks the next stage of CDC's community-based programs. The CTG program integrates best practices and lessons learned from the REACH program into its approach, amplifying the dissemination of these best practices and lessons learned to communities across the nation.

Strategic National Stockpile (-\$38 million)

The FY 2014 budget request includes a decrease of \$38 million for the Strategic National Stockpile, including elimination of \$30 million in one-time PHSSEF funding for pandemic influenza. The reduction will be implemented by not replacing expiring items that rank lower on formulary priorities, based on an annual review of the SNS.

Breast and Cervical Cancer and Colorectal Screening (-\$42 million)

The FY 2014 budget request includes a decrease of \$42 million for the National Breast and Cervical Cancer, Early Detection Program, and Colorectal Cancer Screening Program, including elimination of one-time PPHF investment of \$10 million in FY 2012. As the Affordable Care Act (ACA) increases access to cancer screening services beginning in 2014, the public health need to provide these clinical services will be diminished. The ACA will increase access to cancer screening services for many low-income, underserved women through expanded insurance coverage, similar to the populations covered by CDC's National Breast and Cervical Cancer Early Detection Program. Through the ACA, most health plans are required to cover recommended preventive services, including mammograms and other cancer screenings, without co-pays or deductibles. The law also requires new health plans to cover prevention counseling for women who are at a greater risk for breast cancer and, starting in 2014, it

ensures that no one can be denied health insurance because of a pre-existing condition. The Budget directs limited public health resources to other CDC priorities such as reducing tobacco use, healthcare-associated infections and food safety and reduces funding for direct screenings such as breast, cervical and colorectal screening that are already covered by insurance.

Buildings and Facilities (-\$10 million)

The FY 2014 budget request includes a decrease of \$10 million, which will support all critical repairs and improvements through a combination of proposed budget authority and carryover balances. The FY 2014 request will support the sustainment of the repairs and improvement (R&I) program to ensure continued condition improvement and reduction of deferred maintenance for CDC assets. R&I projects funded in existing owned facilities will be sufficient to maintain CDC's portfolio Condition Index at 90 or higher for laboratory, laboratory support, and critical infrastructure assets, and fund additional critical program-requested R&I projects.

Workplace Wellness (-\$10 million)

The FY 2014 budget eliminates the Workplace Wellness program, which received \$10 million in PPHF funding in FY 2012. These programs were of limited duration and will have completed their work in FY 2014. CDC will integrate lessons learned from these projects into on-going chronic disease prevention programs.

State and Local Preparedness and Response Capability (-\$8 million)

The FY 2014 budget request includes a decrease of \$8 million for State and Local Preparedness and Response Capability. The decrease would reduce the amount of funding awarded to state and local health departments through the Public Health Emergency Preparedness and Cities Readiness Initiative programs.

Environmental Health Tracking Network (-\$6 million)

The FY 2014 budget request includes a decrease of \$6 million for the National Environmental Health Tracking Network. At the requested level, CDC will reduce the amount of funding to states and eliminate technical assistance to other health agencies. The number of public health actions undertaken using Tracking Network data will increase from 15 to 16 with CDC's focus on capacity building for existing grants, but CDC expects health departments to use Tracking Network data for less public health actions than in FY 2012.

Hospitals Promoting Breastfeeding (-\$5 million)

The FY 2014 budget request includes a decrease of \$5 million for the hospitals promoting breastfeeding program. The three-year, \$6 million Hospital Collaboratives grant will come to an end in 2013. With \$3 million proposed in FY 2014, CDC plans to support a new funding opportunity to provide decentralized technical assistance through multiple organizations to assist hospitals in improving maternity care practices in their locale. This decentralized model will focus on overcoming local, state, and regional barriers to breastfeeding and will capitalize on local knowledge, experiences, and challenges in a way that cannot be accomplished by a single national entity. CDC also continues to

support breastfeeding as a strategy to reduce obesity and funds activities proven to increase breastfeeding through the Combined FOA and CTG grants.

Prevention Research Centers (-\$4 million)

The FY 2014 budget request includes a decrease of \$4 million for the prevention research centers. CDC will implement this decrease by streamlining prevention research efforts through the Prevention Research Center program's Comprehensive Centers.

Below are performance measures associated with applicable programs proposed for elimination in the FY 2014 President's Budget. CDC does not require long-term targets for these measures. Not all of the programs proposed for elimination had performance measures in CDC's budget prior to proposed elimination.

Preparedness and Emergency Response Learning Centers and Research Centers

Measure	Most Recent Result	FY 2012 Target	FY 2013 Target	FY 2014 Target
13.A: Academic Centers for Public Health Preparedness (CPHP) and Emergency Response Research Centers	FY 2008: 27	0	0	N/A – performance measure removed

National Occupational Research Agenda Agricultural, Forestry and Fishing Sector (NORA)

Measure	Most Recent Result	FY 2012 Target	FY 2013 Target	FY 2014 Target
9.1.1: Increase the effectiveness of the implementation of the recommendations from the National Academies reviews (Outcome)	FY 2010: Develop implementation plans in response to National Academies recommendations (Target Met)	50% of the [8] evaluated CDC NIOSH programs will receive a score of 2 out of 5 or better, and 50% of these will receive a score of 4 out of 5 or better based on an external review of their progress implementing recommendations from their National Academies reviews	N/A – Data is only available biennially. Therefore, there is no FY 2013 target	100% of the [7] evaluated CDC NIOSH programs will receive a score of 4 out of 5 or better based on an external review of their progress implementing recommendations from their National Academies reviews

Education and Research Centers

Measure	Most Recent Result	FY 2012 Target	FY 2013 Target	FY 2014 Target
9.2.1: Increase the percentage of CDC NIOSH-trained professionals who enter the field of occupational safety and health after graduation	FY 2011: 81.3%	80%	80%	N/A – performance measure removed

9.C: Estimated academic graduates (Output)	FY 2011: 470	460	205	N/A – performance measure removed
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23) Please explain how CDC expects to protect its work in underground mine safety as it has closed its underground testing facility and does not have any specific plans in the FY 2014 request to re-establish this activity. Plus, provide a revised timeline on when the capability will be re-established.

Response: CDC is moving forward to identify potential replacement sites for the mine safety research facility. CDC has finalized program requirements for a replacement facility, and is conducting initial searches to identify existing properties or potential sites that meet the criteria on which to procure or construct a replacement facility. CDC will provide an update to Congressional staff once the initial assessment is complete.

24) **Head Start**

The Department claimed that approximately 70,000 children would be unable to enter Head Start programs as a result of the sequester cuts. In spite of the fiscal constraints reportedly imposed upon the program, several thousand Head Start program directors attended a conference at the National Harbor. To what extent does Head Start Federal funding support such conferences? If Federal funding did in fact fund the conference, please provide a breakout of the total costs and number of participants, to include the cost per attendee.

Response: First, as you are no doubt aware, the Head Start Act requires that any funding reductions be applied proportionately across Head Start activities, including services as well as training, research, and monitoring. As a result, my department cannot choose to make deeper reductions in training activities to limit reductions in funding for Head Start services.

As I think you will agree, we need to maintain high quality services during this period of reduced funding. A critical element of providing high quality services is participating in training opportunities, like the Office of Head Start Birth to Five Leadership Institute you reference in your question.

The Leadership Institute was planned and approved in 2012, and provided training on essential skills that grantees need to meet requirements for program outcomes and continuous improvement. Approximately 2,800 individuals attended the Leadership Institute, and the total cost to HHS was \$861,259. Grantees can utilize their Head Start training and technical assistance funding to attend trainings like the Leadership Institute to improve the quality of services provided. Given fiscal constraints, the Office of Head Start reduced the length of the Leadership Institute this year by one and a half days to reduce costs.

25) The budget request does not address how any safe guards are being contemplated or how this protection can be guaranteed within an initiative to that purports to combine a significant number of large complex datasets that are referred to as NIH "Big Data." Prior to moving down this road, it is imperative that personal protections, health information, and privacy security aspects need to be addressed. Please explain what safe guards and protections are being expected to be put in place to ensure the information to be housed within the NIH proposed Big Data initiative will fully protect all the genomic and personal data of the research subjects to ensure no one or organization can use genetic coding or finger prints to circumvent the de-identification of the subjects or their family members? Please provide any privacy analysis that was conducted prior to proposing this initiative. Plus, what are the long-term cost of this project, the projected funding costs as data continues to build, and who will own/operate/be responsible for the data in this initiative.

Response: NIH has a longstanding legislative mandate and commitment to the dissemination of results of research. The Big Data to Knowledge (BD2K) initiative, which focuses on the extraordinary advances in informatics and computational biology, is an extension of this commitment. Biomedical researchers are increasingly generating and using large, complex, and diverse data sets, and biomedical research is becoming increasingly data-intensive. In the conduct of research involving human subjects and human subject's data, NIH investigators follow longstanding ethical principles of autonomy, beneficence, and justice and adhere to regulations and policies that are in place to protect research participants through requirements, such as seeking informed consent and safeguarding privacy and confidentiality. The BD2K Initiative and the efforts within it will be part of this existing framework of protections.

The BD2K Initiative, which was launched in December 2012, is focusing on addressing the many practical challenges that must be overcome to capitalize on the exponential growth of biomedical research data, such as genomic, imaging, and electronic health record data, and to enable the biomedical research enterprise to maximize the value of biomedical data. BD2K will address these issues by supporting new approaches, standards, methods, tools, software, and training to enable the collection, management, integration, and dissemination of Big Data. As its work progresses, it will certainly also be identifying where additional security measures and protections may be needed for data storage and sharing. For example, BD2K is organizing a conference on "Enabling Research Use of Clinical Data," which will help identify steps NIH can take to enhance the ability of biomedical researchers to make use of clinical data, and will include a discussion of approaches to protecting privacy of patients and confidentiality of data. It is important to clarify that while the BD2K initiative will help advance the development of innovative, transforming approaches and tools for biomedical data, it is not intended, per se, to develop databases for big data at NIH.

At the same time, and along with the BD2K initiative, NIH may determine that certain scientific data are of such value that broad sharing through a centralized repository is warranted. When these determinations are made, NIH assesses the need for additional

policies to enable and facilitate maximal data sharing while protecting participant privacy and confidentiality. For example, in 2007, to help accelerate research on the role of genetic factors in common diseases, NIH issued the NIH Policy for Sharing of Data Obtained in Genome-Wide Association Studies (GWAS). The GWAS policy established a controlled-access repository, called the database of Genotypes and Phenotypes (dbGaP), and procedures for ensuring that de-identified genomic data are shared only for research consistent with the original informed consent, and established security standards for storing and transferring the data. The data submitted to the repository must be de-identified according to both HHS regulations governing the protection of human subjects (45 CFR 46) as well as the HIPAA Privacy Rule (45 CFR 160 and 164). The policy also requires researchers who are granted access to the data to adhere to a code of conduct (https://dbgap.ncbi.nlm.nih.gov/aa/GWAS_Code_of_Conduct.html) that prohibits attempts to re-identify participants from the genomic data; to share the data with others; to use the data for purposes beyond the approved research use. As a further protection for data submitters and secondary users, Certificates of Confidentiality, which enable holders to resist compelled disclosure of data, have been issued to investigators and to the database. There are now more than 2600 data sets in dbGaP from over 500,000 research participants, and more than 10,000 requests for data have been approved for secondary use, resulting in almost 1,000 publications. Most importantly, this tremendous level of data sharing and secondary use has occurred without a single violation of participant privacy.

Another model of data sharing is open-access sharing (e.g., posting data on the internet), which can pose greater risks of re-identification and misuse than sharing through controlled-access databases. These risks were considered theoretical until early this year when a group of informatics experts demonstrated that they were able to identify human research participants by collating and analyzing data available from publicly available data sources.¹ Sharing data in open access has many scientific benefits, but it is critically important to convey to research participants who agree to allow their data to be in open access repositories that privacy cannot be guaranteed and that while certain laws exist to prevent genomic data from being used to make health insurance or employment decisions, there are gaps to be addressed.

NIH's stewardship responsibilities in this area are critically important, and whether stored centrally at NIH or at the institutional level, biomedical data involving human research participants is subject to Federal requirements and agency policies that help ensure its protection and appropriate use. With regard to the project costs, in the short term, NIH plans to invest at least \$40 million in the BD2K program in FY 2014 through the Common Fund. Outyear costs will depend on the availability of funds at the time.

There are long-term costs, including the stewardship costs, associated with facilitating the collection, management, integration, and dissemination of basic and clinical data on a large scale. However, given how integral big data is becoming to the research enterprise and to the way 21st century science is conducted, the costs are justifiable and the returns on the investment will be immeasurable in terms of accelerating our understanding of

¹ M. Gymrek, A. L. McGuire, D. Golan, E. Halperin, Y. Erlich, *Science* 339, 321 (2013).

disease and enabling the development of new approaches to diagnosis, treatment and prevention.

- 26) During the doubling of NIH, NCI announced a goal of reducing cancer to a chronic disease by 2015. Please provide an update on the progress toward this lofty goal that includes the status of the original performance measures and the total amount of funding invested toward this end since 2003. Further, we understand NCI may have adjusted the goal over time, if so, please explain the current approach and targets used to measure progress towards its revised goal and the total investment in cancer research since 2003.

Response: In 2003, then-NCI Director Andrew von Eschenbach announced that the NCI intended “to eliminate suffering and death due to cancer by 2015” ([NCI Goal Aims for Cancer Victory by 2015](#), Science Magazine, 28 February 2003). In speaking about the goal during that period, Dr. von Eschenbach noted that although he was not saying that we could eliminate cancer, he did want to turn cancers into manageable, chronic, non-lethal diseases (thus eliminating the suffering and death due to cancer), and observed that some movement in that direction had been occurring for some important cancers over many years. This 2015 goal was aspirational; it was not accompanied by performance measures. It is my understanding that many members of the cancer research community were skeptical about the likelihood of meeting these aspirations and were concerned about predicting outcomes that could not be met. The two subsequent NCI Directors have not embraced the 2015 timetable for this goal, and it has not been considered part of NCI’s specific research objectives for many years.

Of course, the NCI remains committed to using its funds, personnel, and research activities to reduce the incidence, morbidity, and mortality of every kind of cancer as rapidly as possible. It does this by supporting a wide range of research that includes basic studies of the genetics and biology of normal and cancerous cells as well as the causes of cancer; behavioral and population-based research that examines the many risk factors for cancer; studies that produce and improve tools for cancer screening, diagnosis, monitoring, and therapy; and work on cancer prevention, symptoms, outcomes, and survivorship. In each of these and all other areas of research, the NCI calls upon external and internal advisors to develop plans for building an appropriate research infrastructure, for building an investigative plan, for funding the research activities, and for monitoring progress. Prominent examples of these initiatives in recent years include: The Cancer Genome Atlas, a program to characterize several hundred samples from each of about 20 major cancer types by DNA sequencing and other molecular methods; the reorganization and strengthening of the NCI Cooperative Groups that conduct clinical trials of new therapies and diagnostic procedures; and the Lung Cancer Screening Trial that recently demonstrated the value of helical CT scanning of elderly smokers for evidence of lung cancer.

In addition to monitoring progress during each specific project, the NCI (in collaboration with the Centers for Disease Control and Prevention, the American Cancer Society, and several state and regional cancer registries) follows trends in the incidence and mortality

of many different types of cancers and publishes these data annually in The Report to the Nation. In this way, the NCI and its partners have shown that our efforts have helped to achieve, on average, a persistent annual reduction, for both men and women, in age-adjusted cancer mortality rates of between 1 and 2 percent for more than 10 years (Annual Report to the Nation on the Status of Cancer, 1975-2009, *J Natl Cancer Inst.*, 7 January 2013). But these reports also reveal significant variations among cancers with respect to incidence and mortality—differences that are often related to gender and ethnicity and affect the design of future research plans.

Since 2003, NCI's appropriated budget was, in the aggregate, \$48.7 billion (FY2003–FY2012), with another \$1.3 billion awarded via the American Recovery and Reinvestment Act of 2009.

- 27) The HIV/AIDS epidemic occurred over 25 years ago and since then the efforts, imparted by bio-medical research, have transformed the diagnosis from an acute deadly condition to a more longer-term chronic condition. The NIH has for years implemented an AIDS/Non-AIDS resource allocation method that appears to have remained fairly constant as the scientific knowledge has increased dramatically. When was the last evaluation of the NIH AIDS/Non-AIDS overall resource allocation method completed? Plus, how often and what criteria is used in the resource allocation evaluation to review the directed resources allocations for specific disease categories like AIDS and Non-AIDS (i.e., Cancer, Heart Disease, Mental Health, and others diseases).

Response: The NIH Revitalization Act of 1993 provided OAR with legislative authorities to plan, coordinate, and evaluate AIDS research; to set trans-NIH scientific priorities; and to determine the budgets for all NIH Institute and Center AIDS research. OAR has established comprehensive trans-NIH planning, portfolio analysis, and budgeting processes to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently.

Each year, as required by the law, OAR develops the *Trans-NIH Plan for HIV-Related Research* (<http://www.oar.nih.gov/strategicplan/>). The Plan is developed in collaboration with scientists from NIH, other government agencies, and non-governmental organizations, as well as community representatives. The planning process reviews the state of the science, assesses newly emerged and critical public health needs, and identifies scientific opportunities and priorities. The legislative authorities require OAR to allocate all appropriated NIH AIDS research funds to the ICs according to the *Trans-NIH Plan for HIV-Related Research*. Thus, the strategic Plan serves as the framework for developing the annual AIDS research budget for each IC; for determining the use of AIDS-designated dollars; and for tracking and monitoring all NIH AIDS research expenditures.

Every year, the OAR Director and NIH Director together determine the total amount to be allocated for AIDS-related research within the overall NIH budget. Within that total,

OAR then develops each IC's allocation for AIDS-related research. The careful determination of the balance of the research budget – among Institutes, among areas of science, between AIDS and non-AIDS research, between intramural and extramural research programs, between basic and clinical research, and between investigator-initiated and targeted research – requires a comprehensive knowledge of the science and of the Institute portfolios. Dollars are allocated to the ICs based not on a formula, but on the priorities of the Plan, scientific opportunities, and the IC's capacity to absorb and expend resources for the most meritorious science. This process reduces redundancy, promotes harmonization, and assures cross-Institute collaboration.

The investment in AIDS research has produced groundbreaking scientific advances. AIDS research also is helping to unravel the mysteries surrounding many other cardiovascular, malignant, neurologic, autoimmune, metabolic, and infectious diseases as well as the complex issues of aging and dementia. Despite these advances, however, AIDS is not over and serious challenges lie ahead. The HIV/AIDS pandemic will remain a very serious public health crisis until better, more effective, and affordable prevention and treatment regimens are developed and universally available, including a vaccine and, eventually, a cure.

28) Provide a table that displays FY 2011, FY 2012, FY 2013 President's Budget, FY 2013 final, and FY 2014 President's Budget funding for ACA implementation by detailed activity and funding source. For each activity, provide a narrative explanation of the mechanism by which funds will be expended, such as grants, contracts, internal operations, and FTE's.

Response: CMS has implemented many parts of the Affordable Care Act from initial setup of the Federally-facilitated Marketplace (FFM) to establishing model programs under the Centers for Medicare and Medicaid Innovation. ACA responsibilities are now a part of CMS' core mission and many of the activities are supported through our base operations; therefore, it is difficult to breakout all of our expenditures related to ACA. CMS is able to breakout the costs associated with CMS' Marketplace responsibilities. In FY 2011 and FY 2012, CMS spent \$118 million and \$304 million on Marketplace activities, respectively, from the Health Insurance Reform Implementation Fund (HIRIF), CMS Program Management, and the Secretary's Transfer. In FY 2013, CMS is planning to spend \$1.5 billion from Program Management, the Secretary's Transfer Authority, Non-Recurring Expenses Fund, HIRIF, and the Prevention Fund. In the FY 2014 President's Budget, CMS requested a total of \$2 billion for the Marketplace implementation. That includes \$1.5 billion in appropriated funds and \$450 million in user fees.

The various sources of funding are applied to resource needs as follows:

- Program Management: Contracts, FTE
- HIRIF: Contracts, FTE
- Secretary's Transfer Authority: Contracts
- Prevention and Public Health Fund: Contracts, Grants
- Non-recurring Expenses Fund: Contracts
- Marketplace User Fees: Contracts, Grants

CMS looks forward to working with the committee to provide more detailed information.

29) For each activity for which the Prevention and Public Health Fund will be used to fund CMS implementation of the Affordable Care Act, provide the legal interpretation of how section 4002 of the Affordable Care Act which authorizes the Prevention and Public Health Fund allows for such use of funds.

Response: The purpose of the Prevention and Public Health Fund is to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs. In FY 2013 CMS will invest resources from the Prevention Fund to assist Americans in gaining affordable health care coverage which aligns with the purpose of the funds which may be used for prevention, wellness, and public health activities. Specific activities will include consumer engagement and education, eligibility support including support for appeals, assistance with enrollment, and the Navigator program to help individuals understand options available and enroll in health insurance. Implementing the Health Insurance Marketplace is the Administration's top public health activity which has large potential to improve prevention in the next year by enabling individuals to enroll in coverage through private health insurance. Increasing access to care and in particular preventive services is a component of our national efforts to restrain the cost of health care and ensure more Americans can lead healthy lives, which is a key intent of the Prevention Fund.

30) Provide a table that displays Prevention and Public Health Funding by operating division and activity for FY 2010 final, FY 2011 final, FY 2012 final, FY 2013 President's Budget, FY 2013-final, and FY 2014 President's Budget.

Response: The information requested is provided in the table below.

Prevention and Public Health Fund

(dollars in millions)

	FY 2010	FY 2011	FY 2012	FY 2013		FY 2014
	Final	Final	Final	President's Budget	Final	President's Budget
ACL						
Chronic Disease Self-Management Program.....	--	--	10,000	10,000	7,086	10,000
Alzheimer's Disease Prevention Education and Outreach.....	--	--	4,000	--	0.150	14,700
Elder Justice.....	--	--	6,000	--	2,000	--
ACL Subtotal.....	--	--	20,000	10,000	9,236	24,700
AHRQ						
Healthy Weight Practice-Based Research Networks.....	0.500	--	--	--	--	--
Clinical Preventive Services Research.....	5,000	5,000	5,000	5,000	--	--
Clinical Preventive Services Task Force.....	--	7,000	7,000	7,000	6,465	--
AHRQ Subtotal.....	5,500	12,000	12,000	12,000	6,465	--
CDC						
Community Guide / Community Preventive Services Task Force.....	5,000	7,000	10,000	10,000	7,378	10,000
Prevention Research Centers.....	--	10,000	10,000	--	6,456	--
Public Health Research.....	--	20,000	--	--	--	--
Prevention Education and Outreach.....	--	2,000	--	--	--	--
Coordinated Chronic Disease Prevention Program.....	--	41,700	--	--	--	--
Nutrition, Physical Activity, and Obesity Activities.....	--	10,000	10,000	--	8,823	--
Diabetes Prevention Program.....	--	--	10,000	--	--	--
HIV/AIDS.....	30,367	--	--	--	--	--
Viral Hepatitis.....	--	--	10,000	--	--	--
Public Health Workforce.....	7,500	25,000	25,000	25,000	15,609	25,000
National Public Health Improvement Initiative.....	50,000	40,200	40,200	40,200	21,663	40,200
Laboratory Efficiency Initiative.....	--	--	--	20,000	--	--
Healthcare-Associated Infections.....	--	11,750	11,750	11,750	11,750	11,750
Epidemiology and Laboratory Capacity Grants.....	20,000	40,000	40,000	40,000	32,424	40,000
Promoting Breastfeeding.....	--	--	7,050	2,500	2,500	2,500
Let's Move Activities/Healthy Weight Task Force Obesity Activities.....	--	--	5,000	4,000	4,000	4,000
Community Transformation Grant Program.....	--	146,340	226,000	146,340	146,340	136,340
ARRA: Putting Communities to Work.....	44,433	--	--	--	--	--
Section 317 Immunization Program.....	--	100,000	190,000	72,460	90,883	72,460
Racial & Ethnic Approaches to Community Health (REACH).....	--	25,000	40,000	--	--	--
Tobacco Prevention (Media and Outlines).....	14,500	50,000	83,000	89,000	60,302	95,000
Healthcare Surveillance and Statistics.....	19,858	30,000	35,000	35,000	28,514	35,000
Environmental Public Health Tracking.....	--	35,000	35,000	29,000	20,740	29,000
National Prevention Strategy.....	0.142	1,000	1,000	1,000	0.922	1,000
Promoting Obesity Prevention in Early Childhood Programs.....	--	0.660	--	--	--	--
National Youth Fitness Survey.....	--	6,000	--	--	--	--
Workplace Wellness.....	--	9,250	10,000	4,000	--	--
Birth Defects and Developmental Disabilities.....	--	--	--	107,089	--	74,796
Cancer Prevention and Control.....	--	--	10,000	260,871	--	173,064
Million Hearts Program.....	--	--	--	5,000	4,612	5,000
CDC Subtotal.....	191,800	610,900	809,000	903,210	462,916	755,110
HRSA						
Public Health Workforce Development.....	14,829	20,000	25,000	10,000	--	4,776
Mental Health Training.....	--	--	10,000	--	--	--
Alzheimer's Disease Prevention Education and Outreach.....	--	--	2,000	--	1,847	5,300
HRSA Healthy Weight Collaborative and Activities.....	5,000	--	--	--	--	--
Primary Care Residencies and Physician Assistant Training.....	198,122	--	--	--	--	--
Traineeships for Nurse Practitioner Students.....	31,431	--	--	--	--	--
State Health Workforce Development Grants for Primary Care.....	5,750	--	--	--	--	--
Nurse Managed Care Centers.....	15,268	--	--	--	--	--
Nutrition, Physical Activity, and Screen Time Standards.....	0.255	--	--	--	--	--
Poison Control Centers.....	--	--	--	--	--	18,830
Universal Newborn Screening.....	--	--	--	--	--	18,660
Newborn Screening for Heritable Disorders.....	--	--	--	--	--	9,834
HRSA Subtotal.....	270,655	20,000	37,000	10,000	1,847	57,400

SAMHSA						
Tribal Prevention Grants.....	--	--	--	40,000	--	--
Primary & Behavioral Health Integration.....	20,000	35,000	35,000	28,000	--	28,000
Suicide Prevention.....	--	10,000	10,000	--	--	--
Screening, Brief Intervention and Referral to Treatment.....	--	25,000	25,000	30,000	--	30,000
SAMHSA Healthcare Surveillance.....	--	18,000	18,000	--	14,733	--
Prescription Drug Overdose.....	--	--	4,000	7,000	--	--
SAMHSA Subtotal.....	20,000	88,000	92,000	105,000	14,733	58,000
OS						
Tobacco Media Activities.....	--	10,000	10,000	5,000	--	--
Obesity Media Activities.....	9,120	9,100	--	--	--	--
Prevention Education and Outreach.....	--	--	20,000	--	--	--
ASPA Subtotal.....	9,120	19,100	30,000	5,000	--	--
Alzheimer's Disease.....	0.100	--	--	--	--	--
Healthy Living Innovation Awards/ Healthy Beginning Challenge.....	0.100	--	--	--	--	--
ASPE Subtotal.....	0.100	--	--	--	--	--
Tobacco Cessation.....	0.900	--	--	--	--	--
President's Council on Fitness, Sports, and Nutrition.....	0.925	--	--	--	--	--
Natl Prevention, Hlth Promotion and Pub. Hlth Council Strategic Planning.....	1,000	--	--	--	--	--
OAH Teen Pregnancy Prevention Grants.....	--	--	--	104,790	--	104,790
OASH Subtotal.....	2,825	--	--	104,790	--	104,790
Alzheimer's Disease Plan Activities.....	--	--	--	100,000	--	--
Subtotal, All OS.....	12,045	19,100	30,000	209,790	--	104,790
CMS						
Health Insurance Enrollment Support.....	--	--	--	--	453,803	--
Total, All Activities.....	500,000	750,000	1,000,000	1,250,000	949,000	1,000,000

31) The FY 2013 allocation of the Prevention and Public Health Fund by the Administration included \$454 million to CMS for implementation of the ACA that previously had received no PPHF funding during FY 2010 – FY 2012. This massive reallocation significantly cut funding for many activities that had previously been supported by the PPHF such as immunization, public health workforce development, diabetes, Racial and Ethnic Approaches to Community Health (REACH), environmental public health tracking, cancer prevention and control, Alzheimer's Disease Prevention Education and Outreach, and other activities. What, if any, process did the Administration undertake to consult with external partners and grantees of the programs that experienced PPHF funding reductions from FY 2012 to FY 2013? Was there any process to receive public comment or input on this massive reprogramming of resources prior to the announcement of the Administration's FY 2013 allocation decision?

Response: The Prevention Fund allocation is developed following the annual federal budget process. HHS considers comments, stakeholder input, and current priorities in developing a yearly strategy for these resources. This year presented circumstances which resulted in HHS revising the initial allocation developed for FY 2013. The FY 2013 President's Budget presented a planned allocation for the resources totaling \$1.25 billion. After the Budget was released, the Middle Class Tax Relief and Job Creation Act of 2012 reduced this funding to \$1 billion. The Prevention Fund was then further reduced by \$51 million in sequestration reductions. As a result of these changes in law and because the FY 2013 appropriation did not provide the resources requested by the Administration for implementation of the Health Insurance Marketplace to fully

enable individuals to access affordable health care, the Department is leveraging and reallocating existing resources from multiple sources to provide short term and immediate funding for these efforts. In recognition that some key prevention and public health activities should be continued at resource levels higher than can be provided through the Prevention Fund alone in FY 2013, HHS is providing additional base resources for specific programs within CDC and SAMHSA through the use of transfer authority within the Department.

- 32) The dramatic reduction in public health training centers at HRSA is a reversal of prior Administration decisions to invest in this training mechanism that supports the public health workforce. Was there a programmatic reason for the elimination of the financial support of this program from the Prevention and Public Health Fund?

Response: The Administration recognizes the valuable contributions of Public Health Training Centers (PHTCs) across the Nation. HRSA's FY 2014 budget includes \$5.4 million for the PHTC Program—\$2.2 million of which is from the Prevention and Public Health Fund—to fund schools of public health and other programs that provide graduate or specialized training in public health to enhance training opportunities focused on the core competencies and capabilities of the current and future public health workforce. The determination to reduce funding for this program reflects the need to respond to a challenging budget environment and to consider tough choices.

- 33) CDC Global Polio Eradication -- is the goal of global polio eradication and certification by 2018 achievable? Is there a strategic plan to achieve that goal? What resources – by the international community, private sector donors, and the U.S. Government – are required to achieve that goal?

Response: CDC will continue to push forward until eradication is complete. This is a commitment all partners in the Global Polio Eradication Initiative (GPEI) have to finish the job. The Endgame Strategic Plan outlines contingencies to adopt should events conspire to prevent the deadline for interruption of wild poliovirus by 2015 from being met.

Failure means loss of the investment of more than \$10 billion from partners around the world—including \$2.2 billion from the USG—towards polio eradication since 1988. This investment is expected to yield \$40 to 50 billion in cost savings by 2035. In the United States, polio vaccination has already resulted in a net savings of over \$180 billion and prevented approximately 1.1 million cases of paralytic polio and over 160,000 deaths. The GPEI, UNICEF and World Health Organization jointly estimate that if current efforts are not maintained, within a decade there could be 200,000 children paralyzed each year.

The United States has played a key role through the Group of Eight (G-8) leadership process to garner global support for polio eradication, and has provided significant and

long-term financial support and technical expert assistance from CDC and USAID. Since 1988, the number of polio-endemic countries has declined from 125 to three countries in 2012 (Afghanistan, Nigeria and Pakistan). India achieved a remarkable milestone by stopping polio virus circulation in 2011. This year we have seen the fewest number of cases in the fewest number of countries ever. Eradication is within reach, and CDC remains committed to its accomplishment.

CDC's strategic plan, which contributes to WHO's strategic plan, includes:

Goal 1 - Detecting and interrupting wild poliovirus. Working with WHO, UNICEF, and other key partners, CDC will continue to expand its involvement in Afghanistan, Nigeria and Pakistan, the three remaining endemic countries are adopting the comprehensive approach successfully employed in India.

This includes:

1. Strengthening surveillance and ensuring immunization activities are implemented regularly and effectively
2. Increase frequency of Supplemental Immunization Activities (SIAs)
3. Purchase vaccine to ensure adequate supply
4. Using monitoring data to identify and respond to problems and risks
5. Overcoming operational challenges, including vaccine refusal and insecurity, to ensure every child can be reached during immunization campaigns
6. Improving commitment and accountability at all levels
7. Identifying and mapping the most under-served populations, including systematically tracking nomadic movements
8. Creating a sophisticated social mobilization network involving religious advocates, community leaders and other influential members of society to ensure that parents understand the value and safety of vaccines

CDC scientific experts will provide assistance in person at all stages of implementation.

Goal 2 - Strengthening routine immunization, introducing Inactivated Polio Vaccine (IPV) and withdrawing Oral Polio Vaccine (OPV) globally. In the final stages of polio eradication, high routine immunization coverage is essential to effectively manage the immediate and long-term risks of polio. In addition to facilitating interruption of wild poliovirus transmission, high routine immunization coverage reduces the risk of wild poliovirus importation and spread. OPV withdrawal is a necessary step toward completely eliminating the disease. The plan calls for OPV withdrawal to take place in 2015-2016, but there are significant logistical and regulatory hurdles to a successful switch to IPV.

CDC currently is planning initial pilot projects to test the best method for introducing IPV into the routine immunization system. Further funding will allow us to expand these tests and more rapidly evaluate which methods will work best under what conditions. CDC experts will then be able to advise the regulatory bodies whose approvals for the IPV switch are necessary on the best way to accomplish it. CDC will also use some of its vaccine funds to ensure there is adequate supply of IPV at the lowest possible price.

To enable this switch and the eventual cessation of all OPV, it will be necessary to strengthen routine immunization systems and develop more affordable IPV. High immunization coverage is essential to effectively manage the immediate and long-term risks of polio. High routine immunization coverage reduces the risk of poliovirus spread in the event of an importation. Strengthening routine immunization aligns closely with the goals and objectives of the USG-endorsed Global Vaccine Action Plan (GVAP).

CDC will aid the strengthening of routine immunization through training, seed funding for personnel, and technical advice on the best methods of delivery in various settings.

Goal 3 - Containing the virus and certifying eradication. Following the interruption of wild poliovirus transmission, CDC and the GPEI will take steps to protect against further outbreaks of the virus. The process for providing verified data for the certification of eradication will be led by the WHO with significant technical support from CDC. Countries must surpass three years without reporting a case of wild poliovirus to be considered for polio free status by the regional certification commissions.

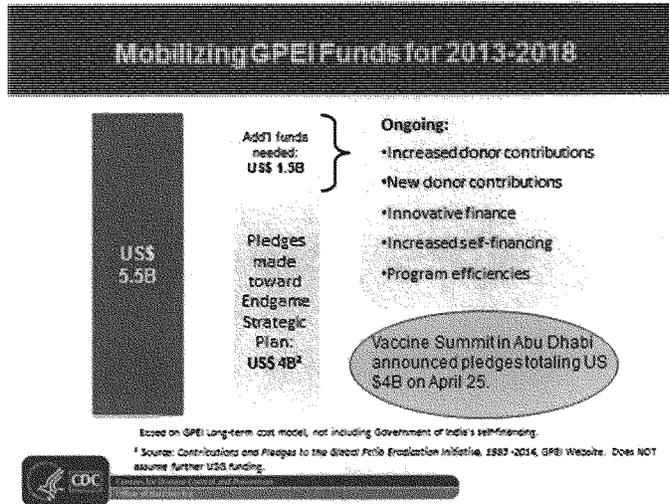
CDC will play a vital role in verifying the data used to certify polio eradication in all WHO regions. CDC's polio laboratory will be one of the few facilities to retain poliovirus stocks and will play a leadership role in setting safe handling and bio-containment procedures. Strengthening global laboratory-based environmental surveillance to detect virus circulation is vital. CDC is a global leader in defining and helping to implement the global poliovirus environmental surveillance strategy.

The systematic sampling of sewage for polioviruses must be geographically expanded to help identify any residual transmission in endemic areas, to provide early indication of new importations into recurrently re-infected areas, and to document the elimination of Sabin viruses following the tOPV-bOPV switch and eventual bOPV cessation. However, Acute Flaccid Paralysis Surveillance will remain the primary system for detection of polio. The importance of environmental surveillance was shown by Egypt's discovery of wild poliovirus in sewage samples taken through environmental surveillance in January 2013. A strong surveillance system and laboratory confirmation of the virus's Pakistani origin allowed emergency measures to be taken to prevent further importation and spread of polio in the local population.

Goal 4 - Planning for polio's legacy. As polio eradication approaches key milestones, successful legacy planning will include the mainstreaming of essential polio infrastructure, personnel, and functions such as, ensuring the transfer of lessons learned to benefit other development goals and global health priorities. CDC will continue to play a major role in this "Transition Planning" in keeping with the leadership role it plays in the field of global immunization and in global health in general. It is important that the transfer of knowledge and assets from the polio eradication program to routine immunization will be orderly and thorough post-eradication. There is a need to ensure that detailed consultation, and planning and implementation processes ensure the

investments made in polio eradication by the United States provide public health and economic dividends for years to come.

Resource needs as identified by the Global Polio Eradication Initiative, as well as current resource levels, are depicted below.



34) CDC Budget-- what is the cut to the Centers for Disease Control and Prevention's Fiscal 2013 total program level? What is the project impact of those reductions on core CDC functions? And what is your definition of core CDC functions, and what CDC programs fit into that category?

Response: Final FY 2013 funding levels are not yet available. HHS provided notifications on the use of the Nonrecurring Expense Fund, the Prevention and Public Health Fund, and the Secretary's transfer authority, which adheres to the authority provided by Congress. HHS will provide revised FY 2013 operating plans that reflect sequestration, reprogramming, and use of the Secretary's transfer authority, and will continue to inform Congress of any additional transfer and reprogrammings as appropriate. Final FY 2013 amounts will be provided in the FY 2015 President's Budget. However, CDC has identified the following as its core functions, which all CDC programs support:

- Protecting Americans from infectious diseases
- Preventing the leading causes of disease, disability, and death
- Keeping Americans safe from environmental and work-related hazards
- Protecting Americans from natural and bioterrorism threats

- Monitoring health and ensuring laboratory excellence
- Ensuring global disease protection

35) NIH 2013 Reductions--Of the funding reductions to NIH's Fiscal 2013 budget, how much will be levied on NIH's intramural program, NIH's extramural research program, and what is the overall percentage reduction to NIH's extramural and intramural program, respectively? What will be the impact of sequestration on new grants projected to be awarded by NIH? What will be the projected success rate for new grants? Will that vary by Institute? Are NIH intramural grants subject to similar peer review process as NIH extramural grantees?

Response: NIH's intramural research program received a reduction of \$140 million, or -4.1 percent, compared to FY 2012. The extramural research program, comprised of Research Project, Research Center, Other Research and Training grant mechanisms plus the R&D contract mechanism, received a reduction of \$1,532 million, or -6.1 percent, compared to FY 2012. The estimated number of new or competing research project grants (RPGs) declined by 703 from the FY 2012 level. The projected success rate for RPGs declined to 16 percent from 18 percent in FY 2012, with the impact varying by Institute or Center (IC).

Funds assigned to NIH intramural scientific programs are determined by a rigorous, multilevel peer review process to ensure that the NIH mission is fulfilled. The process outlined below has demonstrated repeatedly its success in ensuring the highest quality research and training. The review process begins with external peer review panels, or Boards of Scientific Counselors, chartered under the Federal Advisory Committee Act (FACA) as are all extramural review panels, and overseen by the Office of Intramural Research (OIR), Office of the Director, which reviews each intramural research program every 4 years. Emphasis is on high-risk science that is not being done, or could not be done elsewhere, and duplicative or "me-too" science is not tolerated. Reviewers comment on methodology, budget, timeliness, and originality of the research and these reviews are used to increase or decrease resources, or close non-productive laboratories. Reviews are both retrospective, reflecting the past success of scientific staff, and prospective, projecting new projects and ideas. A key feature of intramural research is the selection of the most talented researchers through an extensive international search process that is also overseen at the level of OIR. The intramural Scientific Directors (SD) are responsible for assignment of resources based on the search and review processes. The performance of the SDs is reviewed by outside committees every 4-6 years. In addition, an overall review of the quality, productivity, innovativeness, and impact of each IC's intramural program is conducted by a separate external Blue Ribbon Panel approximately every 10 years. The recommendations of these reviews are reported to the IC Director, the Deputy Director for Intramural Research, and the NIH Director to guide any changes needed for the future.

36) In 2004, the HHS OIG had 284 FTE who worked on typical OIG functions related to oversight and audits of the HHS discretionary funded programs. In fiscal year 2012, the FTE had reduced to 262 or less than 15 percent of the total OIG FTE

staff. Furthermore, the funding was \$38.6 million out of \$222.5 million in FY 2004 for traditional OIG programs and only \$50 million of the 307.3 million in FY 2012. It appears the primary mission for the function called the OIG is primarily focused on health care fraud activity and not the remaining almost 300 programs funded through HHS. Please provide specific management suggestions on how Congress can be assured that given the significant level of funding and FTE devoted to non-traditional OIG programs that the traditional oversight and audit function for the other HHS programs is conducted at an appropriate level of effort.

Response: The general composition of OIG's work depends on the funding made available to OIG. Approximately 80 percent of OIG's funding comes from the Health Care Fraud and Abuse Control Program (HCFAC), and the restrictions on this funding stream limit expenditures to Medicare and Medicaid oversight. To oversee the remaining 300 plus programs in the Department, OIG relies on funding available for that purpose.

The FY 2012 President's Budget requested \$63 million for oversight of these 300 plus programs, a +\$13 million increase above the FY 2010 enacted level. It was proposed that \$10 million of that increase would be funded via the PHS Evaluation set-aside. The FY 2013 President's Budget requested \$59 million for oversight of these 300 plus programs, a +\$8 million increase above the FY 2011 enacted level. Congress has not provided these requested increases, along with increases to the HCFAC program that were authorized by the Budget Control Act of 2011, leaving OIG largely flat funded.

The decrease in staff outlined in the question is not due to a purposeful reduction in oversight of these 300 plus programs, but rather is a reflection of funding available for this work. OIG manages work across agency staff to maximize its oversight of these programs.

OIG recognizes the need for additional oversight of the non-Medicare/Medicaid programs of the Department. Under current funding levels OIG has been forced to implement a hiring freeze for over a year and has offered a voluntary early retirement authority and voluntary separation incentive payment to employees. To improve OIG's ability to perform oversight, the FY 2014 President's Budget requests a \$19 million increase over FY 2013 Enacted levels that would be solely dedicated to the oversight of these 300 plus programs. These additional funds will allow OIG to expand the breadth and quantity of its work in these programs.

Questions from **Congressman Mike Simpson**

1. It was my understanding that the ACA required children to have dental coverage. But it appears that parents who buy health insurance inside the exchange are not required to purchase the dental coverage for their children.

However, everyone (including families without children) who buy their insurance outside the exchange must purchase pediatric dental essential health benefit coverage. Can you explain how the agency made that determination?

Response: Several provisions of the Affordable Care Act affect the coverage of pediatric dental essential benefits. Section 1302 of the Affordable Care Act requires issuers in the individual and small group markets inside and outside the Marketplaces to offer essential health benefits. Essential health benefits requirements apply to health insurance issuers, which must offer certain benefits – they are not requirements for individuals or families to obtain coverage for a particular benefit.

In the essential health benefits final rule, CMS provided a clarification regarding situations in which issuers outside the Marketplace would not be found to be non-compliant with the requirement to offer essential health benefits if the issuer is reasonably assured that the applicant has obtained the pediatric dental essential health benefit through a Marketplace-certified stand-alone dental plan. With respect to issuers inside a Marketplace, however, section 1302(d)(4)(F) of the Affordable Care Act allows issuers to omit pediatric dental coverage if there is a stand-alone dental plan offering the pediatric dental essential benefit in that Marketplace.

2. If a state runs its own exchange, may they require the purchase of a pediatric dental essential health benefit inside the exchange for families with children?

Irrespective of the agency's position, may a state that is operating under a federally-facilitated or partnership arrangement choose to require the purchase of a pediatric dental essential health benefit inside the exchange in that state for families with children?

Response: States may, as a matter of state law, require individuals to purchase pediatric dental coverage.

3. Is it true that individuals purchasing stand-alone dental plans in the exchange will have a grace period of ninety days to pay their premiums?

If this is true, what is the remedy if the plan is cancelled because the individual fails to pay the premium but receives care during the ninety-day period?

Has the agency provided guidance concerning how, and how often, premium payments will be collected from individuals?

Response: The Affordable Care Act provides that if an individual is enrolled in a qualified health plan (including a stand-alone dental plan) and receiving an advance payment of the premium tax credit (APTC), there is a 90-day grace period for non-payment of premiums. In the Exchange Final Rule, issued in March 2012, 45 CFR 155.430(b)(2)(ii)(A) and (B) CMS noted that the grace periods for nonpayment of premiums are not the same for individuals receiving advance payments of the premium tax credit and other enrollees. The 90-day grace period for non-payment of premiums for individuals receiving advance payments of the premium tax credit is addressed 45 CFR 156.270(d). For individuals who are not receiving tax credits, 45 CFR 155.430(d)(5) CMS clarified that the last day of coverage for individuals not receiving advance payments of the premium tax credit should be consistent with existing state laws regarding grace periods for non-payment.

With respect to remedies for plans canceled due to non-payment of premium, in the Exchange Final Rule at 45 CFR 156.270(d)(1) and (d)(2), qualified health plan (QHP) issuers must pay all appropriate claims for services provided during the first month of the grace period. However, CMS acknowledges that as the amount owed by an enrollee increases during the 3-month grace period, the risk of non-payment increases as well. To decrease the financial risk to issuers, and to individuals, the final rule permits QHP issuers to pend claims in the second and third months. QHP issuers may still decide to pay claims for services rendered during that time period in accordance with company policy or state laws, but the option to pend claims exists.

With respect to frequency of payment, CMS expects that, as is the case with health insurance today, premiums will be paid on a monthly basis.

4. (closing) **Will you consider revising ACA implementations** to ensure consumers are treated fairly regardless of whether they select dental coverage as part of a medical-dental package or in a separate stand-alone plan?

Specifically, will the agency support an adjustment that requires subtracting the separate cost-sharing maximum for stand-alone dental plans from the overall out-of-pocket cost-sharing maximum?

Also, will the agency support a system to tier the separate out-of-pocket limits for the stand-alone plans according to income in a manner consistent with the criteria applied to qualified health plans?

Response: CMS articulated the final policy with respect to stand alone dental plan cost sharing for the 2014 plan year in the final Essential Health Benefits Rule, issued in February 2013 and the final Annual Letter to Issuers in Federally-facilitated and State Partnership Marketplaces, issued in March 2013. CMS will consider updates to the policy for the 2015 plan year.

5. I understand that earlier this week that Surgeon General Benjamin issued a statement officially endorsing community water fluoridation as "one of the most effective choices communities can make to prevent health problems while actually improving the oral health of their citizens." As a dentist I understand the benefits of water fluoridation. I have seen what a difference it can make in oral health – especially of children. Thank you and the Surgeon General for making that statement.

The Surgeon General's endorsement is coming at a very important time.

Anti-fluoridationists have mounted very strong challenges to get communities to turn off water fluoridation. I believe that the science supports the safety and efficacy of water fluoridation. What is the Department's plan to help communities who will be challenged by the other side when this new directive comes out?

Response: In April 2013, CDC published a new competitive Funding Opportunity Announcement (FOA) for the State Oral Disease Prevention Program. The purpose of this funding is to assist state health departments to build and/or maintain effective public health capacity for implementation, evaluation, and dissemination of best practices associated with oral disease prevention and improvement of oral health. The FOA consists of two separate components: 1) Basic Capacity for Collective Impact and 2) Implementation of Evidence-based Community Preventive Interventions and Access to

Clinical Preventive Service. Awards totaling approximately \$6 million are expected to be announced in late summer with a start date of July 30th.

6. I understand that the HHS is in the process of issuing a final notice on the recommended level of fluoride in drinking water. Can you tell us when the final announcement will be released? Will you have a press conference to announce this change?

Response: CDC is working closely with other HHS components and the HHS Expert Panel to review and address public and peer comments on the Federal Register Notice that proposed lowering the optimal level of fluoride in drinking water. The recommendation is being reviewed in light of the population's access to other fluoride sources. Plans for the release of the final recommendation are in development.

7. Many communities that have been fluoridating for years need to replace their aging equipment. The CDC has traditionally been able to provide grants for this purpose. Will funding for these grants be available in the coming year? Have you conducted any surveys to see how great the need is?

Response: A goal of Component 2 of the new CDC FOA is to increase the proportion of the population with access to optimally fluoridated water. Strategies to support this goal include surveying the status of and purchasing, if necessary, fluoridation equipment. CDC has not conducted national surveillance on the status of fluoridation equipment.

8. A number of my colleagues in Congress have expressed their concern to you about the impact of sequestration on chemotherapy drugs. I share their concern. Please provide my office with more information about the impact sequestration will have on the price and availability of chemotherapy drugs, particularly in rural states like Idaho.

Response: The Administration strongly opposes the across-the-board sequestration cuts and continues to urge Congress to take action to replace sequestration with balanced deficit reduction. The effect that sequestration will have on individual oncology clinics or other facilities that administer chemotherapy drugs depends on the size of the facilities and the mix of drugs and services they provide. Under current law, Medicare payments for Part B drugs, including chemotherapy drugs, must be reduced pursuant to sequestration.

Question from Congressman Womack:

The President's FY14 budget proposal seems to base its recommendations for rehabilitation hospitals on a "straw man" analysis by wanting to ensure rehab hospitals are "appropriately" classified and ensure against the possibility that such hospitals may be treating patients who "are not appropriate" for rehab hospital care. What hard data is there that conclusively demonstrates the need to adopt either the 75 percent rule or to pay rehab hospitals nursing home-based rates for certain conditions? These are troubling proposals that would have a disproportionate impact on rehab hospitals and the patients that require their services.

Response: The President's Budget aims to provide Medicare beneficiaries with the most efficient health care possible. Inpatient rehabilitation facilities provide intensive rehabilitation care that is not appropriate for all patients. The Budget proposal to increase the requirement that 60 percent of patients treated have one or more of thirteen conditions requiring this level of care to 75 percent reinstates a standard that was in place prior to 2007 and ensures that Medicare pays for and patients receive appropriate care. Similarly, some conditions currently treated within Inpatient Rehabilitation Facility do not require intensive rehabilitation and are treated successfully in other, less-intensive care settings, such as skilled nursing facilities. The Budget proposals to reinstate the 75-percent standard and equalize payment rates to skilled nursing facilities and rehabilitation facilities for specific conditions reflect the Administration's aim to ensure that inpatient rehabilitation facilities focus on treating patients that require this higher level of care.

Questions from Congressman Andy Harris:

1. As discussed during the Subcommittee hearing, faith-based charities, hospitals and schools have filed suit against the mandate that forces them to provide health care coverage for items that go against their deeply held beliefs. Many of these faith-based plaintiffs have been told by the courts that they cannot seek injunctive relief until the Administration issues its final rule. Please provide a specific timeline for the issuance of the final rule.

Response: HHS will be issuing this final rule in the near future.

2. How many comments were received regarding the HHS Mandate? Of the comments submitted during the comment period how many were in favor of the proposed rule and how many were against?

Response: HHS received a total of 472,082 regarding this proposed rule. All submitted comments are available at www.regulations.gov/#!docketDetail;D=CMS-2012-0031.

3. As you know, Judge Edward Korman of the Eastern District of NY recently ruled that your decision to require a prescription for girls 16 and younger to access Plan B, was arbitrary, capricious and unreasonable. What is your position on his ruling and do you plan to file an appeal? In addition, on May 1, 2013 the FDA ruled that Plan B should be made available without a prescription to girls 15 years of age and older. Do you agree with their decision and if not what actions will you take to reverse

Response:

The Department does not comment on ongoing litigation. Questions on next steps should be directed to the Department of Justice. The April 30, 2013, approval action for Plan B One-Step was FDA's decision. The agency reviewed and approved Teva's application to make Plan B One Step available as a nonprescription product for women age 15 years old and older. I was briefed by Commissioner Hamburg about the review process and data submission involving Teva's application, and support the agency's decision.

4. BARDA – Earlier this year, Congress passed and the President signed into law the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA). This new law demonstrates Congress' commitment to continuing to prepare for chemical, biological, and nuclear threats. Last week, the bombs in Boston and the ricin laced letter addressed to our Senate colleague reminded us of the reality of these threats by. One of the key components of PAHPRA is the reauthorization of the Project BioShield Special Reserve Fund (SRF) at \$2.8 billion for the next 5 years. Biotechnology companies that have partnered with BARDA and HHS to develop essential medical countermeasures have looked at the SRF as a signal of the US government's commitment to development and purchase these medicines. I am very disappointed that the President's Budget fails to provide sufficient funds to support the SRF and the Biodefense Enterprise at HHS. In addition, the new multi-year contracting language is NOT sufficient to make up for a mere \$250 million, less than one-fifth of the authorized \$2.8 billion. What impact do you believe the Project BioShield Special Reserve Fund has had on our nation's ability to develop and stockpile medical countermeasures? How does the current budget reflect this belief? Other than insufficient, multi-year contracting language, how will you ensure that the Project BioShield Special Reserve Fund is available for the next 5 years?

Response: The Special Reserve Fund has resulted in HHS's creation of a robust development pipeline containing more than 80 medical countermeasure candidates for chemical, biological, radiological, and nuclear threats. This development has resulted in the delivery of 11 new medical countermeasures (MCMs) to the Strategic National Stockpile (accessible by Emergency Usage Authorization) and the FDA licensure of two of these MCMs.

The FY 2014 President's Budget requests funding for BARDA across three categories: Advanced Research and Development (ARD), Pandemic Influenza and Project BioShield. Based on MCM development and procurement across multiple years and relevant PHEMCE priorities, BARDA determined that \$250 million was needed for procurements in FY 2014. This funding request will support the replenishment of Modified vaccinia Ankara (MVA) vaccine (smallpox), vendor-managed inventory (VMI) costs for an anti-neutropenia cytokine acquisition to treat acute radiation syndrome, and a new BioShield award for artificial skin to treat thermal burn patients. The FY 2014 President's Budget also explicitly commits to a renewed multi-year funding commitment supporting the procurement of MCMs via Project BioShield for the Strategic National Stockpile (SNS). BARDA expects that at least 12 new MCMs in the present advanced development pipeline will mature sufficiently from FY 2014-2018 for consideration of procurement under Project BioShield. Moving forward, BARDA will continue to support the development and procurement of new MCMs, substantially improving the nation's preparedness.

For future funding of BioShield, the FY 2014 President's Budget requests \$250 million available until expended. HHS requests no-year funding to maximize the flexibility and provide stability to align with the original BioShield appropriation.

Originally, Project BioShield's funding of \$5.6 billion was expected to be a sufficient incentive to bring large, fully-integrated pharmaceutical companies into the biodefense market space. Unfortunately, a limitation on these funds was that, with minor exceptions, they could not be used to pay MCM vendors until a product was delivered to the SNS, thereby placing the majority of risk on the private sector. Over the past nine years, HHS has developed additional tools to foster its relationship with these partners to address this concern. This development has included the establishment of BARDA, the provision of ARD funding, and the expansion of authorities under Project BioShield – most notably the introduction of milestone payments in contracts. More recently, per recommendations from the Secretary's Review of the Public Health Emergency Medical Counter Measure Enterprise (PHEMCE) following the 2009 H1N1 pandemic, came the establishment of Centers of Innovation for the Advanced Development and Manufacturing (CIADM). These public-private partnerships allow BARDA to pair large established pharmaceutical companies with smaller firms. These pairings mitigate the scientific and manufacturing risks associated with MCM development by providing the necessary expertise to bring promising technologies to the marketplace. Additionally, the PHEMCE Review recommended the establishment of a MCM Strategic Investor, an independent non-profit entity, which uses HHS funding to support capital investments in private companies with promising technologies. By providing critical capital in exchange for a strategic role in the management of these small firms, HHS is able to mitigate the financial and management risk that some small firms face, thereby increasing the probability of successful technologies and products.

Since the development and procurement of MCMs is an inherently risky endeavor, BARDA remains focused on keeping sufficient incentives in place for its industry partners. This effort includes an HHS intra-agency multi-year budgeting

practice driven by the long-lead time necessary for MCM development and acquisition. Large pharmaceutical companies (e.g., Amgen, GlaxoSmithKline, etc.) are now joining the biodefense MCM sector, using long-range budget planning routinely as a good business management practice. Venture capital investors, which fund many small biotech companies in the biodefense sector, may choose to support biotech companies in a different sector that has a better benefit-to-risk profile than biodefense. These circumstances support the critical need to ensure a long-term funding commitment is maintained with annual appropriations in the future. Maintaining the progress that has been achieved in the recent years requires Congress' continued support for these future activities.

5. Public relations contracts - Recently, the Administration was awarded \$8 million to public relations firm Weber Shandwick to promote enrollment in Obamacare's exchanges. This is in addition to millions of dollars that have previously been spent to promote the law. How much money has the government spent on advertising for PPACA? How are contracts to these public relations firms awarded?

Response:

As the principal agency responsible for protecting the health of all Americans and providing essential human services, effective outreach to the general public is central to our mission. CMS communications contracts play a central role in helping carry out this vital mission. Contracts to support implementation of the Affordable Care Act are awarded in accordance with Federal acquisition laws and regulations. CMS will work with the committee to provide additional information on funding utilized for outreach efforts as CMS continues with implementation of the Affordable Care Act and works to ensure individuals and small businesses have the information they need to make informed choices.

6. PPACA Nondiscrimination Language - Public Health Service Act Section 2706(a), that was included in PPACA, on so-called "provider non-discrimination" could put the Federal government in the position of undercutting, interpreting or misapplying state scope of practice law, thus abridging State's rights. How does the agency plan to proceed on this matter so that we don't see an explosion of costly Federal lawsuits on such state issues? Will this provision have the effect of driving up healthcare costs and premiums by allowing paraprofessionals to order excessive tests? Could this provision undercut the push for coordinated team-based care that is found throughout the ACA?

Response: CMS has not issued guidance on this provision but does intend to do so in the near future.

7. SGR and PPACA Delay - Secretary Sebelius, you said recently that, "no one fully anticipated" the difficulties involved in setting up Obamacare. Democratic Senator Jay Rockefeller at a recent hearing said that PPACA is "probably the most complex piece of legislation ever passed by the US Congress." When referring to implementation he says

"If it isn't done right the first time, it will simply get worse." Henry Chao, deputy chief information officer at CMS admitted "We are under 200 days from open enrollment (in Obamacare) and I'm pretty nervous. The time for debating . . . is it a world-class experience, that's what we used to talk about two years ago. Let's just make sure it's not a third-world experience." The Administration clearly wants to the law to be successful, so why don't you support delaying it one year so you have more time? There is an added benefit to delaying. I have seen an estimate that a one year delay would save about \$130 billion. That number is very close to the \$138 billion we need to permanently fix the Medicare Sustainable Growth Rate Formula which is a constant problem we have to address. Do you support a one year delay in implementation so we can finally deal with the "Doc Fix" for good?

Response: Both the State and Federally-facilitated Marketplaces will be ready to begin enrollment on October 1, 2013 for coverage beginning January 1, 2014. The Administration is committed to working with Congress to reform Medicare physician payments to provide predictable payments that incentivize quality and efficiency in a fiscally responsible way. However, any delay in implementation of the Affordable Care Act would deprive tens of millions of Americans of health insurance.

As part of efforts to reform Medicare physician payments, the Administration supports a period of payment stability lasting several years to allow time for the continued development of scalable accountable payment models. Such models would encourage care coordination, reward practitioners who provide high quality, efficient care, and hold practitioners accountable through the application of financial risk for consistently providing low quality care at excessive costs. HHS will welcome input from physicians and other professionals in designing these models. Following the period of stability, practitioners will be encouraged to partner with Medicare by participating in an accountable payment model, and over time, the payment update for physician's services would be linked to such participation.

8. GME - With the growth in the number of the people with health insurance as a result of the law, the need for physicians and other providers will dramatically increase. That is why I find it odd that at the exact time we need an increase in the number of physicians, your budget proposes to GUT Graduate Medical Education and Children's Hospitals Graduate Medical Education. In your budget you propose to cut CHGME by \$177 million - that is literally a 67% cut to the program. Does the administration think it is not important to ensure that we have a supply of physicians to care for our children? For GME, your budget proposes a cut of \$11 billion over 10 years. If you cut this investment it will result in us having fewer physicians. Is that the Administration's goal?

Response: The Administration believes that a well-trained health care workforce is critical to reforming the nation's health care system. Our investments in the primary care workforce include general pediatrics through the National Health Service Corps, the Primary Care Residency Expansion initiative, the Primary Care Training and

Enhancement Program, Pediatric Loan Repayment, and the Teaching Health Center GME Program.

While the CHGME program has supported pediatric training at many facilities across the country, we are working within the context of a budget that requires tough choices. A challenging budget environment required a closer examination of how resources are spent. The FY 2014 President's Budget provides \$88 million to fund the direct medical education portion of the CHGME payment. This funding supports expenses that directly support the residents and faculty so that training in pediatric care can continue, but does not provide funding for the indirect graduate medical education costs.

The proposal in the President's Budget to reduce Medicare Graduate Medical Education payments is narrowly targeted and unlikely to adversely affect patient access to care. It is important to note that this proposal would not reduce the number of graduate medical education slots supported by Medicare, nor would it reduce the payments CMS makes to support the direct costs of graduate medical education, such as residents' salary and benefits. Rather, the proposal is limited to indirect graduate medical education (IME) payments, which support the higher costs associated with providing patient care in a teaching hospital. Independent analyses by MedPAC have concluded that IME payments are significantly higher than is empirically justified² – the proposed 10% reduction to IME in the President's Budget would only partially correct this discrepancy.

Note that in addition to the reduction to IME, the President's Budget proposal would also allow the Secretary to set new standards for teaching hospitals to encourage primary care and high-quality care delivery. These requirements will help ensure that the teaching hospitals train a medical workforce that can fully meet patients' needs in the years and decades to come.

9. Access to Care - As I travel throughout the Eastern Shore of Maryland, time and time again I hear of Medicare beneficiaries struggling to find physicians who are accepting Medicare patients. The never ending threat from the SGR, and now the President's sequestration, have made physicians decide to stop accepting Medicare patients and driven many physicians, both primary care and specialists, from rural to urban areas. As more and more seniors enroll in Medicare each day, what actions are you taking to ensure seniors have access to the care they need from the physician they choose? (could then move to IPAB)

Response: The Affordable Care Act includes a number of important delivery system reforms that will enable Americans to get better care at lower costs and will help the health care system operate more efficiently. We continue to carefully monitor access to services, and to date, access to services remains strong. Hospitals will also benefit from the insurance coverage expansions in the Affordable Care Act, adding new sources of

² In 2010, MedPAC found that only 40% - 45% of IME payments in 2009 could be analytically justified. For more details see Chapter 4 of MedPAC's June 2010 report.

revenues for most health care providers. Furthermore, a number of provisions in the Affordable Care Act were designed to strengthen the health care workforce, such as Medicare payment bonuses for primary care providers and providers in underserved areas and investments in health professional training programs to increase supply. We will continue to carefully monitor access to ensure our policies continue to lower costs while maintaining access to quality services.

10. The occurrence of tragedies involving people with serious mental illness is rising and the scope of these incidences is broadening. Clearly, access to appropriate treatment for serious mental illness is not available for many who need it. I understand Acting CMS Administrator Marilyn Tavenner recently told the Senate Finance Committee that “Medicare beneficiaries have access to FDA approved products” in the treatment of serious mental illness. However, I am aware that at least one FDA-approved medical device for the treatment severe, chronic treatment-resistant depression is not currently covered by Medicare. What, in your opinion, should be done to make treatment options such as this available to Medicare beneficiaries?

Response: Medicare covers a comprehensive range of mental health services in both inpatient and outpatient settings, including a set of intensive outpatient services known as “partial hospitalization” for patients with acute psychiatric conditions who would otherwise require hospitalization. In addition, psychiatric medications are covered under Medicare Part D for beneficiaries enrolled in a prescription drug plan.

In regard to Medicare coverage of particular services or devices, national coverage is considered through the national coverage determination process based on a review of the best available clinical evidence, with multiple opportunities for public input. In some cases where the evidence is insufficient to support unlimited coverage, Medicare coverage may be available under “coverage with evidence development”, which facilitates access to new innovative technologies for beneficiaries enrolled in a clinical study designed to generate further evidence. Absent a national coverage determination, coverage may be determined at the local level through local coverage determinations or case-by-case determinations by the contractor medical director. More information about these coverage processes is available on the CMS Coverage website at <http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html>, including guidance on how to submit requests for coverage for a particular item or service. In addition, national and local coverage policies on particular items and services may be accessed through the Medicare Coverage Database at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>.

11. Please provide information regarding the funding and program activities of the CDC Community Preventive Task Force, including 1) annual budgets and funding sources for fiscal years, 2004-2012; 2) details on how the task force allocates its budget, who directs the budget, how grants for research and programs are selected, approved, and

evaluated; 3) a list of all grant recipients from fiscal years 2009-2012; and 4) plans regarding dissemination of the Community Guide.

Response:

1) Annual budgets and funding sources for fiscal years, 2004-2012

The Task Force is an independent panel. Section 399U of the Public Health Service Act specifies the role of CDC to “provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.” In support of those efforts, Community Guide funding allocations from FY 2004 to FY 2012 are below:

Fiscal Year	Funding Allocation
FY 2012	\$10,500,000
FY 2011	\$8,177,000
FY 2010	\$6,630,000
FY 2009	\$1,737,000
FY 2008	\$1,831,000
FY 2007	\$1,796,000
FY 2006	\$1,886,000
FY 2005	\$1,587,000
FY 2004	\$1,400,000

2) Details on how the task force allocates its budget, who directs the budget, how grants for research and programs are selected, approved, and evaluated

CDC is congressionally mandated to provide ongoing administrative, research, and technical assistance to the Community Preventive Services Task Force. Within CDC, the Director of the Epidemiology and Analysis Program Office is responsible for planning and executing the Community Guide budget. The budget associated with the Community Guide is allocated by the three functions that support the Task Force and that are outlined in the FY 2012 Congressional Justification. See the table below for a breakdown of the FY 2012 budget. The Community Preventive Services Task Force does not provide grants or fund original research.

<i>FY2012 Budget</i>	
Systematic Review and Science	\$5,000,000
Dissemination	\$2,700,000
Task Force and Operations	\$2,800,000

Total Expenses

\$10,500,000

3) A list of all grant recipients from FY 2009 – FY 2012
The Community Preventive Services Task Force does not provide grants.

4) Plans regarding dissemination of the Community Guide.

The Community Guide dissemination activities aim to increase awareness of, access to, and usefulness of Task Force recommendations among its key user audiences—including decision makers in communities, companies, health departments, health plans and healthcare systems, non-governmental organizations, and at all levels of government. Dissemination activities focus on helping users become aware of, locate, identify, choose, and implement evidence-based recommendations that best meet the needs, preferences, available resources, and constraints of their constituents. With scientific and technical support provided by CDC, the Task Force works with its partners—including official federal agency and organizational liaisons; state, tribal, local, and territorial health agencies; and others—to:

- Develop targeted communication products—all of which are free of charge—for state, territorial, local, and tribal health agencies and other potential users;
- Expand the range of formats and channels by which potential users can access information about Task Force recommendations—including refining and extending The Community Guide website, developing additional stories of communities and businesses using The Community Guide, and developing materials that partners can include in electronic and print newsletters;
- Provide targeted training and technical assistance to liaisons; state, territorial, local, and tribal health agencies; and others requesting assistance in selecting and understanding Task Force recommendations;
- Incorporate use of the Community Guide into key public health improvement activities such as public health department accreditation and performance improvement.

12. Please provide information regarding enforcement of anti-advocacy law for CDC grant recipients, including Section 503, Division F, Title V of the FY 2012 Consolidated Appropriations Act. Specifically, provide 1) the mechanics of the current oversight program to prevent violations; 2) a list of research and program grant recipients found in violation; 3) details as to how the CDC rejects applications by those found in violation.

Response:

1) The mechanics of the current oversight program to prevent violations

CDC's policy prohibits lobbying at the federal, state, and local levels. These restrictions apply to all CDC grants. All CDC awardees are informed at multiple junctures about the federal laws relating to use of federal funds, including applicable anti-lobbying provisions. CDC's *Additional Requirement 12, "Lobbying Restrictions"* (AR-12) states CDC's policy prohibiting awardees from using any appropriated federal funds for "any

activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body..” CDC’s policy on lobbying by grantees, as expressed in the AR-12, has been in place for over a decade. This language reflects revisions to the AR-12 to reflect new language in the FY 12 appropriations law.

In addition to making these restrictions part of grant awards, to ensure grantees understood the limits on use of the awards, CDC staff has provided numerous reminders and conducted trainings for awardees on these prohibitions. For example, in CDC’s CPPW program, these steps included an initial pre-award teleconference; presentations at the CPPW Communities kick-off meeting in April 2010; and multiple training sessions during the grant period of performance, including a mandatory meeting for all program managers and principal investigators to review the prohibitions outlined in the AR-12.

Continuing with CPPW as an example, CDC regularly monitors grantee performance in order to ensure that federal funds are used effectively and appropriately. CDC project officers interact with these awardees every month to ensure that they are implementing the activities and strategies set forth in the awardee’s work plan and that awardees are adhering to administrative requirements, including provisions relating to lobbying. For CPPW grant recipients, the following steps would be taken if a project officer identified information that indicated the recipient was conducting activities that violated AR-12:

- The project officer would implement a risk mitigation plan, which is agency procedure whenever any potentially unallowable activity performed by a grant recipient is identified. Under this plan, CDC would contact the grant recipient via telephone to request additional information and ask that the activity cease immediately until further information could be gathered by the CDC.
- The project officer would then investigate the activity to gather additional information. This information would then be presented and reviewed at a risk mitigation meeting, which would have included the program director of the CPPW program and the project officer, as well as other CDC staff. If this group determined that no violation of AR-12 occurred, a note would be made in the file and no further action would be taken beyond regular monitoring of the grant recipient.
- If during the risk mitigation meeting it was determined that a violation occurred, written findings and recommendations would be elevated within the Agency and a determination made on appropriate enforcement action.

2) A list of research and program grant recipients found in violation

In the case of the South Carolina Department of Health, a CDC project officer identified emails sent to the CDC that demonstrated CPPW-funded staff at the South Carolina Department of Health significantly contributed to planning and scheduling a press event designed to influence the decision of city council members with regard to a smoke-free ordinance. It was determined that this recipient conducted lobbying activities, and as a result, the amounts associated with the activities were disallowed as expenses under the grant. The grantee was also reeducated on all restrictions and requirements. There are

two other grants with respect to which CDC has internally reached a tentative conclusion that the grantee conducted impermissible lobbying activities; CDC has been in contact with the grantees about the issue and will be following up soon with formal letters disallowing the costs and reeducating them on all restrictions and requirements.

3) Details as to how the CDC rejects applications by those found in violation.

CDC has an extensive review process for grant applications. The review panel for each grant is provided information on award objectives and provided information on anti-lobbying restrictions. Application budgets and work plans are reviewed thoroughly by the panel. Applications sometimes can include proposals for additional funds, unallowable activities or other issues not within the scope of the grant. However, a work plan is created with approved activities to be performed within the scope of the grant. The agreed upon work plan represents the work that the grantee will actually perform with federal funds. CDC staff then monitors grantee activity to ensure that grantees are using federal funds to perform activities within their work plan.

Congresswoman Barbara Lee – Questions for the Record

Nursing Workforce Development

Registered Nurses (RNs) and Advanced Practice Nurses (APRNs) are expert clinicians who provide high-quality and cost-effective care in every care setting and community – and they are in particular demand in our nation's most medically-underserved areas.

Despite this need, according to the American Association of Colleges of Nursing *2012-2013 Enrollment and Graduations Survey*, nursing schools were forced to turn away 79,659 qualified applications from entry-level baccalaureate and graduate nursing programs in 2012, citing faculty vacancy as a top reason. The Title VIII Faculty Loan Program is critical to alleviate this demand, but the budget request for FY2014 for this program was level to the FY 2012 enacted amount of \$24.5 million.

Question: Please describe HHS's strategy to address this shortfall, particularly given the health system's growing reliance on and need for nurses?

Response: HRSA's Advanced Nursing Education (ANE) program supports the enhancement and expansion of advanced nursing education and practice, including doctoral education programs which train future nursing faculty. ANE programs support training for registered nurses who are preparing to become nurse practitioners, clinical nurse specialists, nurse midwives, nurse anesthetists, nurse administrators, nurse educators (including faculty), public health nurses, and other specialties requiring advanced education. In Academic Year 2011-2012, ANE grantees trained over 7,800 students. Among them, over 3,000 were minority and/or disadvantaged students.

In addition to continued funding for the ANE program, the President's FY2014 Budget includes funding, that if sustained over the next five years, will boost the advanced practice nurse workforce, specializing in primary care, by 1,400 practitioners by FY 2018.

Racial and Ethnic Disparities

Question: How does your budget reflect the Department's goal to reduce and eventually eliminate racial and ethnic disparities, and have you established – and if not are you willing to establish – benchmarks that measure progress towards goal of health disparity elimination?

Response: HHS continues to serve as the lead Federal agency for coordinating efforts across the government to reduce and eliminate health disparities. Within HHS, the Office of Minority Health leads efforts across the agency through policy development and coordination of HHS resources in the operating divisions that focus on health disparities among racial and ethnic minorities and improved health outcomes for this population. Total HHS investments in minority health for FY 2014 include HRSA at \$2.5 billion, NIH at \$2.5 billion, IHS at \$5.6 billion, CDC at \$99 million, CMS at \$15 million, FDA at \$3 million, and SAMHSA at \$128.7 million and \$41 million in the Office of the Secretary for minority health programs.

In FY 2014 these efforts are supported through implementation and monitoring of Affordable Care Act provisions to improve the health of racial and ethnic minorities, and underserved and vulnerable populations, and coordination and monitoring of HHS health disparity programs and activities to better leverage resources and extend effective HHS programs by replicating best practices.

An important strategy guiding our efforts is the *HHS Action Plan to Reduce Racial and Ethnic Health Disparities*. The Disparities Action Plan provides a framework for a department-wide approach to reduce health disparities; builds on the foundation of the Affordable Care Act; and leverages other key national initiatives which taken together, represents a comprehensive Federal commitment to address and reduce racial and ethnic health disparities. Furthermore, the Disparities Action Plan includes specific actions and the lead component within HHS responsible for supporting those actions. The Department's progress in achieving the Plan goals is reviewed so that we can monitor and refine strategies for addressing health disparities.

Additionally important for ensuring progress is data collection and analysis. The *Healthy People 2020* initiative provides important data on health disparities in the U.S. population by tracking rates of death, chronic and acute diseases, injuries, and other health-related behaviors for populations that experience health disparities. Data on *Healthy People 2020* indicators is available using the web tool Data2020, which is posted on the HHS website at <http://www.healthypeople.gov/2020/data/default.aspx>. This data will help inform

decisions about where program and other Federal resources for reducing and eliminating health disparities will be most effectively spent.

Finally, our efforts to measure the progress toward reducing health disparities has been enhanced through the Health System Measurement Project, which provides publicly accessible data on racial and ethnic minorities in the U.S. in an understandable, navigable, and transparent way. Launched in 2012, the project will track key measures and include data at the national level and regional and state level as available; in a way that permits interested stakeholders to view data and establish baselines on disparities for key indicators and track progress toward disparities elimination. The Health System Measurement is posted on the HHS website at <https://healthmeasures.aspe.hhs.gov/>.

Question: How do you plan to invest in the critical workforce training and cultural competency programs that were authorized but not appropriated in the Affordable Care Act?

Response: HHS continues to work within its existing resources to implement a range of programs that address critical workforce training needs. Several of our programs were made possible through the Affordable Care Act. With an emphasis on expanding and strengthening our primary care workforce, these programs are yielding results. For example, the Primary Care Residency Expansion program is supporting training of more than 500 medical residents over five years (FY 2010-FY 2015) and Teaching Health Center program grantees are currently supporting over 325 primary care resident FTE with a focus on training in ambulatory care settings that often serve rural and underserved populations. This program is growing quickly and we expect the number of primary care resident FTE to increase significantly with the entrance of new cohorts of residents and programs. With other ACA funds to expand our health workforce, HRSA is managing programs that will support the addition of 600 advanced practice nurses in primary care, 600 physician assistants, and 200 mental/behavioral health providers.

Additionally, HRSA's ongoing programs to strengthen the diversity of our health professionals are designed to improve the recruitment and enhance the academic preparation of students from disadvantaged backgrounds into health professions. This is a key strategy for increasing access to culturally competent care across the country, as well as improving access and care in underserved areas. Greater diversity among health professionals is also associated with improved access to care for racial and ethnic minority patients, greater patient choice and satisfaction, and better patient-clinician communication. For example, HRSA's Nursing Workforce Diversity (NWD) program increases nursing education opportunities for individuals from disadvantaged backgrounds, including racial and ethnic minorities underrepresented among registered nurses, by supporting activities such as the provision of student stipends and scholarships, pre-entry preparation, advanced education preparation, and retention activities. Increasing nursing education opportunities for individuals from disadvantaged backgrounds will help meet the increasing need for culturally-aligned, quality health care for the nation's rapidly diversifying population and help improve health equity. Data from the most

recent academic year showed that grantees of the NWD program offered over 90 different types of structured training programs and reached over 4,800 trainees.

Other examples of programs that support efforts to increase the diversity of our health workforce include HRSA's Centers of Excellence (COE) program and the Scholarships for Disadvantaged Students (SDS) program. The COE program funds education and training enhancement programs to increase opportunities for underrepresented minority (URM) individuals to enter and successfully complete a health professions academic program. The SDS program provides grants to health professions and nursing schools for use in awarding scholarships to students from disadvantaged backgrounds with financial need.

Lastly, in addition to these HRSA-led efforts to train and increase the diversity of our health care workforce, HHS also promotes culturally and linguistically appropriate services and training more broadly in the public health arena. For example, HHS recently released the enhanced *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care* (CLAS Standards), along with *A Blueprint for Advancing and Sustaining CLAS Policy and Practice*. The enhanced CLAS Standards update guidelines that were previously released by the HHS Office of Minority Health (OMH) in 2000. Furthermore, through the OMH, HHS also provides a set of Culturally Competency Curriculum Modules that are based on the CLAS Standards and that aim to equip providers with cultural and linguistic competencies to help promote patient-centered care for all patients, including racial, ethnic, and linguistic minorities. This free online educational program is accredited for Continuing Medical Education credits for physicians, as well as for Continuing Education Units for physician assistants, nurse practitioners, registered nurses, social workers, and emergency response personnel.

Racial and Ethnic Approaches to Community Health (REACH). There are more than 150 journal articles documenting the achievements of the REACH program in reducing health disparities. The program has been cited by the GAO and in your action plan as an exemplary program. The HHS congressional justification suggest that the Community Transformation Grant program (CTG) "marks the next stage of CDC's community-based programs".

Question: What evidence can you provide to demonstrate that the CTG or Communities Putting Prevention to Work (CPPW) program have had comparable impact in reducing racial and ethnic health disparities?

Response: REACH investments have established a foundation for addressing racial and ethnic populations' health disparities and have contributed to the national capacity to reduce such disparities for more than 10 years. During this time period, CDC has supported awardees to establish community-based programs and culturally-tailored interventions to reduce health disparities among African Americans, American Indians, Hispanics/Latinos, Asian Americans, Alaska Natives, and Pacific Islanders. REACH interventions in targeted communities have demonstrated improvements in physical

activity, consumption of fruits and vegetables, smoking, cholesterol screening and diabetes management.

Established in 2010, the goal of the Communities Putting Prevention to Work (CPPW) program was to reduce risk factors, prevent and delay chronic disease, and promote wellness in both children and adults. CPPW programs implemented high-quality, evidence-based programs at both the state and local levels to: (1) increase levels of physical activity; (2) improve nutrition; and (3) decrease smoking prevalence, teen smoking initiation, and exposure to second-hand smoke. Through CPPW, communities and states—including urban, small, rural, and tribal areas—implemented locally-driven strategies to make healthy living easier, such as improving access to active transportation; increasing the availability of healthy food and beverage options in schools; limiting exposure to secondhand smoke; and increasing available tobacco cessation support.

CPPW has successfully implemented population-wide interventions that have targeted and impacted directly racial and ethnic health disparities, producing broad, high-impact, sustainable health outcomes for communities. Examples of successes found in CPPW include:

- Medical facilities in Santa Clara County, California, serving low-income residents have implemented smoking cessation in their clinical practices, across five clinics, reaching approximately 135,000 patients annually. A large majority of the patients served are uninsured and low-income Hispanic and Latino residents.
- In the Cherokee Nation, Oklahoma, schools within five school districts now provide healthier food and beverage options in vending machines, including low-fat snacks, fruit drinks with at least 50% real juice, and water. The changes benefit nearly 63,000 students.

With the launch of the Community Transformation Grants (CTG) program in September 2011, CDC has worked to ensure prioritization of “strategies to reduce racial and ethnic disparities, including social, economic, and geographic determinants of health,” and that “not less than 20 percent of such grants [be] awarded to rural and frontier areas” (Affordable Care Act). To that end, CDC will ensure that activities support 1) population-wide interventions with a health equity lens, and 2) targeted interventions that address populations with the greatest burden. CTG’s 107 Implementation, Capacity Building, National Network and Small Community awardees are required to implement strategies that achieve health equity. Through these efforts, it is expected to reach more than four out of 10 citizens – about 130 million Americans, including those with the greatest racial and ethnic health disparities, and populations in rural and frontier settings.

To evaluate the impact of the five-year CTG intervention-based programs, CDC designed a multicomponent national evaluation that includes a targeted surveillance and biometric study for enhanced evaluation. Currently under review with the Office of Management and Budget (OMB), the study proposes to assess the reduction in health disparities among special populations (e.g., African-American, Hispanic, and rural) in CTG awardee areas. CDC will continue to evaluate CTG and REACH awardee efforts to address health disparities in order to better understand and quantify program and strategy impacts.

CDC is committed to building on past successes and reaching people who experience the greatest burden of death, disability, and suffering from chronic diseases and other chronic conditions. Further, CDC is ensuring that the legacy and lessons learned from the REACH Program will continue to be integrated into current and future community health models in order to achieve greater impact in reducing racial and ethnic health disparities.

End Stage Renal Disease

There is significant concern among the kidney care community that patient access to quality dialysis care could be disrupted if the payment adjustment to the Medicare ESRD bundle contained in the fiscal cliff bill is not properly designed and implemented by CMS.

I share the concerns about adjusting the bundle without considering how a reduction affects the overall payment amount could threaten patient access.

Based on their analysis of dialysis facility cost reports, MedPAC reported that Medicare profit margins for dialysis facilities are just 2-3%. Those margins are prior to the 2% cut from sequestration and the effect of the rebasing-which the CBO estimated as at least a negative 4-5% cut.

For an industry with those slim margins, and where 87% of patients are on Medicare and approximately 50% are dual eligibles, the risk of significant center closures seems real, and I'm worried about the impact on patient access, especially in underserved areas, urban and rural.

Question: Please describe the steps HHS and CMS will take to ensure that implementation of the bundle adjustment will fairly ensure that reimbursements remain adequate to maintain patient access to high quality care?

Response: We agree with the importance of appropriate payments to ensure access to dialysis treatment for ESRD beneficiaries. Section 632(a) of the American Taxpayers Relief Act of 2012 added section 1881(b)(14)(I) to the Social Security Act, which requires that the ESRD prospective payment system (PPS) rate be reduced beginning in 2014 to reflect the change in utilization of drugs and biologicals from 2007 to 2012. Before we make any changes to the ESRD PPS rate, we will carefully analyze the data on utilization and include the proposed payment change based on the data in the CY 2014 ESRD PPS proposed rule for public comment. We will review comments and take into consideration issues raised by stakeholders to ensure that beneficiaries continue to have access to the medications they need before we make a final decision on the payment change. CMS welcomes your input to help ensure that payments are adequate and appropriate in the Medicare ESRD program.

National Asthma Control Program

Asthma is a life-threatening and costly chronic disease. Asthma kills approximately 9 people a day and costs the nation \$56 billion annually in health care costs. The burden of asthma is growing, particularly among vulnerable populations. The CDC National Asthma Control Program (NACP) works with states to promote education and proper disease management, and reduce emergency room visits due to asthma.

Question: How have funding cuts to NACP impacted the program's ability to serve the growing population with asthma?

Response: In FY 2014, CDC expects to fund up to 36 health departments through a new, competitive cooperative agreement to fund asthma-friendly school efforts such as school-based asthma management, self-management education for students, educational training for school personnel, and indoor air quality improvement and trigger reduction. Funding will also support asthma surveillance, research translation and guidance, and community outreach training.

NIH-Chronic Obstructive Pulmonary Disease

Chronic Obstructive Pulmonary Disease (COPD) is the third leading cause of death in the U.S. It kills 141,075 Americans annually. Approximately 12 million adults have been diagnosed with COPD, and it is estimated that another 12 million are unaware that they have it.

Question: How does NIH research on COPD contribute to HHS-led public health interventions?

Response: Several NIH institutes support synergistic research related to COPD that contributes substantially to HHS-led public health interventions. Cigarette smoking (current or past) is the major cause of COPD, and research on smoking cessation or prevention, largely funded through NIDA and NCI, provides evidence-based direction for activities to prevent COPD and other smoking-related diseases.

NHLBI is partnering with the CDC to acquire data through the Behavioral Risk Factor Surveillance Survey about COPD prevalence at the state level, which will inform activities to improve awareness, diagnosis, and treatment.

The NHLBI-led *Learn More Breathe Better* campaign to raise public awareness of this debilitating disease and encourage susceptible people to seek testing is a partnership with the CDC, among others. NHLBI is funding a program to develop and test a case-finding methodology to address the identification of COPD patients who have not yet been diagnosed.

NHLBI funds a number of intervention trials designed to inform improvements in medical care and delivery. The COPD Clinical Research Network conducts clinical trials to identify treatments that prevent COPD exacerbations. One of its trials found that daily administration of the antibiotic azithromycin reduced the frequency of exacerbations, and another is presently investigating whether a statin drug has a similar effect. Previous

research documented the benefits of oxygen therapy for COPD patients with severe blood oxygen deficiency, and now NHLBI in partnership with CMS is conducting a clinical trial to explore the benefits of long-term oxygen therapy in patients with milder deficiency.

NIH also supports a portfolio of research to improve understanding of the pathogenesis of COPD. COPD is a complex disease with considerable heterogeneity, and patients tend to be afflicted by multiple comorbidities. It is likely that effective treatment will require more specific definitions of patient subpopulations. Two NHLBI-funded programs, COPDGene and SPIROMICS (a partnership with the FDA), are exploring the complexities of COPD, its genetic predispositions, and the comorbidities of affected patients. NHLBI and NCI are jointly funding a program to investigate the link between lung cancer and COPD. Finally, many institutes at NIH, including NHLBI, NIEHS, NIA and NCI, are supporting basic research on mechanisms of the disease, which is expected to generate future interventions to improve public health.

In addition to this research, NHLBI recently organized a meeting of federal agencies that have public health roles related to COPD. Participants included FDA, CDC, CMS, the office of the Surgeon General, AoA, HRSA, and multiple NIH institutes.

Title X, Family Planning

Low-Income Women's Health Access. I was pleased with the request of \$327 million for the Title X family planning program in the Fiscal Year (FY) 2014 budget. Title X providers are often the sole preventive and primary care providers for low-income women and men. As the president's budget recognizes, the current level of Title X funding falls well below what providers need to meet the current demand for publicly subsidized family planning services. Title X has seen a 7.4% reduction in funding since 2010, causing a decline of over 200,000 patients in a single calendar year. Under sequestration, Title X faces an additional 5% cut on top of these cuts already taken.

Question: Can you give us a sense of how these large cuts have affected the providers and the patients they serve?

Response: As providers for a significant number of low-income women and men, with little, if any, ability to pay for healthcare, Title X providers use a significant amount of their funding to cover the cost of patient services. In addition to direct services, Title X funding is used to purchase testing and lab supplies, other medical supplies and equipment as well as the cost of staff salaries, rent and utilities. State contributions to Title X providers have declined as well. Since 2010, there are approximately 200 fewer service deliver sites, reduced hours at many service sites, limited availability of clinical service providers, resulting in over 465,000 fewer clients.

Affordable Care Act Outreach and Enrollment. The success of the Affordable Care Act (ACA) will be determined largely by how many individuals eligible for coverage are ultimately enrolled and able to access the health care they need. The ACA includes

programs, such as “Navigators,” and funding to help newly eligible individuals enroll in insurance coverage. However, there is real concern that coverage gaps will persist.

Question: What role do you see the safety-net, including Title X providers, taking in educating communities about the ACA and enrolling patients in health insurance?

Response: Health centers are expected to play a critical role in raising awareness of affordable insurance options and facilitating enrollment of eligible health center patients and service area residents into affordable health insurance coverage through the Health Insurance Marketplaces, Medicaid, or the Children’s Health Insurance Program.

Safety net programs, like the Title X family planning program, have been at the forefront of providing primary care and related health services to low-income individuals at the community level. Title X providers include federally qualified health centers, community health centers, hospitals, other primary care providers, health departments and stand-alone family planning centers. All Title X providers are community-based organizations, with a strong local presence and a history of providing health care services and outreach and education in their communities. In addition to having strong relationships with communities, Title X family planning centers have participated in determining onsite eligibility for and enrollment in Medicaid. These centers could also help educate and enroll patients eligible for health insurance as a part of the Health Insurance Marketplaces. As a result, the Title X network is well positioned to educate communities about the ACA and enrolling patients in health insurance. Certain Title X providers are eligible to take part as Navigators or are encouraged to partner with health centers.

In addition to Navigators, HHS is working to ensure that other entities will be available to make sure individuals are aware of the new tools, benefits, and protections that will soon be available to them. A proposed rule would establish certified application counselors, who would be certified by the Marketplace to perform many of the same functions as Navigators—including educating consumers and helping them complete an application for coverage. Safety net providers, such as staff at health centers or hospitals or consumer non-profit organizations or Title X centers are examples of possible certified application counselors.

Question: Would you agree that the Title X network is an integral part of the public health safety net and will be critical to the success of the Affordable Care Act (ACA)?

Response: The diversity of the Title X network, the expertise it has in providing quality family planning and primary care services and its priority for serving individuals from low-income families, enables it to be a valuable and integral part of the public health safety net. Sixty-nine percent of the Title X population have incomes at or below 100% of the Federal Poverty Limit (FPL) and approximately 84% are at or below 150% FPL. Six out of ten women who access publicly-funded family planning clinics identify it as their usual source of primary care. Therefore, Title X services significantly impact high-risk populations who experience significant health disparities as compared to those at

higher incomes, resulting in higher morbidity and poorer health outcomes. In addition, these populations are most at risk for experiencing challenges in accessing health care coverage, so they are likely to benefit most from participation of Title X clinics and other safety net providers as part of ACA outreach and enrollment efforts. Title X providers, through an already established infrastructure of over 4,000 service sites across the United States and its territories, are integral in providing family planning and primary care services to priority populations through an already established infrastructure.

WITNESSES

	Page
Clancy, Carolyn M	1
Collins, Francis S	1
Colvin, Carolyn	269
Conway, Patrick	1
Delisle, Deb	335
Frieden, Tom	1
Hyde, Pamela	335
Sebelius, Hon. Kathleen	413
Wakfield, Mary	1

